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COLLEGE OF LAW AND MANAGEMENT STUDIES
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**A constitutional analysis of open consent for genomics
research in South Africa**

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This thesis is submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy

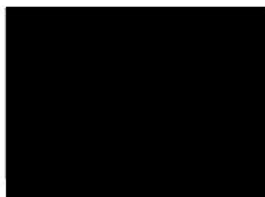
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ABSTRACT

Advancements in genomics, coupled with decreasing sequencing costs and technological innovations, have significantly expanded our understanding of the human genome and its role in health and disease. This progress has fuelled the rapid growth of genomics research globally, including in South Africa. Such research, however, requires vast amounts of data, which is typically gathered from research participants and subsequently extracted and sequenced. Informed consent is essential in this process, ensuring that participants are treated fairly and their rights are protected.

While various modes of consent, such as specific consent, broad consent, and blanket consent, have been utilised in genomics research in South Africa, the concept of open consent remains underexplored. Pioneered by the Personal Genome Project, open consent involves individuals openly sharing their data for research without guarantees of privacy, anonymity, or confidentiality. To ensure that consent is informed, participants undergo (and must pass with full marks) an assessment, in which their understanding of genomics and privacy is tested. Given that open consent has not yet been explored or applied in the South African context, this thesis investigates whether open consent is a suitable mode of consent for genomics research in South Africa through a constitutional lens.

There are four salient constitutional rights and/or values relevant to an analysis of open consent in genomics research in South Africa, namely *autonomy*, a value which underlies informed consent generally; *Ubuntu*, which is an underlying constitutional value that places autonomy in an African perspective, and aims to strike a balance between the individual and society; *freedom of scientific research*, which is a right that contains elements of individual and societal interests and is facilitated by open science; and *privacy*, which is a right and an overriding concern in research generally, but becomes especially problematic in the context of genomics research. Through this analysis, I find that a modified version of open consent – suited to local contexts and cultures – may be usefully applied and used for genomics research in South Africa.

Keywords: consent; genomics; open consent; research; South Africa

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LIST OF ACRONYMS

AB 1	<i>AB v Minister of Social Development 2016 (2) SA 27 (GP)</i>
AB 2	<i>AB v Minister of Social Development 2017 (3) SA 570 (CC)</i>
AOSP	African Open Science Platform
ASSAf	Academy of Science of South Africa
BICEP	Brief Informed Consent Protocol
CARE	Cognisance of collective benefit, authority to control, responsibility, ethics
CKB	China Kadoorie Biobank
DICCT	Deaconess Informed Consent Comprehension Test
DNA	Deoxyribonucleic acid
DoH	Department of Health
DSI	Department of Science and Innovation
DST	Department of Science and Technology
ENCODE	Encyclopedia of DNA Elements
FAIR	Findable, accessible, interoperable, reusable
H3Africa	Human Heredity and Health in Africa
HBM	Human biological material
HGP	Human Genome Project
HPCSA	Health Professions Council of South Africa
HREC	Health Research Ethics Committee
ICT	Information and communications technology
IT	Information technology
LMICs	Low- and middle-income countries
MTA	Material Transfer Agreement
NDoH	National Department of Health
NDPP	National Director of Public Prosecutions
NHA	National Health Act 61 of 2003

NHREC	National Health Research Ethics Council
NM	<i>NM v Smith</i> 2007 (5) SA 250 (CC)
PGP	Personal Genome Project
POPIA	Protection of Personal Information Act 4 of 2013
QuIC	Quality of Informed Consent questionnaire
RALC	Restricted access/limited control theory of privacy
REC	Research Ethics Committee
SA MTA	Material Transfer Agreement for Human Biological Materials GN R719 GG 41781 of 20 July 2018
SABC	South African Broadcasting Corporation
SAHGP	Southern African Human Genome Programme
SAMRC	South African Medical Research Council
SMMEs	Small and medium-sized enterprises
STI	Science, technology, and innovation
TRUST	Transparency, responsibility, user community, sustainability, technology
UN	United Nations
VPN	Virtual Private Network
WHO	World Health Organisation

LIST OF PUBLICATIONS

I have been fortunate to publish several publications based on the research done for this thesis prior to its final submission. Because of this, substantial parts of this thesis consist of, and build upon, material that has featured in the publications listed below:

- Gooden, A & D Thaldar ‘The proposed Code of Conduct for Research in South Africa: Despite good progress, unresolved issues remain’ (2024) 11(1) *Humanities & Social Sciences Communications* 1–7.
- Gooden, A & D Thaldar ‘Toward an open access genomics database of South Africans: Ethical considerations’ (2023) 14 *Front Genet* 1–7.
- Gooden, A ‘A pathway to strengthening open science: Comments on the draft *South African Ethics in Health Research Guidelines*’ (2024) 15 *Front Pharmacol* 1–14.
- Thaldar, D, A Gooden & DL Donnelly ‘Toward an open access genomics database of South Africans: Legal considerations’ (2023) 119(7/8) *S Afr J Sci* 1–4.
- Thaldar, D, A Gooden & M Steytler ‘Open science and human genetic data: recommendations on South Africa’s Draft National Open Science Policy’ (2023) 14 *Front Genet* 1–7.
- Thaldar, D, U Maboea & A Gooden ‘Why the South African National Health Research Ethics Council is wrong about ownership of human biological material and data’ (2025) *Developing World Bioeth* 1–9.

Some sections of this thesis draw significantly from my previous publications, notably Amy Gooden & Donrich Thaldar ‘Toward an open access genomics database of South Africans: Ethical considerations’ (2023) 14 *Front Genet* 1–7, where I first developed certain arguments. Consequently, some formulations in this thesis are substantially based on those in my publications, particularly on pages 9 to 14, pages 20 to 21, pages 24 to 25, pages 119 to 121, pages 132 to 137, and pages 213 to 214.

CHAPTER 1

INTRODUCTION

I INTRODUCTION

Genomics is defined as the examination of genes and their functions.¹ It explores the structure, role, evolution, and interactions of genes within genomes, offering insights into biological processes at the molecular level.² Genomics has transformed the research landscape by enabling comprehensive analysis of entire genomes.³ Genomics research involves the systematic study of genomes to uncover insights into genetic variation, gene functions, and their interactions within organisms and populations. Researchers use advanced sequencing technologies and computational tools to analyse large datasets of deoxyribonucleic acid (DNA) sequences, aiming to understand how genes influence traits, diseases, and evolutionary processes.⁴ This has facilitated breakthroughs in understanding disease mechanisms, identifying genetic factors contributing to various conditions, and guiding personalised medicine.⁵ In South Africa, genomics research holds great potential to improve health and lessen the disease burden in the country.⁶

In order for genomics research to be prosperous, large quantities of data are required. This data is gathered from research participants willing to partake in the project – usually in the form of a human biological sample, which is then sequenced and analysed for the purposes

¹ Genomics explores all genes and how they interact with each other and the environment to contribute to an organism's development. World Health Organization 'Genomics and world health: Report of the Advisory Committee on Health Research' (2002) *World Health Organization* 203; Thomas Finnegan & Alison Hall 'Identification and genomic data' (2017) *PHG Foundation* 11; National Human Genome Research Institute 'A brief guide to genomics' *NIH* 16 August 2022, available at <https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics>, accessed 8 November 2022; World Health Organization 'WHO definitions of genetics and genomics' *WHO* available at <https://www.who.int/genomics/geneticsVSgenomics/en/>, accessed on 4 February 2020.

² Xu Xun 'We are witnessing a revolution in genomics - and it's only just begun' *World Economic Forum* 25 June 2019, available at <https://www.weforum.org/agenda/2019/06/today-you-can-have-your-genome-sequenced-at-the-supermarket/>, accessed on 13 March 2023.

³ Ibid; Petar Brlek, Luka Bulić, Matea Bračić et al 'Implementing whole genome sequencing (WGS) in clinical practice: Advantages, challenges, and future perspectives' (2024) 13(6) *Cells* 1; Frederik Otzen Bagger, Line Borgwardt, Andreas Sand Jespersen et al 'Whole genome sequencing in clinical practice' (2024) 17(39) *BMC Med Genomics* 1.

⁴ National Human Genome Research Institute op cit note 1.

⁵ Stephen A Bustin & Kurt A Jellinger 'Applications of genome editing technology in the targeted therapy of human diseases: Mechanisms, advances and prospects' (2020) 5(1) *Sig Transduct Target Ther* 1.

⁶ C Staunton, R Adams, M Botes et al 'Safeguarding the future of genomic research in South Africa: Broad consent and the Protection of Personal Information Act No. 4 of 2013' (2019) 109(7) *S Afr Med J* 468.

of the research.⁷ But all of this hinges on consent. When one gives consent, one gives permission to partake in research.⁸ Consent is vital in ethical research as it ensures that participants are treated fairly and with respect, safeguarding their rights and well-being throughout the research process.⁹ Over time, different modes of consent have developed. While each have their advantages and uses, all of them seem to have the same fate: It is questioned whether consent is *informed*.

Informed consent is a crucial ethical principle in research that ensures that individuals are fully aware of the risks, benefits, and implications of their participation in a project before they agree to proceed.¹⁰ It involves providing comprehensive information in a clear and understandable manner, including details about the purpose, procedures, potential risks and benefits, alternatives, and the voluntary nature of participation.¹¹ The individual must have the capacity to comprehend this information, weigh their options, and make a voluntary decision without coercion or undue influence.¹² Open consent has been developed specifically for genomics research and has taken the realities of the process into account and has taken steps to ensure that, as far as possible, the consent given by research participants is informed. However, open consent is yet to be explored in detail in South Africa. Could such a model be implemented in genomics research in the country?

In this thesis, I explore the concept of *open consent* in the context of genomics research in South Africa in order to determine whether open consent is suited to the South African

⁷ Roderick A Yao, Oyediran Akinrinade, Marie Chaix et al ‘Quality of whole genome sequencing from blood versus saliva derived DNA in cardiac patients’ (2020) 13(11) *BMC Med Genomics* 1; Brett Trost, Susan Walker, Syed A Haider et al ‘Impact of DNA source on genetic variant detection from human whole-genome sequencing data’ (2019) 56 *J Med Genet* 809; Yueshan Hu, Erik A Ehli, Kelly Nelson et al ‘Genotyping performance between saliva and blood-derived genomic DNAs on the DMET array: A comparison’ (2012) 7(3) *PLoS ONE* 1.

⁸ NIHR ‘Consent’ available at <https://bepartofresearch.nihr.ac.uk/taking-part/Consent/>, accessed on 27 October 2023.

⁹ UK Research and Innovation (UKRI) ‘Consent for research’ UKRI 11 January 2023, available at <https://www.ukri.org/councils/mrc/facilities-and-resources/find-an-mrc-facility-or-resource/mrc-regulatory-support-centre/understanding-health-research/consent-for-research/>, accessed on 27 October 2023.

¹⁰ University of Oxford ‘Informed consent’ available at <https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#:~:text=Informed%20consent%20is%20one%20of,before%20they%20enter%20the%20research.>, accessed on 7 July 2023; Rashmi Ashish Kadam ‘Informed consent process: A step further towards making it meaningful!’ (2017) 8(3) *Perspectives in Clinical Research* 111.

¹¹ Lauren Stewart ‘Understanding informed consent in research’ *Atlas* available at <https://atlasti.com/research-hub/informed-consent-in-research>, accessed on 16 May 2023; NEAC ‘Informed consent’ available at <https://neac.health.govt.nz/national-ethical-standards/part-two/7-informed-consent>, accessed on 16 May 2023; Chinomnso Chinanuekpere Nnebue ‘Informed consent in research’ (2010) 1(1) *AFRIMEDIC Journal* 6.

¹² Dan Kabonge Kaye ‘Why “understanding” of research may not be necessary for ethical emergency research’ (2020) 15(6) *Philos Ethics Humanit Med* 1.

genomics research context through a constitutional lens – examining various constitutional rights and values.

II BACKGROUND

(a) *Genomics research: Progress versus privacy?*

Our understanding of the human genome and its role in health and disease has grown, with decreasing costs and technological advances leading to the proliferation of genome sequencing.¹³ In recent years, genomics research has burgeoned, with many institutions – both local and international – undertaking such research. However, this new development poses its own challenges. Genomics research requires vast amounts of data, which is gathered from research participants and then extracted and sequenced. Generally, this is collected through blood samples.¹⁴ Saliva samples can be used for certain types of sequencing,¹⁵ although they tend not to have the same quality and yield of DNA as blood samples.¹⁶

At the outset, it is important to recognise that genomics research may take different forms. Some genomics research projects collect, sequence, and analyse their own data from participants that they themselves have recruited.¹⁷ Other genomics research entails aggregating samples and data from other research or clinical projects into a single database.¹⁸ And some genomics research encompasses a combination of the two – where both new data is collected

¹³ While sequencing a human genome a decade ago would have cost over \$1 billion, today this can be done for approximately \$1000. John S Mattick, Marie A Dziadek, Bronwyn N Terrill et al ‘The impact of genomics on the future of medicine and health’ (2014) 201(1) *Med J Aust* 17. See also, The Harvard Personal Genome Project ‘Participating in the Harvard PGP’ available at <https://pgp.med.harvard.edu/participate>, accessed on 17 March 2021.

¹⁴ Yao et al op cit note 7 at 1; Trost et al op cit note 7 at 809; Hu et al op cit note 7 at 1.

¹⁵ See, Jean E Abraham, Mel J Maranian, Inmaculada Spiteri et al ‘Saliva samples are a viable alternative to blood samples as a source of DNA for high throughput genotyping’ (2012) 5(19) *BMC Med Genomics* 1–6.

¹⁶ Yao et al op cit note 7 at 9; Trost et al op cit note 7 at 816.

¹⁷ For example, the Personal Genome Project (PGP) and the the Southern African Human Genome Programme (SAHGP) recruit their own participants and collect samples and data. The Harvard Personal Genome Project op cit note 13; Ananyo Choudhury, Michèle Ramsay, Scott Hazelhurst et al ‘Whole-genome sequencing for an enhanced understanding of genetic variation among South Africans’ (2017) 8(2062) *Nature Communications* 2; European Genome-Phenome Archive ‘The Southern African Human Genome Programme’ *EGA* available at [https://ega-archive.org/studies/EGAS00001002639#:~:text=Show%20More\)-,The%20Southern%20African%20Human%20Genome%20Programme%20\(SAHGP\)%20is%20a%20national,t hrough%20understanding%20human%20genetic%20diversity](https://ega-archive.org/studies/EGAS00001002639#:~:text=Show%20More)-,The%20Southern%20African%20Human%20Genome%20Programme%20(SAHGP)%20is%20a%20national,t hrough%20understanding%20human%20genetic%20diversity), accessed on 5 April 2022.

¹⁸ For example, the Multimorbidity in Africa: Digital Innovation, Visualisation and Application project uses existing data collected from previous projects and will not collect its own new data. NIH Fogarty International Center ‘MADIVA (Multimorbidity in Africa: Digital innovation, visualisation and application)’ available at <https://www.fic.nih.gov/Grants/Search/Pages/dsi-u54tw012077.aspx>, accessed on 31 March 2022; NIH Report ‘MADIVA (Multimorbidity in Africa: Digital innovation, visualisation and application)’ available at <https://reporter.nih.gov/project-details/10314291>, accessed on 31 March 2022; Susan M Wolf, Brittney N Crook, Brian Van Ness et al ‘Managing incidental findings and research results in genomic research involving biobanks and archived data sets’ (2012) 14(4) *Genet Med* 362.

by researchers for the project and existing data is utilised.¹⁹ Furthermore, genomics research may differ in terms of the data that is gathered. For example, while some projects may only collect DNA samples from participants which are then sequenced and analysed (such as the 1000 Genomes Project),²⁰ other projects may also collect associated data – such as the Southern African Human Genome Programme (SAHGP),²¹ the United Kingdom (UK) Biobank,²² the China Kadoorie Biobank (CKB),²³ and the Human Heredity and Health in Africa (H3Africa) Initiative.²⁴ The Personal Genome Project (PGP) explicitly states that it not only collects genomic data, but also health and trait data.²⁵ Therefore, the samples collected, and the methods used in different projects may pose their own challenges and hold their own implications for genomics research.

Nevertheless, genomics research holds potential to improve population health through understanding the role of genetic factors (in combination with environment) in predisposition to certain complex genetic diseases²⁶ – such as diabetes, Alzheimer’s disease, cardiovascular disease, and cancer²⁷ – which may result in enhanced clinical observation and lifestyle improvements.²⁸ Genomics research also leads to improved and accurate diagnostics,²⁹ better understanding of prevention and treatment of disease and the avoidance of side effects,³⁰ drug

¹⁹ For example, the International Genome Sample Resource (IGSR) uses data from the 1000 Genomes Project, as well as generating its own data. IGSR: The International Genome Sample Resource ‘The International Genome Sample Resource’ available at <https://www.internationalgenome.org/>, accessed on 14 April 2022.

²⁰ The International Genome Sample Resource ‘1000 Genomes Project’ available at <https://www.internationalgenome.org/1000-genomes-summary>, accessed on 13 April 2022; National Human Genome Research Institute ‘1000 Genomes Project’ 4 October 2017 available at <https://www.genome.gov/27528684/1000-genomes-project>, accessed on 13 April 2022.

²¹ Choudhury et al op cit note 17 at 2; European Genome-Phenome Archive op cit note 17.

²² UK Biobank ‘Biobank’ available at <https://www.ukbiobank.ac.uk/>, accessed on 17 March 2022.

²³ China Kadoorie Biobank ‘China Kadoorie Biobank’ available at <https://www.ckbiobank.org/site/>, accessed on 17 March 2022.

²⁴ H3Africa ‘About’ available at <https://h3africa.org/index.php/about/>, accessed on 24 February 2022.

²⁵ Personal Genome Project: Global network ‘The Personal Genome Project’ available at <https://www.personalgenomes.org/>, accessed on 30 April 2022.

²⁶ The development of complex (or ‘polygenic’) diseases is affected by genetic variation in multiple genes as well as environmental factors, such as diet and lifestyle. C Dandara, J Greenberg, L Lambie et al ‘Direct-to-consumer genetic testing: To test or not to test, that is the question’ (2013) 103(8) *SAMJ* 510. See also, Amy Gooden *Unregulated or Not? A Legal Analysis of South Africa’s Legislative Framework Relevant to Direct-To-Consumer Genetic Testing* (Master of Laws dissertation, University of KwaZulu-Natal, 2021) 45.

²⁷ National Human Genome Research Institute op cit note 1.

²⁸ Mattick et al op cit note 13 at 17.

²⁹ National Human Genome Research Institute op cit note 1; Ramzi G Salloum, Thomas J George, Natalie Silver et al ‘Rural-urban and racial-ethnic differences in awareness of direct-to-consumer genetic testing’ (2018) 18(277) *BMC Public Health* 1; Mattick et al op cit note 13 at 17.

³⁰ Salloum et al op cit note 29 at 1; National Human Genome Research Institute op cit note 1; Mattick et al op cit note 13 at 17.

development,³¹ the provision of evidence that demonstrates clinical efficacy,³² revised mechanisms for decision-making,³³ and the potential for precision medicine.³⁴

Because South Africa historically lacked the infrastructure, funds, resources, and personnel to conduct genome sequencing,³⁵ DNA samples were often sent abroad.³⁶ This posed its own logistical issues as exporting tissue samples requires a permit in terms of the Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes (Import and Export Regulations).³⁷ Additionally, a Material Transfer Agreement (MTA), based on the Material Transfer Agreement for Human Biological Materials (SA MTA),³⁸ is required for transfers of human biological material (or both human biological material and associated data) for research purposes.³⁹ Furthermore, genomics research in South Africa is intertwined with a history of exploitation. ‘Helicopter research’ – where samples and data are collected from developing countries⁴⁰ – resulted in the migration of samples and data abroad, with little or no benefit to local researchers or populations.⁴¹ However, South Africa’s capacity to undertake genomics

³¹ C Staunton & K Moodley ‘Data mining and biological sample exportation from South Africa: A new wave of bioexploitation under the guise of clinical care?’ (2016) 106(2) *S Afr Med J* 136.

³² National Human Genome Research Institute op cit note 1.

³³ Ibid.

³⁴ Ibid.

³⁵ The H3Africa Consortium ‘Enabling the genomic revolution in Africa: H3Africa is developing capacity for health-related genomics research in Africa’ (2014) 344(6190) *Science* 1346; Wits University ‘Why and how Africans need to participate in genetic studies’ 10 February 2022 available at <https://www.wits.ac.za/news/latest-news/research-news/2022/2022-02/why-and-how-africans-need-to-participate-in-genetic-studies-.html>, accessed on 2 February 2022; Mohamed Helmy, Mohamed Awad & Kareem A Mosa ‘Limited resources of genome sequencing in developing countries: Challenges and solutions’ (2016) 9 *Appl Transl Genom* 16.

³⁶ Brigitte Glanzmann, Tracey Jooste, Samira Ghoor et al ‘Human whole genome sequencing in South Africa’ (2021) 11(606) *Nature Research* 2; Staunton & Moodley op cit note 31 at 136.

³⁷ GN R181 GG 35099 of 2 March 2012. This permit is granted by the Director-General of the Department of Health (DoH) following the submission of an application that meets certain requirements.

³⁸ GN R719 GG 41781 of 20 July 2018.

³⁹ Para 2.13 of the SA MTA; Donrich W Thaldar, Marietjie Botes & Annelize Nienaber ‘South Africa’s new standard material transfer agreement: Proposals for improvement and pointers for implementation’ (2020) 21(85) *BMC Med Ethics* 6; Donrich Thaldar ‘One material transfer agreement to rule them all? A call for revising South Africa’s new standard material transfer agreement’ (2020) 7(105) *Humanities & Social Sciences Communications* 1; DW Thaldar & BA Townsend ‘Exempting health research from the consent provisions of POPIA’ (2021) 24 *PER/PELJ* 7.

⁴⁰ Dana Al-Hindi & Brenna Henn ‘How a South African community’s request for its genetic data raises questions about ethical and equitable research’ *The Conversation* 19 April 2022, available at <https://theconversation.com/how-a-south-african-communitys-request-for-its-genetic-data-raises-questions-about-ethical-and-equitable-research-166940>, accessed on 1 May 2022. See also, Joseph Mwelwa, Geoffrey Boulton, Joseph Muliaro Wafula et al ‘Developing open science in Africa: Barriers, solutions and opportunities’ (2020) 19(31) *Data Science Journal* 9–10.

⁴¹ Staunton & Moodley op cit note 31 at 136; Annelize Nienaber ‘Consent to and authorisation of the export and use of human biological specimens for future research – Perspectives from three African countries’ (2011) 44(2) *CILSA* 226.

research has improved,⁴² and with it the potential to tackle the many health concerns facing not only South Africa, but the entire continent.⁴³ In the past, genomics research worldwide focused on individuals of European descent and African individuals have been greatly underrepresented.⁴⁴ Therefore, knowledge of disease, its detection and diagnosis, as well as drug development and clinical care has tended to exclude African populations.⁴⁵ But given that Africa is considered the ‘birthplace’ of humanity,⁴⁶ and because of the continent’s genetic variation,⁴⁷ its population has the oldest and most diverse genes globally,⁴⁸ which holds great benefits for genomics research and global health.

Genomics research requires a balance to be struck between sharing data to advance scientific progress and safeguarding individual privacy.⁴⁹ The unique nature of genomic information and increased data sharing has heightened privacy risks – both for research participants as well as those genetically related to them.⁵⁰ This is because there are serious risks associated with both the publication of identifiable genomic data as well as the sharing of de-identified genomic data, which may violate the privacy of individuals and their relatives.⁵¹

De-identification, which involves removing personal identifiers,⁵² has commonly been implemented in order to protect privacy in genomics research. However, given the nature of

⁴² For example, in 2019 the South African Medical Research Council (SAMRC) opened its own Genomics Centre able to conduct large-scale whole genome sequencing. SAMRC ‘Genomics Centre’ available at <https://www.samrc.ac.za/innovation/genomics-centre>, accessed on 4 April 2022. See also, CPGR ‘Home’ available at <https://www.cpgr.org.za/>, accessed on 4 April 2022; Marion Motari, Uyen Quach, Halla Thorsteinsdóttir et al ‘South Africa – Blazing a trail for African biotechnology’ (2004) 22 *Nature Biotechnology* 37; Babatunde O Adedokun, Christopher O Olopade & Olufunmilayo I Olopade ‘Building local capacity for genomics research in Africa: Recommendations from analysis of publications in Sub-Saharan Africa from 2004 to 2013’ (2016) 9(31026) *Glob Health Action* 4; Staunton & Moodley op cit note 31 at 136.

⁴³ Erisa Mwaka & Lyn Horn ‘Researchers’ perspectives on informed consent and ethical review of biobank research in South Africa: A cross-sectional study’ (2019) 14(4) *J Empir Res Hum Res Ethics* 307.

⁴⁴ Serena Tucci & Joshua M Akey ‘The long walk to African genomics’ (2019) 20 *Genome Biology* 1; Amy R Bentley, Shawneequa L Callier & Charles N Rotimi ‘Evaluating the promise of inclusion of African ancestry populations in genomics’ (2020) 5(5) *NPJ Genomic Medicine* 1.

⁴⁵ Wits University op cit note 35.

⁴⁶ Bentley, Callier & Rotimi op cit note 44 at 1.

⁴⁷ Michael C Campbell & Sarah A Tishkoff ‘African genetic diversity: Implications for human demographic history, modern human origins, and complex disease mapping’ (2008) 9 *Annu Rev Genomics Hum Genet* 403.

⁴⁸ Choudhury et al op cit note 17 at 2; Tucci & Akey op cit note 44 at 1.

⁴⁹ National Human Genome Research Institute ‘Privacy in genomics’ *NIH* 24 February 2020, available at <https://www.genome.gov/about-genomics/policy-issues/Privacy>, accessed on 3 March 2020.

⁵⁰ Jane Kaye ‘The tension between data sharing and the protection of privacy in genomics research’ (2012) 13 *Annu Rev Genomics Hum Genet* 10–1.

⁵¹ Luca Bonomi, Yingxiang Huang & Lucila Ohno-Machado ‘Privacy challenges and research opportunities for genomic data sharing’ (2020) 52 *Nature Genetics* 646.

⁵² Kaye op cit note 50 at 10; Lee Swales ‘The Protection of Personal Information Act and data de-identification’ (2021) 117(7/8) *S Afr J Sci* 2; Elizabeth R Pike ‘Securing sequences: Ensuring adequate protections for genetic samples in the age of big data’ (2015) 37 *Cardozo L Rev* 2018.

genomic data, as well as the fact that re-identification is possible,⁵³ privacy cannot be guaranteed. De-identification of genomic data is not absolute and there are many examples of instances where supposedly de-identified data has been re-identified using different techniques and processes.⁵⁴ The concern of re-identification includes risks such as genetic discrimination, especially in the insurance and employment contexts;⁵⁵ discrimination on grounds of race, sex, and ethnicity;⁵⁶ the revealing of certain genetic predispositions, as well as other delicate health and personal information;⁵⁷ the discovery of family relationships;⁵⁸ and the impact that it may have on social standing and self-image.⁵⁹ Ultimately, this may hamper genomics research by deterring data collection and sharing.⁶⁰

Taking this into account, some solutions have been proposed. Organisational methods include access control systems, passwords, access agreements, and material (or data) transfer agreements, while technical measures encompass encryption,⁶¹ firewalls,⁶² virtual private

⁵³ De-identification entails removing personally identifying information, which has the potential to be re-linked to the data. Kaye op cit note 50 at 10; Swales op cit note 52 at 2; Pike op cit note 52 at 2018.

⁵⁴ Stacey Pereira, Richard A Gibbs & Amy L McGuire ‘Open access data sharing in genomic research’ (2014) 5 *Genes* 740; Kaye op cit note 50 at 10–1; Bradley Malin, David Karp & Richard H Scheuermann ‘Technical and policy approaches to balancing patient privacy and data sharing in clinical and translational research’ (2010) 58(1) *J Invest Med* 4; Pike op cit note 52 at 2016–7; Jennifer Cacchio ‘What you don’t know can hurt you: The legal risk of peering into the gene pool with direct-to-consumer genetic testing’ (2018) 87 *UMKC L Rev* 231; RB Altman ‘Direct-to-consumer genetic testing: Failure is not an option’ (2009) 86(1) *Clin Pharmacol Ther* 16; David B Resnik ‘Direct-to-consumer genomics, social networking, and confidentiality’ (2009) 9(6-7) *Am J Bioeth* 46; Melissa Gymrek, Amy L McGuire, David Golan et al ‘Identifying personal genomes by surname inference’ (2013) 339(6117) *Science* 321–4; Yaniv Erlich, James B Williams, David Glazer et al ‘Redefining genomic privacy: Trust and empowerment’ (2014) 12(11) *PLoS Biol* 1; Zachary Shapiro ‘Big data, genetics, and re-identification’ *Harvard Law* 24 September 2015, available at <https://blog.petrieflom.law.harvard.edu/2015/09/24/big-data-genetics-and-re-identification/>, accessed on 1 June 2022; Mats G Hansson, Hanns Lochmüller, Olaf Riess et al ‘The risk of re-identification versus the need to identify individuals in rare disease research’ (2016) 24 *Eur J Hum Genet* 1553.

⁵⁵ John Lynch, Ashley Parrott, Robert J Hopkin et al ‘Media coverage of direct-to-consumer genetic testing’ (2011) 20 *J Genet Counsel* 487.

⁵⁶ Erlich et al op cit note 54 at 1; Academy of Science of South Africa (ASSAf) *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (2018) 56.

⁵⁷ Shapiro op cit note 54.

⁵⁸ Erlich et al op cit note 54 at 1.

⁵⁹ Jeantine E Lunshof, Ruth Chadwick, Daniel B Vorhaus et al ‘From genetic privacy to open consent’ (2008) *Nature Reviews Genetics* 3.

⁶⁰ Bonomi, Huang & Ohno-Machado op cit note 51 at 646.

⁶¹ Encryption allows private information to be sent over the internet. It mixes up plain text into a secret code that is unreadable by third parties. The recipient, who is the only other party that can read the information, has a code or a decryption key which is used to unscramble the information. Dan Rafter ‘What is encryption and how does it protect your data?’ *Norton* 15 March 2022, available at <https://us.norton.com/internetsecurity-privacy-what-is-encryption.html>, accessed on 3 June 2022.

⁶² A firewall is a network security device that monitors network traffic and allows or prevents data, depending on security rules. It creates a barrier between an internal network and external sources (like the internet) which blocks unwanted traffic such as hackers and viruses. Sotiris Ioannidis, Angelos D Keromytis, Steve M Bellovin et al ‘Implementing a distributed firewall’ (2000) *ACM* 190; Forcepoint ‘What is a firewall?’ available at <https://www.forcepoint.com/cyber-edu/firewall>, accessed on 3 June 2022.

networks (VPNs),⁶³ and anti-malware.⁶⁴ Yet, each of these methods have their own issues. For example, encryption – which is a popular method used to securely transfer and store sensitive information, like genomic data – requires infrastructure, time, and computational resources, depending on the size of the data.⁶⁵ Additionally, because encrypted data needs to be decrypted in order for researchers to be able to work with it, and because that data (in its decrypted state) is vulnerable to theft and disclosure, the type of encryption commonly used fails to fully safeguard data.⁶⁶

Clearly, as privacy is a core issue in genomics research and a constitutional right in South Africa,⁶⁷ privacy is analysed in-depth in this thesis.

(b) Amplifying the progress-privacy dichotomy in genomics research: Open science

Genomics research must also be seen within the broader context of the open science movement. Open science can be broadly described as ‘research and development that is collaborative, transparent and reproducible and whose outputs are publicly available’.⁶⁸ Although open science has been variously defined, it commonly denotes ‘(a) full, frank, and timely publication of results, (b) absence of intellectual property restrictions, and (c) radically increased pre- and post-publication transparency of data, activities, and deliberations within research groups’.⁶⁹ Open science also consists of certain core elements, including open access to literature, access

⁶³ VPNs encrypt an individual’s internet traffic and hide their identities, allowing a secure connection on public networks, while preventing third parties from tracking and stealing data. Kaspersky ‘What is VPN? How it works, types of VPN’ available at <https://www.kaspersky.com/resource-center/definitions/what-is-a-vpn>, accessed on 3 June 2022.

⁶⁴ Anti-malware is a form of software that protects systems and computers by preventing, detecting, and removing malicious software (malware). Linda Rosencrance ‘Antimalware (anti-malware)’ available at <https://www.techtarget.com/searchsecurity/definition/antimalware>, accessed on 3 June 2022; Ciara Staunton, Kathrina Tschigg & Gayle Sherman ‘Data protection, data management, and data sharing: Stakeholder perspectives on the protection of personal health information in South Africa’ (2021) 16(12) *PLoS ONE* 11.

⁶⁵ Alexis B Carter ‘Considerations for genomic data privacy and security when working in the cloud’ (2019) 21(4) *J Mol Diagn* 545.

⁶⁶ Dario Gil ‘How to preserve the privacy of your genomic data’ *Scientific American* 9 November 2020, available at <https://www.scientificamerican.com/article/how-to-preserve-the-privacy-of-your-genomic-data/>, accessed on 3 June 2022.

⁶⁷ Section 14 of the Constitution of the Republic of South Africa Act 108 of 1996 (the Constitution).

⁶⁸ Department of Science and Innovation (DSI) *Draft National Open Science Policy* (2022) 5. See also, Ruben Vicente-Saez & Clara Martinez-Fuentes ‘Open Science now: A systematic literature review for an integrated definition’ (2018) 88 *Journal of Business Research* 11.

⁶⁹ Stephen M Maurer ‘New institutions for doing science: From databases to open source biology’ *European Policy for Intellectual Property Conference on Copyright and database protection, patents and research tools, and other challenges to the intellectual property system* (19 November 2003 University of Maastricht, The Netherlands) 4. See also, Roberto Caso & Rossana Ducato ‘Intellectual property, open science and research biobanks’ (2014) *Trento Law and Technology Research Group Research Paper* 22 15.

to research tools, public access to data, and a means to obtain access.⁷⁰ It is particularly open science's commitment to transparency of data and public access to data that is relevant to this thesis, as it would entail the sharing of data used in genomics research – something that has clear privacy implications.

Yet, open science holds great benefits in that it: (1) promotes efficiency by reducing duplication and cost of work, as well as in gathering, producing, transferring, and re-using data;⁷¹ (2) enhances quality, by allowing broader and thus greater accuracy in the verification of results, as well as making research more reproducible;⁷² (3) promotes disclosure, engagement, and trust in science;⁷³ (4) fosters innovation through increased access to research;⁷⁴ (5) assists in both domestic and international collaboration;⁷⁵ and (6) accelerates research and discoveries that benefit society.⁷⁶

Advances in genomics have facilitated the analysis of vast quantities of data. Adopting an open science approach allows the sharing of genomic data, and collaboration, between researchers and laboratories, thus increasing the possibility of discovering gene-disease associations.⁷⁷ Three essential drivers have been recognised as furthering the open science movement: (1) advances in technology; (2) the production of large quantities and variations of data; and (3) the interdisciplinary nature of current science questions.⁷⁸ These drivers made the Human Genome Project (HGP) – which exemplifies the open science movement – attainable. The HGP, which consisted of both international and cross-disciplinary collaboration, succeeded in mapping and sequencing the human genome. It promoted the open sharing of DNA sequencing information and the open access of software used in analyses. The HGP has

⁷⁰ Ed Levy, Emily Marden, Ben Warren et al 'Patent pools and genomics: Navigating a course to open science' (2010) 16 *BU J Sci & Tech L* 77. See also, Venni V Krishna 'Open science and its enemies: Challenges for a sustainable science–society social contract' (2020) 6(61) *J Open Innov Technol Mark Complex* 3.

⁷¹ OECD 'Open science' available at <https://www.oecd.org/sti/inno/open-science.htm#:~:text=Open%20science%20promotes%20a%20more,and%20re%2Dusing%20scientific%20material.>, accessed on 1 June 2022.

⁷² Ibid; Christopher Allen & David MA Mehler 'Open science challenges, benefits and tips in early career and beyond' (2019) 17(5) *PLoS Biol* 8.

⁷³ Gema Bueno de la Fuente 'What are the benefits of open science?' *Foster* available at <https://www.fosteropenscience.eu/content/what-are-benefits-open-science>, accessed on 1 June 2022.

⁷⁴ Allen & Mehler op cit note 72 at 8.

⁷⁵ Ibid at 9.

⁷⁶ OECD op cit note 71.

⁷⁷ Bill Hathaway 'Yale team finds way to protect genetic privacy in research' *Yale News* 12 November 2020, available at <https://news.yale.edu/2020/11/12/yale-team-finds-way-protect-genetic-privacy-research>, accessed on 1 June 2022; Martin Hetu, Konstantia Koutouki & Yann Joly 'Genomics for all: International open science genomics projects and capacity building in the developing world' (2019) 10(95) *Front Genet* 1–2.

⁷⁸ Rahul Ramachandran, Kaylin Bugbee & Kevin Murphy 'From open data to open science' (2021) 8 *Earth and Space Science* 2.

had significant long-term effects on the fields of biology and medicine – specifically in terms of the development of proteomics,⁷⁹ furthering the understanding of evolution, and the discovery and classification of a ‘parts list’ of nearly all human genes.⁸⁰ Since then, various other genomics research projects have adopted an open science approach. These include the International HapMap Project (HapMap),⁸¹ and the Encyclopedia of DNA Elements (ENCODE) Project.⁸² This shows the value of collaboration and open access and sharing of data in advancing genomics research, relevant discoveries, and ultimately bettering population health.

While the open science movement promises to optimise the benefits of genomics research, it also amplifies the potential risks to privacy of research participants. Can these apparently opposing interests be reconciled? To answer this question, I next discuss the core mechanism used to protect research participants in contemporary society: Informed consent.

(c) Informed consent and its bedrock: Autonomy

Research with human participants must adhere to certain legal and ethical standards in order to protect individuals and ensure that research complies with specified guidelines.⁸³ An important aspect is *consent*, which forms one of the most central issues in genomics research,⁸⁴ and is an expression of autonomy.⁸⁵ Consent is a means by which permission is provided by an individual for a certain purpose.⁸⁶ When consent is granted, it assumes that an individual is aware of, and understands, what he or she is consenting to – in other words, the individual is ‘informed’.⁸⁷ Thus, *informed* consent requires an understanding of the advantages, risks, aims, and possible consequences of a procedure or project so that when an individual agrees to such, he or she does so with full knowledge of all aspects.⁸⁸ Informed consent is a legal and ethical

⁷⁹ Proteomics refers to a field concentrating on ‘identifying and quantifying the proteins present in discrete biological compartments’. Ibid at 3.

⁸⁰ Ibid at 3.

⁸¹ Ibid at 3; National Human Genome Research Institute ‘About the International HapMap Project’ *NIH* 4 June 2012, available at <https://www.genome.gov/11511175/about-the-international-hapmap-project-fact-sheet#al-8>, accessed on 30 April 2022.

⁸² Ramachandran, Bugbee & Murphy op cit note 78 at 3; National Human Genome Research Institute ‘The Encyclopedia of DNA Elements (ENCODE)’ 27 September 2021 available at <https://www.genome.gov/Funded-Programs-Projects/ENCODE-Project-ENCyclopedia-Of-DNA-Elements#informed-consent>, accessed on 6 February 2022.

⁸³ Naresh Manandhar & Sunil Kumar Joshi ‘Importance of consent in the research’ (2020) 10(2) *IJOSH* 89.

⁸⁴ BA Townsend, RE Scott & M Mars ‘The development of ethical guidelines for telemedicine in South Africa’ (2019) 12(1) *S Afr J Bioethics Law* 23.

⁸⁵ Ibid at 23; Manandhar & Joshi op cit note 83 at 90.

⁸⁶ Townsend, Scott & Mars op cit note 84 at 23.

⁸⁷ Ibid at 23.

⁸⁸ ASSAf op cit note 56 at 4.

conditio sine qua non for medical procedures, use of human tissue, research with human participants,⁸⁹ and clinical trials.⁹⁰

Informed consent is seen as ‘an essential component of ethical research’,⁹¹ and is vital, especially in the context of genomics research. It provides the benchmark for ethical and legal research on human participants,⁹² allowing individuals to determine whether and how their samples and associated data are used.⁹³ Instead of being viewed as a mechanistic formality where documents are read and signed, informed consent should be dynamic, involving information exchange and decision making between the researcher and participant,⁹⁴ that allows individuals to understand the nature of the research and its risks, management of their samples and data, and safeguarding of their information.⁹⁵ In order for consent to be informed, individuals must be provided with adequate and understandable information, including the possible advantages and drawbacks, allowing them to make an informed and voluntary decision.⁹⁶

In *genomics* research the adequacy of informed consent has been questioned given the different samples and data collected, the various uses of the samples and data, the potentially unforeseen research projects in which samples and data may be utilised, and a possible lack of understanding of the complex processes involved.⁹⁷ Individuals may not only be consenting to the use of their samples and data for a single research project, but instead they may be agreeing to multiple uses of their samples and data (and possibly associated information), for current and future (and often unidentified) research projects,⁹⁸ and the transfer and sharing of their

⁸⁹ O O'Neill ‘Some limits of informed consent’ (2003) 29 *J Med Ethics* 4.

⁹⁰ Javad Parvizi, Rajit Chakravarty, Bora Og et al ‘Informed consent: Is it always necessary?’ (2008) 39 *Injury Int J Care Injured* 651.

⁹¹ Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* 2 ed (2006) 11. See also, Antonia Xu, Melissa Therese Baysari, Sophie Lena Stocker et al ‘Researchers’ views on, and experiences with, the requirement to obtain informed consent in research involving human participants: A qualitative study’ (2020) 21(93) *BMC Med Ethics* 2; Amy L McGuire & Laura M Beskow ‘Informed consent in genomics and genetic research’ (2010) 22(11) *Annu Rev Genomics Hum Genet* 361.

⁹² Peter A Chow-White, Maggie MacAulay, Anita Charters et al ‘From the bench to the bedside in the big data age: Ethics and practices of consent and privacy for clinical genomics and personalized medicine’ (2015) 17 *Ethics Inf Technol* 191.

⁹³ A Dhai & S Mahomed ‘Biobank research: Time for discussion and debate’ (2013) 103(4) *S Afr Med J* 226.

⁹⁴ A Dhai ‘Informed consent – 2008’ (2008) 1(1) *SAJBL* 27; Manandhar & Joshi op cit note 83 at 90.

⁹⁵ Manandhar & Joshi op cit note 83 at 90; Chow-White et al op cit note 92 at 191.

⁹⁶ Health Professions Council of South Africa *Guidelines for Good Practice in the Health Care Professions* (2016) 3; Manandhar & Joshi op cit note 83 at 89; McGuire & Beskow op cit note 91 at 361.

⁹⁷ McGuire & Beskow op cit note 91 at 361–2.

⁹⁸ Ibid at 361; Jacquelyn Ann K Kegley ‘Challenges to informed consent’ (2004) 5(9) *EMBO Rep* 835; Kieran C O’Doherty, Michael M Burgess, Kelly Edwards et al ‘From consent to institutions: Designing adaptive governance for genomic biobanks’ (2011) 73 *Social Science & Medicine* 367–8.

samples and data with other researchers and institutions⁹⁹ – both in South Africa and abroad.¹⁰⁰ Given the nature and purpose of genomics research and biobanking,¹⁰¹ and as individuals cannot know all the potential uses and fate of their samples and data, it has been questioned whether consent in this context can ever truly be *informed*.¹⁰² Is this a valid critique?

To understand and find answers to pertinent questions like these, one should consider the purpose served by informed consent. The value served by informed consent is *autonomy*. Informed consent safeguards autonomy by requiring individuals to voluntarily agree to a process or procedure based on sufficient information and knowledge.¹⁰³ The four principles of medical ethics suggested by Beauchamp and Childress¹⁰⁴ – namely autonomy, non-maleficence, beneficence, and justice – have influenced healthcare and are essential in recognising and evaluating approaches to ethical problems in the field.¹⁰⁵ Their importance has been aptly illustrated in the below quote by Gillon:¹⁰⁶

‘I think the four principles should also be thought of as the four moral nucleotides that constitute moral DNA – capable, alone or in combination, of explaining and justifying all the substantive and universalisable moral norms of health care ethics and I suspect of ethics generally’.¹⁰⁷

As autonomy is one of the four medical ethical principles, its importance (especially in terms of informed consent in this context) cannot be understated. Beauchamp and Childress assert that ‘the primary justification advanced for requirements of informed consent has been to protect autonomous choice’.¹⁰⁸ Because genomics research may have ramifications for privacy and identity, informed consent is crucial in preserving the *autonomy* of research participants.¹⁰⁹

⁹⁹ McGuire & Beskow op cit note 91 at 361.

¹⁰⁰ Keymanthri Moodley & Anita Kleinsmidt ‘Allegations of misuse of African DNA in the UK: Will data protection legislation in South Africa be sufficient to prevent a recurrence?’ (2021) 21 *Developing World Bioeth* 126.

¹⁰¹ Kegley op cit note 98 at 835.

¹⁰² Juli Murphy, Joan Scott, David Kaufman et al ‘Public perspectives on informed consent for biobanking’ (2009) 99(12) *Am J Public Health* 2128; Kegley op cit note 98 at 835; Kristin Solum Steinsbekk, Bjørn Kare Myskja & Berge Solberg ‘Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?’ (2013) 21 *Eur J Hum Genet* 897; O’Doherty et al op cit note 98 at 367–8.

¹⁰³ Aaron Hamvas, Katherine K Madden, Lawrence M Noguee et al ‘Informed consent for genetic research’ (2004) 158 *Arch Pediatr Adolesc Med* 551.

¹⁰⁴ Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 1 ed (1979).

¹⁰⁵ Katie Page ‘The four principles: Can they be measured and do they predict ethical decision making?’ (2012) 31(10) *BMC Med Ethics* 1.

¹⁰⁶ R Gillon ‘Ethics needs principles – Four can encompass the rest – And respect for autonomy should be first among equals’ (2003) 29(5) *J Med Ethics* 307–12.

¹⁰⁷ Page op cit note 105 at 1.

¹⁰⁸ Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 5 ed (2001) 77.

¹⁰⁹ National Human Genome Research Institute ‘Informed consent’ *NIH* 4 January 2022, available at <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent>, accessed on 7 May 2022.

Autonomy is a complex concept with many different definitions and characteristics. In the Western philosophical tradition, autonomy is typically understood either in a deontological or a utilitarian way. In the African philosophical tradition, with its emphasis on community, autonomy's meaning – and even its importance as a value – might be understood differently. In South Africa, autonomy has been recognised as a 'vital part of dignity',¹¹⁰ which is a constitutional right and value.¹¹¹ Because of autonomy's status as a bedrock of informed consent, I analyse autonomy in-depth in this thesis. This analysis includes autonomy's basis in the Constitution of the Republic of South Africa, 1996 (the Constitution).¹¹²

(d) *The importance of the community: Ubuntu*

An important question to consider is whether a pure autonomy-based understanding of informed consent is aligned with South Africa's constitutional commitment to Ubuntu. Ubuntu is seen as an underlying value of the South African constitutional order – thus making Ubuntu a relevant constitutional value. Ubuntu places 'emphasis on communality and on the interdependence of the members of a community'.¹¹³ In *S v Makwanyane*,¹¹⁴ it was held that:

'[U]buntu translates as *humaneness*...Metaphorically, it expresses itself in *umuntu ngumuntu ngabantu*, describing the significance of group solidarity on survival issues so central to the survival of communities. While it envelops the key values of group solidarity, compassion, respect, human dignity, conformity to basic norms and collective unity, in its fundamental sense it denotes humanity and morality. Its spirit emphasises respect for human dignity, marking a shift from confrontation to conciliation'.¹¹⁵

Although Ubuntu views individuals in relational terms, there is still recognition of the individual as such within the community.¹¹⁶ In terms of Ubuntu, communal relations should not be over-emphasised at the expense of the individual. It entails balancing the interests of the community and the individual, rather than viewing one as superior.¹¹⁷ But how does Ubuntu

¹¹⁰ *NM v Smith* 2007 (5) SA 250 (CC); *Barkhuizen v Napier* 2007 (5) SA 323 (CC) para 57; *Member of the Executive Council for Education: KwaZulu-Natal v Pillay* 2008 (1) SA 474 (CC) para 64 (*Pillay*); *AB v Minister of Social Development* 2016 (2) SA 27 (GP) para 89. See also, Donrich W Jordaan 'Autonomy as an element of human dignity in South African case law' (2009) 9(3) *Journal of Philosophy, Science & Law* 6.

¹¹¹ Section 10 of the Constitution.

¹¹² Act 108 of 1996.

¹¹³ *S v Makwanyane* 1995 (3) SA 391 (CC) para 224 (*Makwanyane*); *South African Police Service v Solidarity obo Barnard* 2014 (6) SA 123 (CC) para 174; *Pillay* para 53.

¹¹⁴ 1995 (3) SA 391.

¹¹⁵ *Makwanyane* para 308.

¹¹⁶ Bonginkosi Shoji *An Afrocentric Approach to CRISPR-Cas9: Analysing the Use of Genetic Technologies in Human Reproduction Through the Lens of Human Rights and African Values* (unpublished PhD thesis, University of KwaZulu-Natal, 2021) 50.

¹¹⁷ *Ibid* at 51.

impact the way in which consent is obtained for genomics research in South Africa? This is something that I explore in this thesis.

Research participants and their communities are not the only stakeholders in genomics research – what about the scientists?

(e) Freedom of scientific research: A promoter of open science

When considering genomics research, informed consent, and the policies surrounding it, freedom of scientific research, as a right in the Constitution,¹¹⁸ is relevant and should be considered. As noted by Thaldar and Steytler, the right to freedom of scientific research has received little attention, hence creating the need to understand the right and its practical application.¹¹⁹

There are three primary purposes that are served by the right to freedom of scientific research: (1) promoting individual autonomy, of both scientists and individuals in society;¹²⁰ (2) facilitating the search for the truth;¹²¹ and (3) supporting democracy, which has been seen to include values such as accountability, transparency, and participation in public life.¹²²

The right to freedom of scientific research, which contains elements of both individual and societal interests, is also facilitated by *open science* (discussed above). Not only does open science support the right to freedom of scientific research, by fostering the accessibility and transparency of knowledge, but freedom of scientific research is also necessary for the realisation of open science. Limiting the dissemination of research results would both violate the right to freedom of scientific research and erode open science.¹²³ Therefore, as part of the Department of Science and Innovation (DSI) *Draft National Open Science Policy*¹²⁴ – which aims to incorporate open science into South Africa’s national strategy – it is important that open science is promoted, and this may be accomplished through reliance on the right to freedom of scientific research – something that I examine in this thesis.

¹¹⁸ Section 16(1)(d) of the Constitution.

¹¹⁹ Donrich W Thaldar & Michaela Steytler ‘Time for Cinderella to go to the ball: Reflections on the right to freedom of scientific research’ (2021) 138 *SALJ* 262.

¹²⁰ Ibid at 272; Donrich Thaldar, Amy Gooden & Michaela Steytler ‘Open science and human genetic data: Recommendations on South Africa’s *Draft National Open Science Policy*’ (2023) 14 *Front Genet* 2.

¹²¹ Thaldar & Steytler op cit note 119 at 276; Thaldar, Gooden & Steytler op cit note 120 at 2.

¹²² Thaldar & Steytler op cit note 119 at 278; Thaldar, Gooden & Steytler op cit note 120 at 2.

¹²³ Thaldar, Gooden & Steytler op cit note 120 at 3.

¹²⁴ DSI op cit note 68.

(f) *Problematizing the modes of informed consent in South Africa*

Clearly, the open science movement in genomics research must plot its path in a legal landscape that is rich in constitutional values. Given that informed consent is the doorway to research, the question arises: To what extent do existing modes of informed consent provide for open science, while respecting the relevant constitutional values?

Two modes of consent currently employed in research in South Africa are specific consent and broad consent. Although blanket consent is not used in research in South Africa,¹²⁵ it features in the literature on the topic.¹²⁶ Specific consent delineates a precise project and restricts the use of samples and/or data to the purpose of that project only, thus necessitating new consent from individuals for future use of samples and/or data.¹²⁷ Broad consent defines a wide array of projects, allowing individuals to consent to the broad use of their samples and/or data for both current and possible future research.¹²⁸ Blanket consent is open-ended, with no limits or restrictions on the sharing and use of samples and data or the type of research to be undertaken.¹²⁹ It should also be noted that the Department of Health (DoH) *Ethics in Health Research: Principles, Processes and Structures* (DoH Ethics Guidelines),¹³⁰ while permitting

¹²⁵ Department of Health *Ethics in Health Research: Principles, Processes and Structures* 2 ed (2015) 31.

¹²⁶ See for example, Staunton et al op cit note 6 at 468–70; DW Thaldar & B Townsend ‘Genomic research and privacy: A response to Staunton et al’ (2020) 110(3) *S Afr Med J* 172–4; Thaldar & Townsend op cit note 39 at 1–31; Victoria Nembaware, Katherine Johnston, Alpha A Diallo et al ‘A framework for tiered informed consent for health genomic research in Africa’ (2019) 51(11) *Nat Genet* 1566–71; Shenuka Singh & Keymanthri Moodley ‘Stakeholder perspectives on the ethico-legal dimensions of biobanking in South Africa’ (2021) 22(84) *BMC Med Ethics* 1–13; Aminu Yakubu, Nchangwi Syntia Munung & Jantina De Vries ‘How should biobanking be governed in low-resource settings?’ (2020) 22(2) *AMA Journal of Ethics* 156–63; Keymanthri Moodley & Shenuka Singh ‘“It’s all about trust”: Reflections of researchers on the complexity and controversy surrounding biobanking in South Africa’ (2016) 17(57) *BMC Med Ethics* 1–9; Mwaka & Horn op cit note 43 at 307–17; Paulina Tindana, Sassy Molyneux, Susan Bull et al ‘“It is an entrustment”: Broad consent for genomic research and biobanks in sub-Saharan Africa’ (2019) 19 *Developing World Bioeth* 9–17; Staunton & Moodley op cit note 31 at 136–8; Beverley A Townsend & Donrich W Thaldar ‘Navigating uncharted waters: Biobanks and informational privacy in South Africa’ (2019) 35(4) *SAJHR* 329–50; Keymanthri Moodley, Nomathemba Sibanda, Kelsey February et al ‘“It’s my blood”: Ethical complexities in the use, storage and export of biological samples: Perspectives from South African research participants’ (2014) 15(4) *BMC Med Ethics* 1–7; Ciara Staunton & Keymanthri Moodley ‘Challenges in biobank governance in Sub-Saharan Africa’ (2013) 14(35) *BMC Med Ethics* 1–8; Jantina de Vries, Syntia Nchangwi Munung, Alice Matimba et al ‘Regulation of genomic and biobanking research in Africa: A content analysis of ethics guidelines, policies and procedures from 22 African countries’ (2017) 18(8) *BMC Med Ethics* 1–9; Paulina Tindana & Jantina de Vries ‘Broad consent for genomic research and biobanking: Perspectives from low- and middle-income countries’ (2016) 17 *Annu Rev Genom Hum Genet* 375–93; Moodley & Kleinsmidt op cit note 100 at 125–30; Safia Mahomed, Kevin Behrens, Melodie Slabbert et al ‘Managing human tissue transfer across national boundaries – An approach from an institution in South Africa’ (2016) 16(1) *Developing World Bioeth* 29–35.

¹²⁷ ASSAf op cit note 56 at 50; Department of Health op cit note 125 at 31; Thaldar, Botes & Nienaber op cit note 39 at 4.

¹²⁸ ASSAf op cit note 56 at 50–1; Department of Health op cit note 125 at 31; Thaldar, Botes & Nienaber op cit note 39 at 4.

¹²⁹ Department of Health op cit note 125 at 31; Thaldar, Botes & Nienaber op cit note 39 at 4.

¹³⁰ Department of Health op cit note 125. The DoH Ethics Guidelines are made legally binding through regulation 2(a) of the Human Research Participant Regulations, thus forming part of the NHA’s subsidiary legislation.

broad consent for health research in South Africa, does not recommend the use of blanket consent.¹³¹ In an attempt to protect research participants, some argue that informed consent should be more *specific*, so that research participants know exactly what they are consenting to.¹³² However, making the purpose for which research data can be used more specific, conflicts with the principles of open science where data is shared openly, without restrictions, and for a variety of purposes often unknown when donation occurs.¹³³

From the perspective of individual privacy rights and personal information protection in the context of genomics research, all these modes of consent are typically used to inform the prospective research participant of the ways in which his or her genomic data will be protected. I have already mentioned the various mechanisms that can be applied, ranging from de-identification to encryption. However, this typical approach assumes too much: It assumes that (1) the current technical protection mechanisms *can* offer the desired measure of data protection; and (2) all research participants *want* to exercise their privacy rights in their genomic data.

Regarding assumption (1), there are good reasons to question its veracity. Based on my discussion above, existing technical mechanisms are problematic and cannot guarantee that privacy will be protected. Regarding assumption (2), if autonomy is the bedrock of informed consent, assuming that all research participants *want* to exercise their privacy rights in their genomic data appears overly paternalistic. Instead of letting research participants decide for themselves whether they are willing to waive their privacy rights, they are given no such option, and it is decided on their behalf what their subjective will is (or ought to be). Furthermore, Ubuntu, with its emphasis on community, may not be suited to the individualistic notions of privacy and the idea that genomic data only belongs to the individual from whom it came from. Additionally, from the perspective of researchers, there may be valid reasons for keeping genomic data identifiable – from maintaining its value to supporting open science.

¹³¹ This is because there are challenges in upholding primarily respect for persons. Further, complete anonymisation of biological materials is not possible, which affects consent insofar as it relates to participant understanding and what is requested. Department of Health op cit note 125 at 31.

¹³² Alma Husedzinovic, Dominik Ose, Christoph Schickhardt et al ‘Stakeholders’ perspectives on biobank-based genomic research: Systematic review of the literature’ (2015) 23 *Eur J Hum Genet* 1611; Tindana et al op cit note 126 at 14.

¹³³ Yann Joly, Gratien Dalpé, Derek So et al ‘Fair shares and sharing fairly: A survey of public views on open science, informed consent and participatory research in biobanking’ (2015) 10(7) *PLoS ONE* 2.

(g) *A possible solution: Open consent*

Instead of focusing on protecting research participants' privacy interests and ensuring that they remain fully in control of their samples and data – which may be a pipedream and a false promise – why not adopt a model in which no such guarantees are made? In such a model, participants can consent to share their data for infinite and unforeseen research projects, across multiple countries, and by numerous institutions – aligned with the principles of open science. This is what *open consent* proposes and what this thesis explores in the context of genomics research in South Africa.

Open consent was pioneered by the PGP. The PGP was launched in 2005 at Harvard University and has since become a worldwide coalition of projects with the aim of generating publicly accessible genome, health, and trait data from 100,000 individuals,¹³⁴ and without active efforts to de-identify such data.¹³⁵ It recognises that, through DNA, it is possible to identify individuals and their traits, making guarantees of privacy (through de-identification or anonymisation) nonsensical. Further, fully de-identifying or anonymising genomic data is challenging and diminishes its quality and value.¹³⁶ Therefore, the PGP adopts an honest and transparent approach, where participants can be 'truly informed' regarding the nature of the research,¹³⁷ rather than merely being required to sign long and incomprehensible consent forms.¹³⁸ This led to the development of *open consent*.¹³⁹

Open consent entails that individuals openly donate and share their data for research.¹⁴⁰ It recognises that privacy cannot be guaranteed, and therefore makes no assurances regarding the anonymity, privacy, or confidentiality of data.¹⁴¹ Instead, open consent entails that participants agree to their genotype-phenotype data being freely published, while being made aware of the benefits and risks of participation (including that some risks may by

¹³⁴ The Personal Genome Project has expanded into Canada, the UK, Austria, and the People's Republic of China. Personal Genome Project: Global network op cit note 25; The Harvard Personal Genome Project 'About' available at <https://pgp.med.harvard.edu/about>, accessed on 22 September 2020. See also, Misha Angrist 'Eyes wide open: The Personal Genome Project, citizen science and veracity in informed consent' (2009) 6(6) *Per Med* 3–4.

¹³⁵ Angrist op cit note 134 at 4.

¹³⁶ Ibid at 2; Henry T Greely 'The uneasy ethical and legal underpinnings of large-scale genomic biobanks' (2007) 8 *Annu Rev Genomics Hum Genet* 352; Pike op cit note 52 at 2018; Anne SY Cheung 'Moving beyond consent for citizen science in big data health and medical research' (2018) 16(1) *Northwest J Technol Intellect Prop* 26.

¹³⁷ Cheung op cit note 136 at 26. See also, Madeleine P Ball, Jason R Bobe, Michael F Chou et al 'Harvard Personal Genome Project: Lessons from participatory public research' (2014) 6(10) *Genome Med* 2.

¹³⁸ Angrist op cit note 134 at 5.

¹³⁹ Oscar A Zarate, Julia Green Brody, Phil Brown et al 'Balancing benefits and risks of immortal data: Participants' views of open consent in the Personal Genome Project' (2016) *Hastings Center Rep* 37.

¹⁴⁰ Fida K Dankar, Marton Gergely & Samar K Dankar 'Informed consent in biomedical research' (2019) 17 *Computational and Structural Biotechnology Journal* 470.

¹⁴¹ Lunshof et al op cit note 59 at 5.

unanticipated),¹⁴² access to samples and data, erosion of privacy and confidentiality, and possible re-identification.¹⁴³ Further, to ensure that such consent is informed, the PGP requires potential participants to undergo (and pass with full marks) an assessment, in which their understanding of genomics and privacy is tested.¹⁴⁴ In essence, open consent is a form of blanket consent to making one's data open access to the public, coupled with an objective assessment of whether the consent is truly informed. However, open consent does differ from blanket consent in certain respects. First, while blanket consent may be utilised for data that has been de-identified, open consent makes no such guarantees, and the publishing and sharing of data is unrestricted and identifiable. Second, open consent can be seen to go a step further than blanket consent in requiring potential participants to pass an assessment in order to ensure that consent is informed. Accordingly, open consent can be perceived as an attempt to marry *open science* – and the benefits associated with it – with *informed consent*.

Given technological advances, the online sharing of information, and the challenges inherent in ensuring that the vast amounts of genomic data and associated information collected for research are made, and remain, anonymous, open consent recognises that assurances of privacy may be unsustainable.¹⁴⁵ Therefore, open consent depends on 'information altruists' to publicly share their data,¹⁴⁶ without guarantees of privacy or anonymity,¹⁴⁷ and instead informs participants of the benefits and risks associated with unconditional access to samples and data.¹⁴⁸ Open consent aims to achieve valid consent through veracity, and voluntariness through strict eligibility criteria, as requirements for informed consent.¹⁴⁹ An important difference between other modes of consent and open consent, as adopted by the PGP, lies in veracity.¹⁵⁰ The PGP's open consent model is based on the view that unrealistic commitments to anonymity invalidate consent, with autonomy and genuine consent only being attained through honest and comprehensive information.¹⁵¹

¹⁴² Jeantine E Lunshof, Jason Bobe, John Aach et al 'Personal genomes in progress: From the Human Genome Project to the Personal Genome Project' (2010) 12(1) *Dialogues Clin Neurosci* 56.

¹⁴³ Ibid at 56; Isabelle Budin-Ljøsne, Harriet JA Teare, Jane Kaye et al 'Dynamic consent: A potential solution to some of the challenges of modern biomedical research' (2017) 18(4) *BMC Med Ethics* 8.

¹⁴⁴ Angrist op cit note 134 at 5.

¹⁴⁵ Dankar, Gergely & Dankar op cit note 140 at 470.

¹⁴⁶ Ibid at 470.

¹⁴⁷ Zarate et al op cit note 139 at 37; Cheung op cit note 136 at 25–6; Budin-Ljøsne et al op cit note 143 at 8.

¹⁴⁸ Zarate et al op cit note 139 at 37; Budin-Ljøsne et al op cit note 143 at 8.

¹⁴⁹ Lunshof et al op cit note 59 at 5.

¹⁵⁰ Angrist op cit note 134 at 3.

¹⁵¹ Ball et al op cit note 137 at 2.

Open consent has been discussed in the literature, and some have attempted to redefine it.¹⁵² However, for purposes of this thesis, I use open consent as it is defined by its pioneer: the PGP. They define open consent as follows:

‘Open consent means that volunteers consent to unrestricted re-disclosure of data originating from a confidential relationship, namely their health records, and to unrestricted disclosure of information that emerges from any future research on their genotype-phenotype data set, the information content of which cannot be predicted. No promises of anonymity, privacy or confidentiality are made’.¹⁵³

Trait data, biospecimens, and any additional information that participants submit to the PGP are publicly available – on the PGP website and/or database.¹⁵⁴ Importantly, the PGP states that data which participants have chosen to publish will not be stored or provided in a confidential or anonymous manner and, further, those who access the data will not be required to manage it confidentially or anonymously.¹⁵⁵

To the definition quoted above I add an important – and I argue crucial – element of the PGP’s informed consent process, namely objective assessment of understanding. The PGP’s consent process comprises an eligibility questionnaire, online training with study material, an entrance assessment where participants must obtain 100%, and the signing of a consent form.¹⁵⁶ The objective assessment, which is used to gauge participants’ understanding

¹⁵² See for example, Mahomed et al op cit note 126 at 32; Steinsbekk, Myskja & Solberg op cit note 102 at 897; Dara Hallinan & Michael Friedewald ‘Open consent, biobanking and data protection law: Can open consent be “informed” under the forthcoming data protection regulation?’ (2015) 11(1) *Life Sciences, Society and Policy* 5; Kegley op cit note 98 at 833; B Hofmann ‘Broadening consent – And diluting ethics?’ (2009) 35 *J Med Ethics* 126; Gabriella Foe ‘Biobanks and informed consent’ (2014-2015) 1 *Voices in Bioethics* 2; Ants Nõmper *Open Consent – A New Form of Informed Consent for Population Genetic Databases* (Doctor Iuris, University of Tartu, 2005) 197.

¹⁵³ Lunshof et al op cit note 59 at 5.

¹⁵⁴ The Harvard PGP, in its consent form, details what the project entails, which data it collects, how it is published, and how it will be used. More specifically, the Harvard PGP holds genetic data (human DNA sequence, gene expression, and associated microbial sequence data), health data, trait data (such as date of birth, height, weight, blood pressure, allergies, immunisations, medications and other medical information, diet, ancestry, lifestyle, and physical traits), environmental exposures, and human cell lines. The Harvard Personal Genome Project ‘How it works’ available at <https://pgp.med.harvard.edu/how-it-works>, accessed on 30 April 2022; The Harvard Personal Genome Project ‘The PGP is not a traditional research study’ available at <https://pgp.med.harvard.edu/about>, accessed on 30 April 2022; The Harvard Personal Genome Project op cit note 13; Harvard Personal Genome Project ‘Consent form’ 12 July 2021 available at https://my.pgp-hms.org/static/PGP_Consent_2021-07-12_online.pdf, accessed 25 October 2021 7.

¹⁵⁵ Harvard Personal Genome Project op cit note 154 at 20.

¹⁵⁶ Zarate et al op cit note 139 at 37. See also, Dankar, Gergely & Dankar op cit note 140 at 470; Cheung op cit note 136 at 26–7; Angrist op cit note 134 at 5.

of the project, the use of their samples and data, and risks to their privacy, ensures that consent is *informed*.¹⁵⁷

Although informed consent is necessary for proper participation in genomics research, the means of obtaining such informed consent have been questioned.¹⁵⁸ For example, requiring individuals to read lengthy and complex documents which they may not understand, does not mean that informed consent has been obtained,¹⁵⁹ and is often deemed insufficient as the *sole* method for obtaining informed consent, given that participants tend not to even read the consent form.¹⁶⁰ While alternative methods to obtaining informed consent have been employed – such as verbal explanations and discussions;¹⁶¹ illustrations and brochures;¹⁶² audio, visuals, and film;¹⁶³ multimedia;¹⁶⁴ and teach back methods¹⁶⁵ – it is the objective assessment required as part of the PGP’s open consent process that warrants attention, and that forms a central element of this thesis.

While I suggest that the use of an objective assessment is an *essential* element of open consent, the Harvard PGP is neither alone in appreciating the value of objective assessments

¹⁵⁷ Jeremy Walter ‘General FAQ’ 18 April 2019 *GitHub*, available at <https://github.com/PGPHarvard/FAQ/wiki/General-FAQ#why-do-i-have-to-get-100-on-your-eligibility-questionnaire-before-i-can-join>, accessed on 5 May 2022.

¹⁵⁸ Lesley Jean Burgess, Berna Gerber, Kathleen Coetzee et al ‘An evaluation of informed consent comprehension by adult trial participants in South Africa at the time of providing consent for clinical trial participation and a review of the literature’ (2019) 11 *Open Access Journal of Clinical Trials* 20; Steven Joffe, E Francis Cook, Paul D Cleary et al ‘Quality of informed consent: A new measure of understanding among research subjects’ (2001) 93 *J Natl Cancer Inst* 139.

¹⁵⁹ Burgess et al op cit note 158 at 20.

¹⁶⁰ Marta S Palmeirim, Amanda Ross, Brigit Obrist et al ‘Informed consent procedure in a double blind randomized anthelmintic trial on Pemba Island, Tanzania: Do pamphlet and information session increase caregivers knowledge?’ (2020) 21(1) *BMC Med Ethics* 2. See also, Mehmet Özgür Özhan, Mehmet Anıl Süzer, İlker Çomak et al ‘Do the patients read the informed consent?’ (2014) 31 *Balkan Med J* 132.

¹⁶¹ Katherine van Loon & Graham Lindegger ‘Informed consent in clinical trials: Perceptions and experiences of a sample of South African researchers’ (2009) 14(1) *Health SA Gesondheid* 4; Kadam op cit note 10 at 111.

¹⁶² William J Heerman, Richard O White, Annie Hotop et al ‘A tool kit to enhance the informed consent process for community-engaged pediatric research’ (2016) 38(5) *IRB* 5–7; Zulfiqar A Bhutta ‘Beyond informed consent’ (2004) 82 *Bull World Health Organ* 775; Kadam op cit note 10 at 110.

¹⁶³ Rico Lie & Loes Witteveen ‘Visual informed consent: Informed consent without forms’ (2015) *Int J Soc Res Methodol* 1–13; Duke Clinical Research Institute ‘Video informed consent leads to faster and more diverse patient enrollment’ 9 April 2018 available at <https://dcri.org/video-informed-consent/>, accessed on 28 March 2022; Bhutta op cit note 162 at 775; Palmeirim et al op cit note 160 at 2; Kadam op cit note 10 at 111; Benoit Lattuca, Nicolas Barber-Chamoux, Benjamin Alos et al ‘Impact of video on the understanding and satisfaction of patients receiving informed consent before elective inpatient coronary angiography: A randomized trial’ (2018) 200 *American Heart Journal* 67–74; BH Figer, M Chaturvedi, SJ Thaker et al ‘A comparative study of the informed consent process with or without audiovisual recording’ (2017) 30(5) *National Medical Journal of India* 262–5; Özhan et al op cit note 160 at 135.

¹⁶⁴ Holly B Jimison, Paul P Sher, Richard Appleyard et al ‘The use of multimedia in the informed consent process’ (1998) 5(3) *JAMA* 245–56; N Bowers, E Eisenberg, J Montbriand et al ‘Using a multimedia presentation to improve patient understanding and satisfaction with informed consent for minimally invasive vascular procedures’ (2017) 15 *Surgeon* 8–10.

¹⁶⁵ Anthea Colledge, Josip Car, Ailsa Donnelly et al ‘Health information for patients: Time to look beyond patient information leaflets’ (2008) 101 *J R Soc Med* 448; Kadam op cit note 10 at 110.

as part of informed consent, nor is the use of objective assessments as part of informed consent new. For example, Kadam observes that ‘participants may have diverse learning abilities and educational backgrounds’,¹⁶⁶ making the evaluation of participant’s informed consent comprehension prior to them consenting fundamental.¹⁶⁷ In 1998, Jimison et al considered the use of multimedia in order to obtain informed consent, part of which included self-test questions.¹⁶⁸ ‘Teach back methods’¹⁶⁹ and questionnaires¹⁷⁰ have also been utilised to assess participant understanding.¹⁷¹ Methods to assess informed consent comprehension – such as the Deaconess Informed Consent Comprehension Test (DICCT);¹⁷² (2) the Quality of Informed Consent (QuIC) questionnaire;¹⁷³ and (3) the Brief Informed Consent Protocol (BICEP)¹⁷⁴ – have also been developed.¹⁷⁵ However, these methods have various weaknesses. For example, the QuIC questionnaire was developed for cancer clinical trials and may therefore be ill-suited to other trials. The QuIC questionnaire and the DICCT are grounded on requirements for consent in the United States of America (US) and may need to be modified for use in other countries.¹⁷⁶ Lastly, all three methods offer limited guidance regarding how to interpret and use potential participants’ test results for the purpose of recruitment.¹⁷⁷

In all of the above examples, enrolment does not appear to be contingent upon participants passing the assessment. Rather, it is merely used to determine whether participants

¹⁶⁶ Kadam op cit note 10 at 110.

¹⁶⁷ Ibid at 110.

¹⁶⁸ Jimison et al op cit note 164 at 250 & 252.

¹⁶⁹ Individuals are asked to describe things in their own words. Kadam op cit note 10 at 110.

¹⁷⁰ ‘Yes/no’, ‘agree/unsure/disagree’, ‘fill in the blanks’, multiple choice, short answer, or open-ended questions may be employed. Kadam op cit note 10 at 110; Laura D Buccini, Don Iverson, Peter Caputi et al ‘Assessing clinical trial informed consent comprehension in non-cognitively-impaired adults: A systematic review of instruments’ (2009) 5(1) *Research Ethics Review* 3.

¹⁷¹ Kadam op cit note 10 at 110.

¹⁷² The DICCT and the BICEP consist of both objective and open-ended, subjective interview questions. Cheryl K Miller, Dannielle C O’Donnell, H Russell Searight et al ‘The Deaconess Informed Consent Comprehension Test: An assessment tool for clinical research subjects’ (1996) 16(5) *Pharmacotherapy* 872–8; Buccini et al op cit note 170 at 5–6; Burgess et al op cit note 158 at 26.

¹⁷³ The QuIC questionnaire is an objective, multiple-choice (agree/unsure/disagree) assessment, also comprising of several subjective questions. Objective questions assess comprehension of complex concepts. Subjective questions gauge how well participants ‘feel’ that they comprehend the project. Joffe et al op cit note 158 at 139–47; Buccini et al op cit note 170 at 5–6; Burgess et al op cit note 158 at 26.

¹⁷⁴ The BICEP objective questions evaluate participants’ therapeutic misunderstandings. Subjective questions aim to ascertain whether participants are satisfied with the informed consent process. Unlike DICCT and QuIC, which provide potential research participants with information, followed by questions which must be answered prior to consenting, the BICEP assessment occurs once consent is given. Jeremy Sugarman, Philip W Lavori, Maryann Boeger et al ‘Evaluating the quality of informed consent’ (2005) 2 *Clinical Trials* 34–41; Buccini et al op cit note 170 at 5–6; Burgess et al op cit note 158 at 26.

¹⁷⁵ Buccini et al op cit note 170 at 3; Kadam op cit note 10 at 110.

¹⁷⁶ Buccini et al op cit note 170 at 7.

¹⁷⁷ Ibid at 7.

are able to sufficiently understand the content of the project and what they are consenting to.¹⁷⁸ According to Burgess et al, although researchers recognise the relevance of testing participants' informed consent comprehension, it is scarcely applied in practice – possibly due to ambiguity regarding the appropriate assessment mechanism, as well as how to manage participants who fail.¹⁷⁹ Questions arise, such as: (1) Should such participants be prevented from enrolling in a research project; and (2) should researchers continue to explain and assess relevant information until all participants pass?¹⁸⁰ The PGP answers these questions.

In terms of (1), the Harvard PGP, specifically, provides prospective participants with unlimited enrolment opportunities by allowing them to take the enrolment examination as many times as they like.¹⁸¹ Linked to this, and in terms of (2), the PGP allows all prospective participants to re-take the enrolment examination until they pass. Because the PGP is an ongoing project that is continuously enrolling new participants and building its database, it is not required that all participants pass the enrolment examination before the project can proceed.

As a brief excursus, there do not appear to be any other genomics research projects anywhere in the world (besides the PGP) that have adopted open consent. Although some other genomics projects provide openly accessible data that is available for anyone to download and use, most of these projects explicitly state that such data is de-identified before being released into the public domain.¹⁸² However, as discussed above, there is reason to be sceptical about claims that genomic data can be truly de-identified.

(i) *Honesty and open consent*

Proponents of open consent frequently highlight honesty as a defining characteristic of the model, emphasising that its transparency about data sharing risks and the uncertain nature of genomics research sets it apart from other consent models.¹⁸³ However, this association

¹⁷⁸ Jimison et al op cit note 164 at 250 & 252.

¹⁷⁹ Burgess et al op cit note 158 at 24.

¹⁸⁰ Ibid at 24.

¹⁸¹ Ball et al op cit note 137 at 2.

¹⁸² Examples include the Human Genome Project (HGP), the 1000 Genomes Project, The Microsetta Initiative (TMI), and the Encyclopedia of DNA Elements (ENCODE). International Human Genome Sequencing Consortium 'Initial sequencing and analysis of the human genome' (2001) 409 *Nature* 866; Pereira, Gibbs & McGuire op cit note 54 at 739–40; The International Genome Sample Resource op cit note 20; The Microsetta Initiative 'General information & how to participate' available at <https://microsetta.ucsd.edu/participant-resources/faqs/#1639185596602-6058c89a-1e1a>, accessed on 6 February 2022; National Human Genome Research Institute op cit note 82; Fred Hutchinson Cancer Research Center 'Research participant informed consent: Open data access to ENCODE data' 26 August 2014 available at https://www.genome.gov/Pages/Research/ENCODE/Approved_ENCODE_Consent_form_9_25_2014_UW.pdf, accessed on 6 February 2022.

¹⁸³ Zarate et al op cit note 139 at 37.

requires careful qualification. For example, broad consent also prioritises transparency and honesty, ensuring that participants are informed about potential future uses and uncertainties of their data. Thus, the claim that open consent is inherently more honest is a strategic argument rather than a distinctive ethical advantage. Recognising this nuance prevents an overly idealistic portrayal of open consent and aligns with a balanced understanding of the diverse consent models that seek to uphold scientific honesty and participant trust.

III LITERATURE REVIEW

(a) *Introduction*

This literature review explores two aspects of the topic of open consent: First, open consent in South Africa; and secondly, open consent in the international literature.

(b) *Open consent in South Africa*

There is currently a dearth of literature on open consent in South Africa. While there is a great deal of literature on other modes of consent in terms of research (and biobanking) – including specific consent,¹⁸⁴ broad consent,¹⁸⁵ tiered consent,¹⁸⁶ dynamic consent,¹⁸⁷ and blanket consent¹⁸⁸ – open consent has only been recently addressed in this context.¹⁸⁹

¹⁸⁴ See for example, Staunton et al op cit note 6 at 468–70; Thaldar & Townsend op cit note 126 at 172–4; Thaldar & Townsend op cit note 39 at 1–31; Singh & Moodley op cit note 126 at 1–13; Moodley & Singh op cit note 126 at 1–9; Tindana et al op cit note 126 at 9–17; Townsend & Thaldar op cit note 126 at 329–50.

¹⁸⁵ See for example, Staunton et al op cit note 6 at 468–70; Thaldar & Townsend op cit note 126 at 172–4; Thaldar & Townsend op cit note 39 at 1–31; Nembaware et al op cit note 126 at 1566–71; Singh & Moodley op cit note 126 at 1–13; Yakubu, Munung & De Vries op cit note 126 at 156–63; Moodley & Singh op cit note 126 at 1–91–9; Mwaka & Horn op cit note 43 at 307–17; Tindana et al op cit note 126 at 9–17; Staunton & Moodley op cit note 31 at 136–8; Townsend & Thaldar op cit note 126 at 329–50; Moodley et al op cit note 126 at 1–7; Staunton & Moodley op cit note 126 at 1–8; de Vries et al op cit note 126 at 1–9; Tindana & de Vries op cit note 126 at 375–93; Moodley & Kleinsmidt op cit note 100 at 125–30; Mahomed et al op cit note 126 at 29–35.

¹⁸⁶ See for example, Thaldar & Townsend op cit note 39 at 1–31; Nembaware et al op cit note 126 at 1566–71; Singh & Moodley op cit note 126 at 1–13; Moodley & Singh op cit note 126 at 1–91–9; Staunton & Moodley op cit note 31 at 136–8; Townsend & Thaldar op cit note 126 at 329–50; Moodley et al op cit note 126 at 1–7; Staunton & Moodley op cit note 126 at 1–8; de Vries et al op cit note 126 at 1–9; Moodley & Kleinsmidt op cit note 100 at 125–30.

¹⁸⁷ See for example, Thaldar & Townsend op cit note 39 at 1–31; Nembaware et al op cit note 126 at 1566–71; Moodley & Singh op cit note 126 at 1–9; Townsend & Thaldar op cit note 126 at 329–50; Tindana & de Vries op cit note 126 at 375–93.

¹⁸⁸ See for example, Staunton et al op cit note 6 at 468–70; Thaldar & Townsend op cit note 126 at 172–4; Thaldar & Townsend op cit note 39 at 1–31; Mwaka & Horn op cit note 43 at 307–17; Gavin Damster & John R Williams ‘The internet, virtual communities and threats to confidentiality’ (1999) 89(11) *S Afr Med J* 1175–8; Tindana et al op cit note 126 at 9–17; Townsend & Thaldar op cit note 126 at 329–50; de Vries et al op cit note 126 at 1–9; Tindana & de Vries op cit note 126 at 375–93; Mahomed et al op cit note 126 at 9–35.

¹⁸⁹ Amy Gooden & Donrich Thaldar ‘Towards an open access database of South Africans: Ethical considerations’ (2023) 14 *Front Genet* 1–7; Donrich Thaldar, Amy Gooden & Dusty-Lee Donnelly ‘Toward an open access genomics database of South Africans: Legal considerations’ (2023) 119 (7/8) *S Afr J Sci* 1–4.

South Africa also has various guidelines and documents that mention consent and research. The DoH *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* (Clinical Trial Guidelines),¹⁹⁰ and the Health Professions Council of South Africa (HPCSA) *Ethical Guidelines for Good Practice in the Health Care Professions*¹⁹¹ cover informed consent in research. However, open consent is absent from both documents. Although the DoH Clinical Trial Guidelines highlight the importance of publishing results, and recommend that certain trial results be made available in scientific journals or presented to scientific forums where they can be *openly* read and inspected¹⁹² – this is in relation to results (not raw data), and to a limited group of people (not the public at large).

Additionally, five South African documents – the Academy of Science of South Africa (ASSAf) Report on *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (ASSAf Report),¹⁹³ the DoH Ethics Guidelines,¹⁹⁴ the ASSAf *POPIA Code of Conduct for Research*,¹⁹⁵ and the recently released National Health Research Ethics Council (NHREC) *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* (NHREC Ethics Guidelines)¹⁹⁶ as well as the ASSAf *POPIA Compliance Framework for Research and Research Institutions* (POPIA Compliance Framework)¹⁹⁷ – relate to genomics and research and, while they cover other modes of consent, none of these documents mention open consent.

Given this gap in the literature and the fact that open consent is yet to be properly explored in South Africa, this thesis addresses the unanswered question of whether open consent is suited to genomics research in South Africa.

(c) *Open consent in the international literature*

¹⁹⁰ Department of Health op cit note 91.

¹⁹¹ HPCSA op cit note 96. Specifically, booklets 4 and 13.

¹⁹² Department of Health op cit note 91 at 37.

¹⁹³ ASSAf op cit note 56.

¹⁹⁴ Department of Health op cit note 125.

¹⁹⁵ Academy of Science of South Africa (ASSAf) *POPIA [proposed] Code of Conduct for Research* (2023) GG 48589 of 12 May 2023.

¹⁹⁶ National Department of Health *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* 3 ed (2024).

¹⁹⁷ The POPIA Compliance Framework was previously known as the *POPIA Code of Conduct for Research*. However, following submission of the *POPIA Code of Conduct for Research* to the Information Regulator, it was decided that the *POPIA Code of Conduct for Research* would be converted into a voluntary POPIA Compliance Framework instead. Academy of Science of South Africa (ASSAf) *POPIA Compliance Framework for Researchers and Research Institutions* [draft] (2024); ASSAf op cit note 195; Academy of Science of South Africa (ASSAf) ‘Update on the draft Code of Conduct for Research and introduction of the ASSAf POPIA Compliance Framework’ 29 February 2024 available at https://www.assaf.org.za/wp-content/uploads/2024/02/ASSAf-Communication-to-Stakeholders-regarding-the-Framework_February-2024.pdf, accessed on 9 August 2024.

Limited literature exists on open consent (as defined by the PGP). Several articles have been written by founders of the PGP and serve to outline the concept of open consent, what it entails, the processes involved, as well as progress that has been made.¹⁹⁸ Instead of properly analysing open consent, much of the literature merely introduces the concept in reference to the PGP, and reiterates what the PGP has said regarding open consent.

Lunshof et al propose that the foremost moral principle in open consent is veracity, which ‘should precede autonomy’,¹⁹⁹ and without which there cannot be ‘authentic autonomy’.²⁰⁰ This has since been repeated by several authors when referring to open consent.²⁰¹ It is clear that open consent values individual autonomy and the provision of open-ended consent.²⁰² However, Foe has argued that because participants may wish to maintain some control in ensuring that their samples are not used in certain studies, in this regard open consent fails to respect autonomy.²⁰³

Discussions on open consent also highlight that ‘[n]o promises of anonymity, privacy or confidentiality are made’.²⁰⁴ What is clear from the literature is that although there are measures available to protect privacy, these have shortcomings and privacy cannot be absolutely guaranteed.²⁰⁵ As such, open consent informs participants of the benefits and risks involved in having unrestricted access to data, including that some risks may be unforeseen.²⁰⁶ However, it has been recognised that certain countries outside of the US – where the PGP was founded – have privacy protection laws which may prevent researchers from using open consent in sharing the health data of participants.²⁰⁷

A concern is that accurately examining the international literature on open consent and identifying trends is not always straightforward, as there are authors who have tended to view

¹⁹⁸ Madeleine P Ball, Joseph V Thakuria, Alexander Wait Zaraneka et al ‘A public resource facilitating clinical use of genomes’ (2012) 109(30) *PNAS* 11920–7; Angrist op cit note 134 at 1–13; Ball et al op cit note 137 at 1–7; Lunshof et al op cit note 59 at 2–7.

¹⁹⁹ Lunshof et al op cit note 59 at 5.

²⁰⁰ Angrist op cit note 134 at 3; Ball et al op cit note 137 at 2; Lunshof et al op cit note 59 at 5.

²⁰¹ See, Yann Joly, Stephanie OM Dyke, Bartha M Knoppers et al ‘Are data sharing and privacy protection mutually exclusive?’ (2016) 167 *Cell* 1151; O’Doherty et al op cit note 98 at 368; Ball et al op cit note 137 at 2; Lunshof et al op cit note 142 at 56.

²⁰² Ball et al op cit note 198 at 11921.

²⁰³ Foe op cit note 152 at 4.

²⁰⁴ Lunshof et al op cit note 59 at 5. See also, Ball et al op cit note 137 at 1; Zarate et al op cit note 139 at 39; Cheung op cit note 136 at 26; Ball et al op cit note 198 at 11921; Budin-Ljøsne et al op cit note 143 at 8.

²⁰⁵ Lunshof et al op cit note 142 at 56; Budin-Ljøsne et al op cit note 143 at 8.

²⁰⁶ Zarate et al op cit note 139 at 39.

²⁰⁷ Joly et al op cit note 201 at 1151–2.

open consent as being synonymous with broad consent or blanket consent.²⁰⁸ While several authors simply equate open consent with blanket consent,²⁰⁹ and even refer to open consent as a synonym of broad consent or general consent,²¹⁰ I suggest that this is incorrect.²¹¹ Those in the literature who have attempted to (re-)define open consent,²¹² or its common features,²¹³ tend to omit certain vital aspects that distinguish open consent from other modes of consent. Open consent, although sharing similarities with other types of consent, is a distinct concept. First, no assurances are made to participants regarding privacy, confidentiality, and anonymity. As such, it is vital that participants understand what the process entails and what they are consenting to, given the high risks involved. In the case of the PGP, this is assessed through a determination of participants' objective understanding. Second, no effort is made to de-identify or anonymise participant data. Third, data is publicly accessible. Unlike broad consent, where there may be emphasis on the de-identification or anonymisation of data, open consent makes no such promises. Open consent can be viewed as a sub-species of broad and blanket consent, but one that is catered to the realities of genomics research.

(d) Nuancing open science and open consent in North-South contexts

Open science and open consent are often celebrated for their potential to democratise scientific research through transparency, data sharing, and collaborative efforts.²¹⁴ In genomics research, open consent promises to accelerate discovery by enabling unrestricted access to datasets,

²⁰⁸ See, Kegley op cit note 98 at 833; Hofmann op cit note 152 at 126; Foe op cit note 152 at 2; Hallinan & Friedewald op cit note 152 at 5; Timothy Caulfield & Blake Murdoch 'Genes, cells, and biobanks: Yes, there's still a consent problem' (2017) 15(7) *PLoS Biol* 1; Mark Sheehan & James Martin 'Can broad consent be informed consent?' (2011) 4(3) *Public Health Ethics* 231.

²⁰⁹ Kegley op cit note 98 at 833; Hofmann op cit note 152 at 126; Foe op cit note 152 at 2; Hallinan & Friedewald op cit note 152 at 5.

²¹⁰ Hallinan & Friedewald op cit note 152 at 5; Caulfield & Murdoch op cit note 208 at 1.

²¹¹ However, it should be noted that there are authors in the literature who note that open consent is neither broad consent nor blanket consent. Hallinan and Friedewald explicitly state that open consent is 'clearly not' blanket consent. The reason for this is that open consent, rather than seeking permission all future uses of data, requires approval for the 'future use of personal data' *in research*. Mahomed et al op cit note 126 at 32; Steinsbekk, Myskja & Solberg op cit note 102 at 897; Hallinan & Friedewald op cit note 152 at 5.

²¹² It is also apparent that the definitions of open consent, put forward by some authors in the literature, are akin to those of broad or blanket consent. For example, Nömpfer defines open consent as 'a research subject's affirmative agreement to participate in a population genetic database and in research projects that use tissue and data from that database'. Nömpfer op cit note 152 at 197.

²¹³ Hallinan and Friedewald put forward three common features of open consent: (1) consent by participants is only provided *once*; (2) participants consent to their samples and data being used for all future research, and not a particular project; and (3) biobanks, rather than participants, decide whether a research project will be granted use of the desired samples and/or data based on their application to request access. Hallinan & Friedewald op cit note 152 at 5.

²¹⁴ Mark Walport & Paul Brest 'Sharing research data to improve public health' (2011) 377(9765) *The Lancet* 537.

fostering innovation and collective benefit.²¹⁵ However, this requires careful scrutiny, particularly in the context of North-South relations where disparities in scientific infrastructure, funding, and capacity shape who benefits from open data regimes.

Staunton et al provide a critique of open science in the context of health data sharing, arguing that while data may be openly accessible, the capacity to analyse and derive benefit from such data is not evenly distributed.²¹⁶ Well-resourced institutions, often situated in the Global North, typically possess advanced equipment, larger teams, and greater funding, enabling them to leverage shared data more effectively than smaller or under-resourced laboratories in the Global South. This imbalance risks reinforcing structural inequalities in global research, where data contributors in lower-resource settings become mere providers of raw data, while the benefits of subsequent analyses – publications, career advancement, patents, and biomedical products – accrue primarily to researchers in wealthier countries.²¹⁷

Yet, this argument requires nuanced consideration. When genomic data originates from South African populations, the ultimate goal should be that the benefits of research – improved healthcare, diagnostics, and treatments – flow back to these communities regardless of where the data analysis occurs.²¹⁸ The scientific value of such data is inherently tied to its source population, underscoring an ethical imperative to ensure equitable benefit-sharing and capacity development in the country of origin.²¹⁹ However, disparities in capacity reflect broader political, economic, and governance challenges, not intrinsic flaws in open science itself. It is the responsibility of countries in the Global South to strategically invest in scientific infrastructure, education, and funding to enable their researchers to engage competitively in global research networks.²²⁰ Seen in this light, open science can act as a catalyst for domestic reform and scientific sovereignty rather than a vehicle for dependency.

While open science and open consent hold significant promise for advancing global genomics research, it is crucial to move beyond idealised portrayals. A critical engagement with North-South inequities, capacity gaps, and governance challenges allows for a balanced

²¹⁵ Zarate et al op cit note 139 at 37.

²¹⁶ Ciara Staunton, Carlos Andrés Barragán, Stefano Canali et al ‘Open science, data sharing and solidarity: Who benefits?’ (2021) 43(4) *Hist Philos Life Sci* 3.

²¹⁷ Ibid at 3.

²¹⁸ Michele Ramsay ‘African genomic data sharing and the struggle for equitable benefit’ (2022) 3 *Patterns* 1.

²¹⁹ Natalia Evertsz, Susan Bull & Bridget Pratt ‘What constitutes equitable data sharing in global health research? A scoping review of the literature on low-income and middle-income country stakeholders’ perspectives’ (2023) 8 *BMJ Glob Health* 1.

²²⁰ Leslie Chan, Angela Okune & Nanjira Sambuli ‘What is open and collaborative science and what roles could it play in development?’ in Sarita Albagli, Maria Lucia Maciel & Alexandre Hannud Abdo (eds) *Open Science, Open Issues* (2015) 87.

appraisal that acknowledges both the ethical potential and the limitations of these approaches. Rather than constraining open science practices to protect existing inefficiencies, the focus should be on strengthening governance and policy frameworks that promote equitable participation and benefit-sharing. This nuanced perspective highlights the need for strategic investments, policy reforms, and participatory governance to ensure that open data initiatives contribute to fair scientific and health outcomes globally. Such an approach aligns closely with South Africa's broader constitutional commitments to equality and social justice, reinforcing the imperative to harness genomics research for national development.

IV STATEMENT OF PURPOSE

The concept of open consent has not yet been explored as a mode of consent to research in South Africa. There are, of course, multiple considerations when deciding on a mode of consent, ranging from practical considerations – such as familiarity with a certain mode of consent by researchers and ethics committee members involved, and whether research participants would be amendable to a certain mode of consent – to financial considerations, such as funder willingness to give grants to projects characterised by a certain mode of consent. In addition, there might be policy considerations, such as alignment with open science, as well as other policy objectives. However, I focus purely on a kind of consideration that I suggest is fundamental – at least from a legal perspective – namely *constitutional* considerations. In my discussion above, I identified four salient constitutional rights and/or values relevant to an analysis of open consent in the genomics research context, namely *autonomy*, a value which underlies informed consent generally; *Ubuntu*, which is an underlying constitutional value that places autonomy in an African perspective, and aims to strike a balance between the individual and society; *freedom of scientific research*, which is a right that contains elements of individual and societal interests and is facilitated by open science; and *privacy*, which is a right and an over-riding concern in research generally, but becomes especially problematic in the context of genomics research.

While consent is utilised in various different areas – from law to medicine – this thesis focuses on open consent in the context of genomics research specifically, and not health research more broadly. This is because of the unique nature of genomic data and the fact that proper de-identification is unlikely, giving rise to privacy and confidentiality concerns.²²¹ As

²²¹ Lunshof et al op cit note 59 at 2.

such, given the unique characteristics and increasing relevance of *genomics* research, my analysis is focused on this type of research.

This thesis does not directly consider the appropriateness of other modes of consent in genomics research in South Africa – such as specific consent, broad consent, tiered consent, dynamic consent, and blanket consent. Analyses of these modes of consent have already been undertaken in South Africa.²²² Existing modes of consent are presented to show what exists currently, and are used to show any potential shortcomings and to differentiate open consent from these modes of consent. However, open consent is a relatively new mode of consent that has not yet been investigated or applied in South Africa, and it may be that open consent is ideally suited to genomics research in this context – something that this thesis examines.²²³

Additionally, this thesis does not undertake a positivist analysis and examine South Africa's legal framework which may be applicable to open consent in genomics research in South Africa. There is no doubt that this is an important topic, but one that will be explored separately. This thesis purely consists of a *constitutional analysis* exploring the concept of open consent in the context of genomics research in South Africa, and whether it is aligned with the various rights and values of the Constitution.

Although the primary focus of this thesis is on the four identified constitutional rights and/or values mentioned above – namely autonomy, Ubuntu, freedom of scientific research, and privacy – this thesis is not limited to such, and where other constitutional rights and/or values are found to be relevant, they are integrated into this thesis.

V RATIONALE

Consent is utilised in various areas, but its importance in genomics research cannot be understated, given the risks involved. Such risks include the privacy and anonymisation of

²²² See for example, Staunton et al op cit note 6 at 468–70; Thaldar & Townsend op cit note 126 at 172–4; Thaldar & Townsend op cit note 39 at 1–31; Nembaware et al op cit note 126 at 1566–71; Singh & Moodley op cit note 126 at 1–13; Yakubu, Munung & De Vries op cit note 126 at 156–63; Moodley & Singh op cit note 126 at 1–9; Mwaka & Horn op cit note 43 at 307–17; Damster & Williams op cit note 188 at 1175–8; Tindana et al op cit note 126 at 9–17; Staunton & Moodley op cit note 31 at 136–8; Townsend & Thaldar op cit note 126 at 329–50; Moodley et al op cit note 126 at 1–7; Staunton & Moodley op cit note 126 at 1–8; Dhali & Mahomed op cit note 93 at 225–7; de Vries et al op cit note 126 at 1–9; Tindana & de Vries op cit note 126 at 375–93; Moodley & Kleinsmidt op cit note 100 at 125–30; Mahomed et al op cit note 126 at 29–35.

²²³ However, this thesis explores the meaning and use of other modes of consent, where appropriate, in order to compare and contrast them with open consent.

data;²²⁴ incidental findings;²²⁵ genetic discrimination;²²⁶ security of, and access to information;²²⁷ and the use and fate of samples and data.²²⁸ Part of the genomics research process involves the collection of samples from individuals, which are then sequenced and analysed to obtain their unique DNA sequence, and subsequently used by researchers in their projects. If such data were to be publicised, the consequences for individuals – who have not consented to the open access and use of their data – could be serious. It is thus important for individuals to understand, and consent to, these potential risks. However, genomics research often makes assertions regarding de-identification and the privacy of individual data. But this cannot be guaranteed – especially given the nature of genomic data.²²⁹ Therefore, it is worth considering whether promises of privacy and anonymity ought to be abandoned in genomics research in South Africa. Is it not desirable to rather focus on veracity and transparency, and alert research participants to the fact that because their samples and data are at risk of re-identification, no guarantees of privacy will be made? This is what open consent promises. I suggest that it is a valuable contribution to knowledge to explore this from a South African constitutional perspective in the genomics research context.

VI RESEARCH QUESTIONS

The main research question to be answered in this thesis is: *From a constitutional perspective, is open consent an acceptable mode of consent for genomics research in South Africa?* As highlighted in my discussion above, there are four main constitutional rights and/or values that are salient to the main research question, namely autonomy, Ubuntu, freedom of scientific research, and privacy. In order to assist in answering the main research question, the following sub-questions are posed:

1. What modes of consent are currently used in genomics research in South Africa?

²²⁴ David S Wendler & Annette Rid 'Genetic research on biospecimens poses minimal risk' (2015) 31(1) *Trends Genet* 2; JM Oliver, MJ Slashinski, T Wang et al 'Balancing the risks and benefits of genomic data sharing: Genome research participants' perspectives' (2012) 15 *Public Health Genom* 109.

²²⁵ For example, research into cardiac disease may discover variants associated with greater risk of breast cancer, which may lead to stress and anxiety. Wendler & Rid op cit note 224 at '2.

²²⁶ Oliver et al op cit note 224 at 109.

²²⁷ M Amorim, S Silva, T Maia et al 'Benefits and risks of sharing genetic data for research purposes: The views of patients and carers' (2020) 30(5) *Eur J Public Health* 136.

²²⁸ Oliver et al op cit note 224 at 109.

²²⁹ Pereira, Gibbs & McGuire op cit note 54 at 740; Kaye op cit note 50 at 10–1; Malin, Karp & Scheuermann op cit note 54 at 4; Pike op cit note 52 at 2016–7; Cacchio op cit note 54 at 231; Altman op cit note 54 at 16; Resnik op cit note 54 at 46; Gymrek et al op cit note 54 at 321–4; Erlich et al op cit note 54 at 1.

2. Is open consent aligned with the constitutional value of *autonomy*?
3. Is open consent aligned with the constitutional value of *Ubuntu*?
4. Is open consent aligned with the constitutional right to *freedom of scientific research*?
5. Is open consent aligned with the constitutional right to *privacy*?
6. Can (or should) open consent be applied to genomics research in South Africa?

VII CONCEPTUAL FRAMEWORK

The conceptual framework that is used in this thesis is two-fold. This thesis adopts a positivist approach in analysing the modes of consent currently used in research in South Africa, through an examination of the extant law. However, this thesis predominantly consists of a constitutional analysis in examining the values of autonomy and Ubuntu, as well as the rights to freedom of scientific research and to privacy, in determining the suitability of open consent for genomics research in South Africa and whether it is aligned with the relevant constitutional rights and/or values.

VIII RESEARCH METHODOLOGY

In order to investigate the research question, this thesis consists of desktop-based doctrinal research complemented by a review of relevant bioethical and philosophical literature. This involves an examination of primary and secondary legal, ethical, and philosophical sources of both print and electronic materials. Primary sources include, but are not limited to, publicly available examples of consent documents; national statutes and regulations; case law from South Africa; national guidelines, policies, government documents, and regulations; recommendations from various organisations and professional bodies; position statements and official reports; interviews, presentations, and panel discussions; statistical and empirical research data; and research reports. Secondary sources largely comprise of scientific, medical, and legal academic textbooks and journals, as well as journal articles; dissertations and theses; internet articles and sources; editorials and opinion pieces; online magazine articles; books; and reports.

The choice of a doctrinal methodology is both deliberate and appropriate for the nature of the research question, which is fundamentally normative, namely whether open consent for genomics research is constitutionally justifiable in the South African legal context. Doctrinal

legal research is particularly suited to studies that seek to interpret, evaluate, and systematise legal principles.²³⁰ In this context, the focus is on analysing four key constitutional concepts – autonomy, Ubuntu, privacy, and freedom of scientific research – and assessing how these can inform the legitimacy of open consent in genomics research in South Africa.

This thesis does not include empirical research, which is a methodological choice reflecting the conceptual and normative aims. Incorporating empirical research, such as interviews with researchers or analysis of consent forms, would have required a different research design and focus. While such data could have added real-world insight into participant experiences or attitudes toward open consent, the choice to focus on desktop-based research was guided by the normative nature of the primary research question – namely, whether open consent is constitutionally acceptable in principle. Nonetheless, the limitations of the doctrinal approach are recognised and empirical research provides a valuable avenue for future research.

IX CHAPTER OUTLINE

(a) Chapter 1 – Introduction

Chapter 1 provides an introduction to the topic and includes the statement of purpose, rationale, research questions, literature review, conceptual framework, and research methodology. This Chapter provides the foundations for the discussions that ensue in subsequent chapters.

(b) Chapter 2 – Problematising the modes of consent used in genomics research in South Africa

This Chapter examines the modes of consent currently used in genomics research in South Africa – with a focus on specific consent, broad consent, blanket consent, tiered consent, and dynamic consent. Chapter 2 also briefly explores more recent and novel modes of consent, such as meta consent, and examines the concept of open consent in more detail. Additionally, this Chapter analyses the conflation of open consent with other modes of consent and determines whether open consent may be reconcilable with the modes of consent currently used in genomics research in South Africa.

²³⁰ Stefan Theil ‘Carefully tailored: Doctrinal methods and empirical contributions’ (2025) *Oxford Journal of Legal Studies* 3.

(c) Chapter 3 – Autonomy and Ubuntu

Chapter 3 considers autonomy and whether (and how), from a constitutional perspective, it can be reconciled with open consent, focusing on genomics research in South Africa. This Chapter also involves a discussion of the constitutional right to bodily and psychological integrity. Autonomy shares close links with Ubuntu and, as such, Chapter 3 examines the principle of Ubuntu and its application to open consent (and autonomy). This Chapter predominantly involves an examination of philosophical texts, academic discussions, and South African case law relating to autonomy and Ubuntu.

(d) Chapter 4 – Freedom of scientific research

This Chapter assesses the right to freedom of scientific research and whether it fits in with open science – and by extension, open consent from a constitutional perspective. Chapter 4 predominantly entails an examination of academic discussions and South African case law relevant to the right to freedom of scientific research.

(e) Chapter 5 – Privacy

Chapter 5 analyses the right to privacy and its relevance to open consent through an evaluation of the concept, specifically in genomics research in South Africa and from a constitutional perspective. This Chapter entails an investigation of the literature and South African case law relevant to privacy.

(f) Chapter 6 – Conclusion

This Chapter forms the conclusion and integrates the findings of this thesis, and point towards areas for further research. Based on the analyses in the previous Chapters, Chapter 6 determines whether, from a constitutional perspective, open consent is suited to the South African genomics research context and, if so, this Chapter makes recommendations for a suitable model of open consent for South Africa.

CHAPTER 2

PROBLEMATISING THE MODES OF CONSENT USED IN GENOMICS RESEARCH IN SOUTH AFRICA

I INTRODUCTION

Consent is vital for genomics research. It ensures protection of privacy, respect for autonomy, addresses ethical concerns, and maintains trust between researchers and participants.¹ But consent alone is insufficient – there is a necessity for this consent to be *informed*. Informed consent is essential in research. It is not only an ethical requirement, but also a legal one.² Informed consent is a process that aims to inform potential participants of the purpose, nature, objectives, benefits, and risks of the research, thereby allowing research participants to exercise their autonomy by deciding whether or not to participate in the research based upon their knowledge of all aspects.³ The provision of accurate information creates an understanding that upholds participant rights, promotes ethical practices, and fosters trust between participants and researchers.⁴ In certain instances, such as genomics research, there has been concern that due to the complexity of the research and the information provided to participants, consent may not be informed.⁵

¹ Aaron Hamvas, Katherine K Madden, Lawrence M Noguee et al ‘Informed consent for genetic research’ (2004) 158 (6) *Arch Pediatr Adolesc Med* 551.

² National Human Genome Research Institute ‘Why is informed consent required?’ *NIH* 25 March 2024, available at <https://www.genome.gov/about-genomics/educational-resources/fact-sheets/why-is-informed-consent-required>, accessed on 18 February 2024.

³ Rasmus Bjerregaard Mikkelsen, Mickey Gjerris, Gunhild Waldemar et al ‘Broad consent for biobanks is best – Provided it is also deep’ (2019) 20 *BMC Med Ethics* 2; National Human Genome Research Institute ‘The informed consent process’ *NIH* 3 January 2022, available at <https://www.genome.gov/about-genomics/educational-resources/fact-sheets/the-informed-consent-process>, accessed on 18 February 2024; National Human Genome Research Institute op cit note 2; National Human Genome Research Institute ‘Informed consent’ *NIH* 4 January 2022, available at <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent>, accessed on 7 May 2022.

⁴ Centre for Genetics Education ‘Research consent’ *NSW Government* 2019 available at <https://www.genetics.edu.au/SitePages/Research-consent.aspx>, accessed on 18 February 2024; National Human Genome Research Institute op cit note 2.

⁵ Juli Murphy, Joan Scott, David Kaufman et al ‘Public perspectives on informed consent for biobanking’ (2009) 99(12) *Am J Public Health* 2128; Jacquelyn Ann K Kegley ‘Challenges to informed consent’ (2004) 5(9) *EMBO Rep* 835; Kristin Solum Steinsbekk, Bjørn Kare Myskja & Berge Solberg ‘Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?’ (2013) 21 *Eur J Hum Genet* 897; Kieran C O’Doherty, Michael M Burgess, Kelly Edwards et al ‘From consent to institutions: Designing adaptive governance for genomic biobanks’ (2011) 73 *Social Science & Medicine* 367–8; Amy L McGuire & Laura M Beskow ‘Informed consent in genomics and genetic research’ (2010) 22(11) *Annu Rev Genomics Hum Genet* 361–2.

Whereas informed consent traditionally required participants to voluntarily partake in research based on the provision of adequate information and understanding, advances in science and technology have caused a shift in the type of research that can now be undertaken.⁶ The collection, use, storage, and sharing of human biological samples and associated data for genomics research has made it challenging to detail or foresee all future uses and research at the time of collection.⁷ As a result, various modes of consent have been developed which will be utilised – depending on the type and nature of the research, the participants involved, the context, and a range of ethical, legal, and practical considerations.

II CHAPTER OVERVIEW

In order to place the different modes of consent in context, this Chapter examines the various modes of consent that exist in South Africa (and elsewhere in the world), but specifically focuses on those modes of consent that are currently used in genomics research in South Africa. This Chapter begins by exploring consent in South Africa, specifically where it features in statutes and guidelines. It then continues by defining and assessing the various modes of consent in South Africa, including specific consent, broad consent, blanket consent, tiered consent, and dynamic consent – whilst also mentioning those that have not yet been examined in this context, such as meta consent and open consent – as well as addressing any problems. This Chapter includes reference to legislation, guidelines, and reports in exploring the modes of consent currently used in genomics research in South Africa. Additionally, this Chapter examines the concept of open consent in more detail – briefly exploring its utilisation in genomics research and its conflation with other modes of consent. This Chapter concludes by considering whether open consent can be reconciled with any of the existing modes of consent in South Africa.

III CONSENT IN SOUTH AFRICA

There are various modes of consent in existence, some of which are utilised in genomics research – not only in South Africa, but worldwide. While authors in the literature have discussed different modes of consent in general, and for genomics research in particular,⁸ South

⁶ McGuire & Beskow op cit note 5 at 361.

⁷ Ibid at 361.

⁸ C Staunton, R Adams, M Botes et al ‘Safeguarding the future of genomic research in South Africa: Broad consent and the Protection of Personal Information Act No. 4 of 2013’ (2019) 109(7) *S Afr Med J* 468–70; DW Thaldar & B Townsend ‘Genomic research and privacy: A response to Staunton et al’ (2020) 110(3) *S Afr Med J* 172–4; Victoria Nembaware, Katherine Johnston, Alpha A Diallo et al ‘A framework for tiered informed consent for

Africa has various legal instruments that also mention consent and research. Importantly, in the context of research and experiments, section 12(2)(c) of the Constitution provides that ‘[e]veryone has the right to bodily and psychological integrity, which includes the right...not to be subjected to medical or scientific experiments without their informed consent’.⁹ Although not stipulating the mode of consent, it is clear that the Constitution requires consent to be *informed*.

Furthermore, the National Health Act 61 of 2003 (NHA),¹⁰ the Protection of Personal Information Act 4 of 2013 (POPIA), the Regulations Relating to the Use of Human Biological Material (Human Biological Material Regulations),¹¹ the Regulations Relating to Research with Human Participants (Human Research Participant Regulations),¹² and the SA MTA each contain their own modes of consent for research. Each of these instruments will be expanded upon below.

The DoH Clinical Trial Guidelines,¹³ and the HPCSA *Ethical Guidelines for Good Practice in the Health Care Professions*¹⁴ cover informed consent in research. The DoH Clinical Trial Guidelines state that informed consent is ‘an essential component of ethical

health genomic research in Africa’ (2019) 51(11) *Nat Genet* 1566–71; Shenuka Singh & Keymanthri Moodley ‘Stakeholder perspectives on the ethico-legal dimensions of biobanking in South Africa’ (2021) 22(84) *BMC Med Ethics* 1–13; Aminu Yakubu, Nchangwi Syntia Munung & Jantina De Vries ‘How should biobanking be governed in low-resource settings?’ (2020) 22(2) *AMA Journal of Ethics* 156–63; Keymanthri Moodley & Shenuka Singh ‘“It’s all about trust”: Reflections of researchers on the complexity and controversy surrounding biobanking in South Africa’ (2016) 17(57) *BMC Med Ethics* 1–9; Paulina Tindana, Sassy Molyneux, Susan Bull et al ‘“It is an entrustment”: Broad consent for genomic research and biobanks in sub-Saharan Africa’ (2019) 19 *Developing World Bioeth* 9–17; Beverley A Townsend & Donrich W Thaldar ‘Navigating uncharted waters: Biobanks and informational privacy in South Africa’ (2019) 35(4) *SAJHR* 329–50; Keymanthri Moodley, Nomathemba Sibanda, Kelsey February et al ‘“It’s my blood”: Ethical complexities in the use, storage and export of biological samples: Perspectives from South African research participants’ (2014) 15(4) *BMC Med Ethics* 1–7; Ciara Staunton & Keymanthri Moodley ‘Challenges in biobank governance in Sub-Saharan Africa’ (2013) 14(35) *BMC Med Ethics* 1–8; Jantina de Vries, Syntia Nchangwi Munung, Alice Matimba et al ‘Regulation of genomic and biobanking research in Africa: A content analysis of ethics guidelines, policies and procedures from 22 African countries’ (2017) 18(8) *BMC Med Ethics* 1–9; Paulina Tindana & Jantina de Vries ‘Broad consent for genomic research and biobanking: Perspectives from low- and middle-income countries’ (2016) 17 *Annu Rev Genom Hum Genet* 375–93; Safia Mahomed, Kevin Behrens, Melodie Slabbert et al ‘Managing human tissue transfer across national boundaries – An approach from an institution in South Africa’ (2016) 16(1) *Developing World Bioeth* 29–35.

⁹ Section 12(2)(c) of the Constitution.

¹⁰ Sections 7 and 55 of the NHA.

¹¹ GN R177 GG 35099 of 2 March 2012. Regulation 3(1)(a) of the Human Biological Material Regulations.

¹² GN R719 GG 38000 of 19 September 2014. Regulation 2(f) of the Human Research Participant Regulations.

¹³ Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* 2 ed (2006).

¹⁴ Health Professions Council of South Africa *Guidelines for Good Practice in the Health Care Professions* (2016). Specifically, booklets 4 and 13.

research'.¹⁵ Additionally, several South African documents – the ASSAf Report,¹⁶ the DoH Ethics Guidelines¹⁷ (as well as the recently released NHREC Ethics Guidelines¹⁸), and the ASSAf draft *POPIA Compliance Framework for Research and Research Institutions* (draft POPIA Compliance Framework)¹⁹ (as well as the proposed *POPIA Code of Conduct for Research*)²⁰ – relate to genomics and research and cover different modes of consent.

Before proceeding, certain technicalities relating to the South African documents mentioned above would be beneficial to discuss. First, the DoH Ethics Guidelines. The second edition of the DoH Ethics Guidelines was published in 2015 and has served to guide health research in South Africa.²¹ However, the DoH Ethics Guidelines have since been amended, with the final version of the NHREC Ethics Guidelines being published in May 2024.²² The NHREC Ethics Guidelines make substantial changes to the DoH Ethics Guidelines, and at the time of writing this thesis, various academics have filed appeals with the NHREC, the body tasked with revising the national guidelines for health research ethics,²³ challenging the validity of various aspects of the NHREC Ethics Guidelines – such as ownership of human biological material and data, benefit sharing, and the alignment with POPIA.²⁴ Therefore, placing sole reliance on the NHREC Ethics Guidelines at this stage would be premature given their potential invalidity. As such, in the headings below I mention where the NHREC Ethics Guidelines refer to different modes of consent, but I do not rely on their position as authoritative. Second, the proposed *POPIA Code of Conduct for Research*. ASSAf submitted the proposed *POPIA Code of Conduct for Research* to the Information Regulator in April 2023 for review. However, this proposed *POPIA Code of Conduct for Research*, was rejected – primarily due to procedural and representational issues.²⁵ ASSAf has since chosen to convert the proposed *POPIA Code of*

¹⁵ Department of Health op cit note 13 at 11.

¹⁶ Academy of Science of South Africa (ASSAf) *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (2018).

¹⁷ Department of Health *Ethics in Health Research: Principles, Processes and Structures* 2 ed (2015).

¹⁸ National Department of Health *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* 3 ed (2024).

¹⁹ Academy of Science of South Africa (ASSAf) *POPIA Compliance Framework for Researchers and Research Institutions* [draft] (2024).

²⁰ Academy of Science of South Africa (ASSAf) *POPIA [proposed] Code of Conduct for Research* (2023) GG 48589 of 12 May 2023.

²¹ Department of Health op cit note 17.

²² National Department of Health op cit note 18.

²³ Ibid at ii.

²⁴ Paul Esselaar, Lee Swales, Devarasi Bellengère et al 'Forcing a square into a circle: Why South Africa's draft revised material transfer agreement is not fit for purpose' (2024) 15 *Front Pharmacol* 1–8.

²⁵ Academy of Science of South Africa (ASSAf) 'Update on the draft Code of Conduct for Research and introduction of the ASSAf POPIA Compliance Framework' 29 February 2024 available at https://www.assaf.org.za/wp-content/uploads/2024/02/ASSAf-Communication-to-Stakeholders-regarding-the-Framework_February-2024.pdf, accessed on 9 August 2024.

Conduct for Research into a voluntary draft POPIA Compliance Framework.²⁶ Although the draft POPIA Compliance Framework is still in its infancy, it will aim to guide researchers and research institutions in complying with POPIA. Although the draft POPIA Compliance Framework remains a draft at the time of writing this thesis, I refer to it where necessary as it will replace the proposed *POPIA Code of Conduct for Research* and will hopefully be finalised in the future.

South Africa's legal landscape defines the type of consent that must be obtained from participants for data collection, research, storage, and sharing.²⁷ Consent for research is covered by several South African statutes, albeit in varying degrees and in differing ways. Although not the core focus of this thesis, open consent cannot be fully examined and understood without briefly giving credence to South Africa's legal landscape and the relevant statutes that cover different modes of consent.

(a) *National Health Act 61 of 2003 and its related regulations*

The NHA,²⁸ the Human Biological Material Regulations,²⁹ the Human Research Participant Regulations,³⁰ and the SA MTA each contain their own provisions on consent. In terms of research on human participants, section 71(1)(b) of the NHA requires 'written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health'. Written informed consent is required to have biological material removed for *inter alia* genetic health research, in terms of the Human Biological Material Regulations.³¹

The Human Research Participant Regulations provide that research involving human participants must 'be undertaken with appropriate consent processes'.³² Regulation 5 of the Human Research Participant Regulations stipulates the information that research participants are required to be informed of, which includes: The purpose of the research; the possible risks and benefits; and 'the extent to which confidentiality and privacy will be maintained'. There are two aspects that require attention. First, the requirement of a recognisable purpose in regulation 5(g) of the Human Research Participant Regulations seems to imply that blanket

²⁶ Ibid.

²⁷ DW Thaldar & BA Townsend 'Exempting health research from the consent provisions of POPIA' (2021) 24 *PER/PELJ* 4.

²⁸ Sections 7 and 55 of the NHA.

²⁹ Regulation 3(1)(a) of the Human Biological Material Regulations.

³⁰ Regulation 2(f) of the Human Research Participant Regulations.

³¹ Regulation 3(1)(a) of the Human Biological Material Regulations.

³² Regulation 2(f) of the Human Research Participant Regulations.

consent is prohibited. But as it is possible for multiple studies to have a single, over-arching purpose, it appears that broad consent is allowed under the Human Research Participant Regulations.³³ Second, regulation 5(g) of the Human Research Participant Regulations does not require that confidentiality and privacy *actually* be maintained, thus allowing the possibility of an open consent model where no guarantees of confidentiality and privacy are made and research participants are informed of this.

The SA MTA defines informed consent as ‘a formal agreement that a Donor (with legal capacity to do so) signs to give permission for donation of Materials, after being informed about the project and includes an on -going information sharing process which allows a Donor to consent to participate and determine whether and how their Materials will be utilised in the Project, as approved by the HREC from time to time’.³⁴

(b) Protection of Personal Information Act 4 of 2013

POPIA is South Africa’s seminal data protection legislation and aims to balance the constitutional rights of privacy and access to information. Section 1 of POPIA defines ‘consent’ as ‘any voluntary, *specific* and informed expression of will in terms of which permission is given for the processing of personal information’ (own emphasis).

POPIA’s specific consent requirement differs from the norm in South Africa where genetic research is typically conducted using broad consent, allowing researchers to utilise, and participants to consent to the use of, genetic data for a wide range of current as well as prospective, unknown purposes.³⁵ Although there has been debate in the literature regarding the specificity of consent required in terms of POPA – with Staunton et al arguing that a purposive interpretation of the provisions of POPIA pertaining to consent for research allow broad consent³⁶ – Thaldar and Townsend have clarified that interpreting POPIA purposively supports its ordinary meaning, namely that specific consent is required in order to collect and

³³ Thaldar & Townsend op cit note 27 at 5.

³⁴ Para 2.12 of the SA MTA.

³⁵ However, problems may arise in terms of the broad consent model as it may not always be feasible to inform consumers of every research project in which their data will be used. Staunton and Moodley argue that broad consent may encompass sample exportation as participants consent to the storage and reuse of samples for future, unidentified research, which could encompass research in another country. Thaldar & Townsend op cit note 8 at 172; C Staunton & K Moodley ‘Data mining and biological sample exportation from South Africa: A new wave of bioexploitation under the guise of clinical care?’ (2016) 106(2) *SAMJ* 137.

³⁶ Staunton et al contend that requiring specific consent for genetic research could impede progress because it would necessitate re-contacting and re-consenting participants who originally gave broad consent. They assert that genetic research serves the public interest, and specific consent could undermine this broader goal. Therefore, they advocate interpreting POPIA in a way that supports broad consent for using personal information in research, aligning with the public interest in advancing scientific innovation. Staunton et al op cit note 8 at 468.

process personal information.³⁷ But what is the meaning of specific consent, as POPIA defines it? This is discussed below.

(c) *Department of Health Ethics in Health Research: Principles, Processes and Structures*

Although not a statute in itself, the DoH Ethics Guidelines are legally binding on researchers and institutions conducting health research with human participants through regulation 2(a) of the Human Research Participant Regulations.³⁸ The DoH Ethics Guidelines provide three types of consent deemed acceptable for use in research, namely narrow (restrictive) consent, tiered consent, and broad consent.³⁹ Although these forms of consent are satisfactory, the DoH Ethics Guidelines – in stark contrast with POPIA, which specifies that consent must demonstrate an ‘expression of will’,⁴⁰ and information must be collected for a ‘specific’ purpose⁴¹ – state that consent should be ‘broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health’⁴² – thereby purporting to allow, and prefer, broad consent for genetic research.⁴³ The NHREC Ethics Guidelines do not provide such a preference and instead present the modes of consent that it deems acceptable – namely narrow consent, broad consent, and tiered consent.⁴⁴

Since a brief overview of the relevant South African statutes that cover consent and research has been provided, below I examine some of the most prominent modes of consent – namely specific consent, broad consent, blanket consent, tiered consent, and dynamic consent – in order to establish how they are positioned and utilised in the South African research context.

³⁷ In *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism* 2004 (4) SA 490 (CC) para 91, the Constitutional Court endorsed a purposive approach to statutory interpretation. This approach considers the context while still respecting the literal meaning and importance of the words used. In *Bertie Van Zyl (Pty) Ltd v Minister for Safety and Security* 2010 (2) SA 181 (CC) para 22, the Constitutional Court emphasised that the purposive interpretation of a statute must stay true to its actual wording. Therefore, Thaldar et al argue that trying to reinterpret ‘specific’ as ‘broad’ in POPIA seems to rely too heavily on purposive interpretation, potentially straying from the statute’s intended meaning. See also, *South African Airways (Pty) Ltd v Aviation Union of South Africa* 2011 (3) SA 148 (SCA) paras 25–30; *Natal Joint Municipal Pension Fund v Endumeni Municipality* 2012 (4) SA 593 (SCA) para 18; Thaldar & Townsend op cit note 8 at 172; Donrich W Thaldar, Marietjie Botes & Annelize Nienaber ‘South Africa’s new standard material transfer agreement: Proposals for improvement and pointers for implementation’ (2020) 21(85) *BMC Med Ethics* 4. See also, Townsend & Thaldar op cit note 8 at 329–50.

³⁸ Amy Gooden ‘A pathway to strengthening open science: Comments on the draft *South African Ethics in Health Research Guidelines*’ (2024) 15 *Front Pharmacol* 2.

³⁹ Department of Health op cit note 17 at 31.

⁴⁰ Section 1 of POPIA.

⁴¹ Section 13(1) of POPIA; ASSAf op cit note 16 at 52.

⁴² Department of Health op cit note 17 at 31; Thaldar, Botes & Nienaber op cit note 37 at 4.

⁴³ Department of Health op cit note 17 at 31.

⁴⁴ National Department of Health op cit note 18 at 66.

IV THE VARIOUS MODES OF CONSENT IN SOUTH AFRICA

(a) *Specific consent*

The consent model that offers the most protection to research participants, but is the most restrictive to researchers,⁴⁵ is specific consent. In terms of specific consent, participants consent to a defined and specific research project.⁴⁶ Specific consent delineates a precise project and restricts the use of samples and/or data to the purpose of that project only, thus necessitating new consent from participants for future use of samples and/or data.⁴⁷

Specific consent has been viewed as impractical and costly in genomics research, given the need to re-contact and re-consent participants for each new project⁴⁸ – which may hinder research and innovation.⁴⁹ This has caused researchers to suggest broader forms of consent.⁵⁰ While such approaches may suit researchers, they limit the control that participants have over their data and the studies in which it is used.⁵¹

Specific consent features in South African legislation. Section 7(3) of the NHA provides that informed consent means ‘consent for the provision of a *specified* health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6’ (own emphasis).⁵² Further, the DoH Ethics Guidelines define narrow or restrictive consent (which can be equated to specific consent) as ‘the donor permits use of the biological specimen for single use only; no storage of leftover specimen; and no sharing of data or specimen. This form necessitates new consent if further use is desirable’.⁵³ The NHREC Ethics Guidelines outline several different consent models and, except for blanket or unrestricted consent which it deems unacceptable as it cannot support foundational ethical principles,⁵⁴ it does not expressly appear to prohibit the use of other modes of consent – including specific consent.

⁴⁵ ASSAf op cit note 16 at 50; Thaldar & Townsend op cit note 27 at 2–3.

⁴⁶ Thaldar & Townsend op cit note 27 at 2–3; Tindana et al op cit note 8 at 10; Thaldar, Botes & Nienaber op cit note 37 at 4; Thaldar & Townsend op cit note 8 at 172.

⁴⁷ ASSAf op cit note 16 at 50; Department of Health op cit note 17 at 31; Thaldar & Townsend op cit note 27 at 2–3; Tindana et al op cit note 8 at 10; Francis Masiye, Walter Jaoko & Stuart Rennie ‘Stakeholder views on informed consent models for future use of biological samples in Malawi and South Africa’ (2023) 24 *BMC Med Ethics* 4.

⁴⁸ Staunton et al op cit note 8 at 469; Thaldar & Townsend op cit note 8 at 173; Townsend & Thaldar op cit note 8 at 336; ASSAf op cit note 16 at 50.

⁴⁹ Staunton et al op cit note 8 at 469.

⁵⁰ Townsend & Thaldar op cit note 8 at 336–7.

⁵¹ Ibid at 337.

⁵² Section 7(3) of the NHA.

⁵³ Department of Health op cit note 17 at 43.

⁵⁴ National Department of Health op cit note 18 at 67.

The NHREC Ethics Guidelines note that specific consent is the most constrictive.⁵⁵ The ‘donor/participant permits single use only of biological materials; no storage; no sharing of data or specimen; new consent if further use wanted’.⁵⁶

Specific consent has also been a prominent topic in terms of POPIA. POPIA defines consent as ‘any voluntary, *specific* and informed expression of will in terms of which permission is given for the processing of personal information’ (own emphasis).⁵⁷ Both the proposed *POPIA Code of Conduct for Research* and the draft POPIA Compliance Framework adopt the same position as that in POPIA regarding consent: That consent is to be *specific*, voluntary, informed, and explicit.⁵⁸ Additionally, section 13(1) of POPIA requires that personal information be collected for a ‘*specific*, explicitly defined and lawful purpose related to a function or activity of the responsible party’ (own emphasis).⁵⁹ It has been argued that the use of the singular ‘purpose’ in section 13(1) of POPIA suggests that consent must be given for each specific purpose, rather than providing all-encompassing consent for a wide array of purposes.⁶⁰

Despite what has been said in the literature regarding whether a purposive interpretation of POPIA allows for broad consent or specific consent,⁶¹ it is important to distinguish between POPIA consent and ethics consent. Although there may be areas of overlap, assuming that the consent in POPIA can be equated with specific consent, as it is understood in the ethics discourse, is not entirely accurate. When understanding the use of the term ‘specific’ in POPIA, it seems that the question in terms of POPIA is whether the focus should be on the consent or the purpose. One may get two different results if they focus on specific consent and a specific purpose. POPIA defines consent as including the word *specific*,⁶² but it seems more to be the case that reference to specific is rather referring to the specificity of the purpose and not to the mode of consent. POPIA’s requirement for consent to be specific likely means that it must be for a specified purpose, not just any purpose.

⁵⁵ Ibid at 67.

⁵⁶ Ibid at 67 & 104.

⁵⁷ Section 1 of POPIA.

⁵⁸ ASSAf op cit note 20 at 18–9; ASSAf op cit note 19 at 12.

⁵⁹ Section 13(1) of POPIA.

⁶⁰ Dusty-Lee Donnelly *Privacy by (re)Design: A Comparative Study of the Protection of Personal Information in the Mobile Applications Ecosystem under United States, European Union and South African Law* (unpublished Doctor of Laws thesis, University of KwaZulu-Natal, 2020) 244.

⁶¹ Staunton et al op cit note 8 at 468; Thaldar & Townsend op cit note 8 at 172; Thaldar, Botes & Nienaber op cit note 37 at 4. See also, Townsend & Thaldar op cit note 8 at 329–50.

⁶² Section 1 of POPIA.

The draft POPIA Compliance Framework refers to ‘POPIA consent’, which is defined as ‘[c]onsent required by POPIA’ and not as specific consent.⁶³ In terms of the need for POPIA consent to be specific, the draft POPIA Compliance Framework states that POPIA consent must be clear in describing the specific purpose for which personal information is being processed. It is insufficient to obtain consent to ‘conduct research’, and the consent must link to a clearly defined project.⁶⁴ As such, health research or genomics research may be considered a specific purpose in terms of POPIA. In contrast, specific consent in the ethics context is much narrower – such as consent for a defined research project, like a five-year grant-funded health research project with specific objectives and parameters. As such, from a legal perspective, broad consent – as it is typically defined by ethicists – can fit within POPIA’s requirement for consent to be for a specific purpose.

In terms of POPIA, the purpose must be clear enough for individuals to understand why their personal information is being collected and how it will be used.⁶⁵ But how specific must this purpose be? POPIA does not define the term ‘specific’ and the draft POPIA Compliance Framework merely states that ‘simply obtaining consent to “conduct research” will not be sufficient’.⁶⁶ If stating ‘research’ as a purpose is too broad, should the focus then be narrowed down to the specific discipline, such as genomics research? Or are researchers required to provide even more detail, such as specifying the type of genomics research, for example, the genetic variations associated with diabetes? This level of specificity can become a slippery slope. Imposing such restrictions could hinder the right to freedom of scientific research (discussed in Chapter 4) and impede and progress of science and medicine.⁶⁷

In an attempt to protect research participants, some argue that informed consent should be more *specific*, so that research participants know exactly what they are consenting to.⁶⁸ However, making the purpose for which research data can be used more specific, conflicts with

⁶³ ASSAf op cit note 19 at 48.

⁶⁴ Ibid at 12.

⁶⁵ Ibid at 12.

⁶⁶ Ibid at 12.

⁶⁷ Amy Gooden *Unregulated or Not? A Legal Analysis of South Africa’s Legislative Framework Relevant to Direct-to-Consumer Genetic Testing* (unpublished Master of Laws dissertation, University of KwaZulu-Natal, 2021) 194.

⁶⁸ Alma Husedzinovic, Dominik Ose, Christoph Schickhardt et al ‘Stakeholders’ perspectives on biobank-based genomic research: Systematic review of the literature’ (2015) 23 *Eur J Hum Genet* 1611; Tindana et al op cit note 8 at 14.

the principles of open science where data is shared openly, without restrictions, and for a variety of purposes often unknown when donation occurs.⁶⁹

(b) Broad consent

Prior to the proliferation of genomics research and biobanking, specific consent was the norm for research involving human participants.⁷⁰ Participants consented to every project being undertaken, and it was only that project for which their consent was valid.⁷¹ However, genomics research and biobanks have created challenges regarding specific consent, especially given the number of participants involved and the numerous studies being undertaken.⁷² This has resulted in the development of adapted consent models that cater to this type of research.⁷³

Broad consent defines a wide array of projects, allowing individuals to consent to the use of their biological samples and associated data in primary research undertaken at the time of sample collection, as well as future (and possibly unknown) research.⁷⁴

Although broad consent typically defines a wide range of studies, they may come with certain restrictions.⁷⁵ For example, future use of samples may be governed by an access committee,⁷⁶ new studies may require review by an independent research ethics committee,⁷⁷ research participants may consent to only certain types of future research,⁷⁸ and research participants may be allowed to withdraw their consent and may need to provide new consent if the research framework changes.⁷⁹

Given that there may be difficulties and resources involved in re-contacting research participants to obtain their consent for every new research project,⁸⁰ especially where the biological material and associated data of vast numbers of individuals has been utilised, broad

⁶⁹ Yann Joly, Gratien Dalpé, Derek So et al 'Fair shares and sharing fairly: A survey of public views on open science, informed consent and participatory research in biobanking' (2015) 10(7) *PLoS ONE* 2.

⁷⁰ Mikkelsen et al op cit note 3 at 1.

⁷¹ Ibid at 1.

⁷² Ibid at 1.

⁷³ Ibid at 1.

⁷⁴ Tindana & de Vries op cit note 8 at 376; Tindana et al op cit note 8 at 10; ASSAf op cit note 16 at 50–1; Department of Health op cit note 17 at 31; Thaldar, Botes & Nienaber op cit note 37 at 4; Townsend & Thaldar op cit note 8 at 337; Staunton & Moodley op cit note 8 at 2; Thaldar & Townsend op cit note 27 at 3.

⁷⁵ Thaldar & Townsend op cit note 8 at 172; Thaldar & Townsend op cit note 27 at 3; Tindana et al op cit note 8 at 10.

⁷⁶ Nembaware et al op cit note 8 at 2.

⁷⁷ Erisa Mwaka & Lyn Horn 'Researchers' perspectives on informed consent and ethical review of biobank research in South Africa: A cross-sectional study' (2019) 14(4) *J Empir Res Hum Res Ethics* 6.

⁷⁸ Ibid at 6.

⁷⁹ Ibid at 6.

⁸⁰ Moodley et al op cit note 8 at 2; Moodley & Singh op cit note 8 at 3.

consent has featured as a preferred mode of consent.⁸¹ Research participants provide consent once, at the time of sample collection, and then their samples and data may be used for a range of research projects that fall within the broad category for which consent was granted.⁸² Broad consent is seen by some as being aligned with current research practices, it upholds research participant autonomy, it involves minimal risks to research participants (especially in terms of future research), and it permits the re-use of samples whilst avoiding the need to recruit new participants, which is both expensive and time-consuming.⁸³

However, broad consent is not without its criticisms. It has been questioned whether broad consent provides research participants with sufficient information about the research,⁸⁴ and thereby limits research participant autonomy.⁸⁵ Further, concern has been expressed as to whether broad consent is truly informed⁸⁶ – especially given that certain research may be unforeseen at the time that consent is given.⁸⁷

In South Africa, broad consent features in the DoH Ethics Guidelines, which it defines as ‘the donor donates materials with permission to use them for a broad range of future studies, subject only to further prior ethics review and approval’.⁸⁸ The DoH Ethics Guidelines show a preference for broad consent, by stating that research ethics committees should consider ‘the vision of the H3Africa Initiative and its recommendation that consent should be “broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health”’.⁸⁹

The NHREC Ethics Guidelines also include broad consent, defining it as ‘donor/participant permits use of HBM or data for future similar but as yet unspecified studies, subject to further prior ethics review and approval’.⁹⁰ The NHREC Ethics Guidelines recognise that although broad consent has greater flexibility than tiered consent (discussed below), it is not without restrictions. It allows the research participant to consent to the current project, as

⁸¹ Staunton & Moodley op cit note 8 at 2.

⁸² Mwaka & Horn op cit note 77 at 4.

⁸³ Tindana et al op cit note 8 at 10; Tindana & de Vries op cit note 8 at 376.

⁸⁴ Singh & Moodley op cit note 8 at 9.

⁸⁵ Tindana & de Vries op cit note 8 at 376.

⁸⁶ Singh & Moodley op cit note 8 at 9.

⁸⁷ Tindana & de Vries op cit note 8 at 376.

⁸⁸ Department of Health op cit note 17 at 30 & 53.

⁸⁹ Ibid at 31.

⁹⁰ National Department of Health op cit note 18 at 104.

well as permit storage and future use of samples and data within the ambit of the current research.⁹¹

(c) *Blanket consent*

In contrast to specific consent, blanket consent is open-ended, with no limits or restrictions on the sharing and use of samples and data or the type of research to be undertaken.⁹² With blanket consent, no project is defined and there are no limits on the type and range of research that may be undertaken,⁹³ or the future use of biological samples and associated data.⁹⁴ Blanket consent requires research participants to consent to their samples and data being used in a multitude of research, at the discretion of the researcher.⁹⁵ Unlike broad consent, blanket consent offers less information to research participants regarding the type of research to be undertaken,⁹⁶ and provides research participants with little control over the use of their samples and data.⁹⁷

In South Africa, blanket consent is not recommended. The DoH Ethics Guidelines,⁹⁸ while permitting broad consent for health research, does not recommend the use of blanket or ‘unrestricted’ consent.⁹⁹ This is because there are challenges in upholding primarily respect for persons. Further, complete anonymisation of biological materials is not possible, which affects consent insofar as it relates to participant understanding and what is requested.¹⁰⁰ The NHREC Ethics Guidelines also reject blanket or unrestricted consent due to it being unable to bolster crucial ethical principles.¹⁰¹

Additionally, the ASSAf Report provides that blanket consent is unsuitable in South Africa, both legally and ethically.¹⁰² First, blanket consent conflicts with POPIA,¹⁰³ which requires that consent be *specific*¹⁰⁴ – thereby excluding blanket consent and broad consent.¹⁰⁵

⁹¹ Ibid at 67.

⁹² Department of Health op cit note 17 at 31; Thaldar, Botes & Nienaber op cit note 37 at 4.

⁹³ Thaldar & Townsend op cit note 8 at 172; Thaldar & Townsend op cit note 27 at 2; Townsend & Thaldar op cit note 8 at 337.

⁹⁴ Tindana et al op cit note 8 at 10; Masiye, Jaoko & Rennie op cit note 47 at 4.

⁹⁵ Mahomed et al op cit note 8 at 32.

⁹⁶ Thaldar & Townsend op cit note 27 at 3.

⁹⁷ Mahomed et al op cit note 8 at 32.

⁹⁸ Department of Health op cit note 17. The DoH Ethics Guidelines are made legally binding through regulation 2(a) of the Human Research Participant Regulations, thus forming part of the NHA’s subsidiary legislation.

⁹⁹ Ibid at 43.

¹⁰⁰ Ibid at 43.

¹⁰¹ National Department of Health op cit note 18 at 67.

¹⁰² ASSAf op cit note 16 at 52.

¹⁰³ Ibid at 52.

¹⁰⁴ Sections 1 & 13(1) of POPIA.

¹⁰⁵ Thaldar & Townsend op cit note 8 at 172.

Second, blanket consent overlooks the traditional ethical principles that promote informed consent.¹⁰⁶

(d) *The conflation of broad consent and blanket consent*

There has been discussion regarding the difference between broad consent and blanket consent, with the literature tending to conflate these two modes of consent.¹⁰⁷ Broad consent has been used to denote consent encompassing a range of future uses, *inclusive* of blanket consent.¹⁰⁸ However, it must be noted that broad consent and blanket consent are two distinct concepts.¹⁰⁹ Blanket consent is consent to unlimited and unknown future studies. Blanket consent involves participants agreeing to unrestricted use of their samples and data¹¹⁰ – there is no specific project, no constraints are placed on the type of research that may be undertaken (currently and in the future),¹¹¹ there are no limits on the length of consent,¹¹² and no additional approvals are required.¹¹³ Blanket consent appears to emphasise the fact that consent is for unlimited future uses of samples and data. On the other hand, broad consent commonly entails ‘consenting to a framework for future research of certain types’;¹¹⁴ ethical review;¹¹⁵ and measures to inform participants, allow withdrawal, and re-consent participants should there be revisions in the

¹⁰⁶ ASSAf op cit note 16 at 52.

¹⁰⁷ Murphy et al op cit note 5 at 2128; Raymond Gene De Vries, Tom Tomlinson, Hyungjin Myra Kim et al ‘Understanding the public’s reservations about broad consent and study-by-study consent for donations to a biobank: Results of a national survey’ (2016) 11(7) *PLoS ONE* 2; Mwaka & Horn op cit note 77 at 7.

¹⁰⁸ De Vries et al op cit note 107 at 3.

¹⁰⁹ For example, while blanket consent may suggest consent for unlimited purposes without oversight, broad consent may denote consent for undefined uses with some control. De Vries et al op cit note 107 at 3; Mahomed et al op cit note 8 at 32.

¹¹⁰ David Wendler ‘Broad versus blanket consent for research with human biological samples’ (2013) 43(5) *Hastings Center Rep* 3.

¹¹¹ Thaldar & Townsend op cit note 27 at 2; Rachel Thompson & Michael J McNamee ‘Consent, ethics and genetic biobanks: The case of the Athlome project’ (2017) 18(Suppl 8) *BMC Genomics* 53.

¹¹² Jeantine E Lunshof, Ruth Chadwick, Daniel B Vorhaus et al ‘From genetic privacy to open consent’ (2008) *Nature Reviews Genetics* 4.

¹¹³ Thompson & McNamee op cit note 111 at 53.

¹¹⁴ Steinsbekk, Myskja & Solberg op cit note 5 at 897; Anne SY Cheung ‘Moving beyond consent for citizen science in big data health and medical research’ (2018) 16(1) *Northwest J Technol Intellect Prop* 27; Mahomed et al op cit note 8 at 32; Adrian Thorogood & Ma’n H Zawati ‘International guidelines for privacy in genomic biobanking (or the unexpected virtue of pluralism)’ (2015) *Journal of Law, Medicine & Ethics* 694; Jane Kaye, Jessica Bell, Linda Briceno et al ‘Biobank Report: United Kingdom’ (2016) 44 *Journal of Law, Medicine & Ethics* 101; Ma’n H Zawati ‘There will be sharing: Population biobanks, the duty to inform and the limitations of the individualistic conception of autonomy’ (2014) 21 *Health Law Journal* 108.

¹¹⁵ Department of Health op cit note 17 at 53; Steinsbekk, Myskja & Solberg op cit note 5 at 897; Cheung op cit note 114 at 27; Mahomed et al op cit note 8 at 32; Thorogood & Zawati op cit note 114 at 694; Kaye et al op cit note 114 at 101; Zawati op cit note 114 at 108.

framework.¹¹⁶ This implies that broad consent is consent to various future studies, but with *some* restrictions.¹¹⁷

What is clear is that there is a lack of consensus regarding uniform definitions of broad consent and blanket consent.¹¹⁸ However, for the purpose of this thesis I use the definitions adopted in the ASSAf Report.¹¹⁹ The ASSAf Report's definition of broad consent reads as follows:

'Broad consent describes the situation where, at the time of providing the sample, the person consents to general use of the sample for genetic and genomic research, including for unspecified future projects. An example would be a narrowly defined future use for certain kinds of research. In this case it must provide a description of the governance framework for access to the samples by third parties, including the need for further ethics review and approval for the proposed further use'.¹²⁰

And its definition of blanket consent reads as follows:

'Blanket consent is all-encompassing consent, i.e. open-ended and without limitations on the use of samples or data. Consent at recruitment to the study covers the present study and all future use and sharing without limits or restrictions'.¹²¹

There is no general consensus regarding the ideal type of consent that should be used in genomics research – although broad consent and blanket consent appear to feature prominently. Yet, it is important to note that '[b]road consent is not open, neither is it blanket consent'.¹²²

As mentioned in Chapter 1, specific consent and broad consent are the two modes of consent currently used in genomics research in South Africa – with tiered consent also featuring in the literature. Although blanket consent is mentioned in the DoH Ethics Guidelines, it is not recommended for health research.¹²³

¹¹⁶ Steinsbekk, Myskja & Solberg op cit note 5 at 897; Cheung op cit note 114 at 27; Mahomed et al op cit note 8 at 32; Thorogood & Zawati op cit note 114 at 694; Kaye et al op cit note 114 at 101; Zawati op cit note 114 at 108; Tindana & de Vries op cit note 8 at 376.

¹¹⁷ Wendler op cit note 110 at 3; J de Vries, K Littler, A Matimba et al 'Evolving perspectives on broad consent for genomics research and biobanking in Africa. Report of the Second H3Africa Ethics Consultation Meeting, 11 May 2015' (2016) 1(13) *Global Health, Epidemiology and Genomics* 2.

¹¹⁸ Mahomed et al op cit note 8 at 32.

¹¹⁹ ASSAf op cit note 16.

¹²⁰ Ibid at 51.

¹²¹ Ibid at 52.

¹²² Mahomed et al op cit note 8 at 32.

¹²³ Department of Health op cit note 17 at 31.

(e) *Tiered consent*

Two additional (and more sophisticated) modes of consent are tiered consent and dynamic consent. The DoH Ethics Guidelines offer the following definition of tiered consent: '[T]he donor provides consent for the primary project and chooses whether to permit storage for future use, sample and data sharing'.¹²⁴ According to the NHREC Ethics Guidelines, tiered (or differentiated) consent refers to 'donor/participant permits use of biological materials for current project; and chooses whether to permit storage for future use, sample and data sharing'.¹²⁵ However, I agree with Thaldar and Townsend that this provides only a restricted and superficial meaning of tiered consent.¹²⁶ Rather, tiered consent offers participants a 'range of consent options'¹²⁷ – they may 'opt for broad consent, opt to be recontacted before the sample is used, or opt for a REC [research ethics committee] to consent on their behalf'.¹²⁸ Tiered consent provides research participants with choices in terms of the ambit of the research, sharing, and storage of their samples and data.¹²⁹ As such, tiered consent may entail a combination of specific and broad consent, permitting individuals to provide separate consent to the various aspects of a project – such as partaking in the primary project and then also consenting to the storage and use of their sample and/or data in future projects.¹³⁰

Challenges associated with tiered consent, especially in low- and middle-income countries (LMICs) like South Africa, include: Explaining such a model to participants, especially in multiple languages;¹³¹ the electronic capturing, storing, and managing of samples and data that all have different participant approvals;¹³² and limited resources for maintaining such a system.¹³³ Although tiered consent has been seen to promote autonomy,¹³⁴ having too many options may overwhelm participants and lead to less informed decisions, which erodes autonomy.¹³⁵ But whilst broad consent and dynamic consent pose their own challenges in

¹²⁴ Ibid at 43.

¹²⁵ National Department of Health op cit note 18 at 67 & 104.

¹²⁶ Thaldar & Townsend op cit note 27 at 6.

¹²⁷ Staunton & Moodley op cit note 8 at 3; Singh & Moodley op cit note 8 at 10.

¹²⁸ Staunton & Moodley op cit note 8 at 3. See also, Townsend & Thaldar op cit note 8 at 337; Singh & Moodley op cit note 8 at 10.

¹²⁹ Thaldar & Townsend op cit note 27 at 3.

¹³⁰ ASSAf op cit note 16 at 50–1; Department of Health op cit note 17 at 31; Thaldar, Botes & Nienaber op cit note 37 at 4.

¹³¹ Nicki Tiffin 'Tiered informed consent: Respecting autonomy, agency and individuality in Africa' (2018) 3 *BMJ Glob Health* 1.

¹³² Thaldar & Townsend op cit note 27 at 3; Tiffin op cit note 131 at 1.

¹³³ Staunton & Moodley op cit note 8 at 3; Singh & Moodley op cit note 8 at 10.

¹³⁴ Nembaware et al op cit note 8 at 1567; Tiffin op cit note 131 at 2; Staunton & Moodley op cit note 8 at 3; Singh & Moodley op cit note 8 at 10.

¹³⁵ Thaldar & Townsend op cit note 27 at 3.

Africa – for example, broad consent limits participant choice regarding the use of their samples and data, and dynamic consent is hampered by technological restrictions (discussed below)¹³⁶ – tiered consent may offer a solution through the provision of adequate information regarding the use, storage, and withdrawal of samples and/or data; and allowing participants to answer a series of questions and choosing the level of sample and/or data sharing that suits them.¹³⁷

(f) Dynamic consent

There are participants who want to be informed of the future use of their samples and/or data for research.¹³⁸ From this, dynamic consent has emerged, which aims to keep research participants involved in decisions regarding their samples and data,¹³⁹ through continuous engagement and the provision information and consent¹⁴⁰ – thus upholding participant autonomy.¹⁴¹ Typically, dynamic consent uses electronic communication approaches, such as smartphones, mobile apps, websites, emails, and social media platforms.¹⁴² In this way, participants maintain control of their data and remain in contact with researchers¹⁴³ – allowing them to opt-in or opt-out of the use of their samples and/or data in further projects.¹⁴⁴ Whilst tiered consent permits participants to choose whether to be asked about the use of their samples and/or data in the future, dynamic consent ‘allows for implementation of this choice’,¹⁴⁵ and provides each participant with a tailored interface.¹⁴⁶

There have been concerns around implementing a dynamic consent model in LMICs, like South Africa, given low literacy levels and restricted access to modern technologies (such as mobile phones and computers),¹⁴⁷ as well as limited internet capacity.¹⁴⁸ However, dynamic consent need not always involve modern electronic communications. It has been suggested that

¹³⁶ Nembaware et al op cit note 8 at 1567.

¹³⁷ Ibid at 1567.

¹³⁸ Tindana & de Vries op cit note 8 at 385; Moodley & Singh op cit note 8 at 7.

¹³⁹ Tindana & de Vries op cit note 8 at 385–6.

¹⁴⁰ Nembaware et al op cit note 8 at 1567; Townsend & Thaldar op cit note 8 at 348; Moodley & Singh op cit note 8 at 7.

¹⁴¹ Nembaware et al op cit note 8 at 1567.

¹⁴² Thaldar & Townsend op cit note 27 at 3; Tindana & de Vries op cit note 8 at 385–6; Townsend & Thaldar op cit note 8 at 348.

¹⁴³ Townsend & Thaldar op cit note 8 at 348.

¹⁴⁴ Thaldar & Townsend op cit note 27 at 3; Harriet JA Teare, Megan Pricor & Jane Kaye ‘Reflections on dynamic consent in biomedical research: The story so far’ (2021) 29 *Eur J Hum Genet* 649; Jane Kaye, Edgar A Whitley, David Lund et al ‘Dynamic consent: A patient interface for twenty-first century research networks’ (2015) 23 *Eur J Hum Genet* 142.

¹⁴⁵ Moodley & Singh op cit note 8 at 7.

¹⁴⁶ Thaldar & Townsend op cit note 27 at 3.

¹⁴⁷ Tindana & de Vries op cit note 8 at 385–6; Thaldar & Townsend op cit note 27 at 3.

¹⁴⁸ Nembaware et al op cit note 8 at 1567.

the usage of basic text messages in LMICs – which many participants are able to receive without smartphones or internet access – allows ongoing engagement between researchers and participants,¹⁴⁹ or in-person meetings with communities provides a means to relay the findings and fate of stored samples and data.¹⁵⁰

(g) *Meta consent*

Meta consent was developed by Ploug and Søren as a new model of informed consent. It arose due to concerns that with the rise of big data came the possibility of the secondary use of health data without renewed consent.¹⁵¹ However, it was also recognised that maintaining informed consent for every specific research project may pose practical challenges and impede valuable research efforts.¹⁵² As such, a proposed solution is meta consent. The meta consent model revolves around allowing individuals to proactively determine how and when they wish to give consent for the use of their health data in the future.¹⁵³ This approach involves individuals selecting the type of consent for each category of data or context from a predefined set of options.¹⁵⁴ This empowers individuals by actively involving them in the consent process and promotes transparency regarding how their data will be utilised. This approach is considered practical, respectful, and supportive of autonomy, as it enables individuals to make informed decisions and maintain control over their personal information.¹⁵⁵ While promising, the meta consent model has received some criticism, such as the costs and infrastructure required to set up and maintain such a framework.¹⁵⁶

Although meta consent has not yet been used (or even mentioned) in the South African genomics and health research context, it is a useful mode of consent to bear in mind.

¹⁴⁹ Thaldar & Townsend op cit note 27 at 3.

¹⁵⁰ Ibid at 3; Tindana & de Vries op cit note 8 at 385–6.

¹⁵¹ Thomas Ploug & Søren Holm ‘Meta consent – A flexible solution to the problem of secondary use of health data’ (2016) 30 (9) *Bioethics* 721–732; Thomas Ploug & Søren Holm ‘Eliciting meta consent for future secondary research use of health data using a smartphone application - A proof of concept study in the Danish population’ (2017) 18 *BMC Med Ethics* 1.

¹⁵² Ploug & Holm op cit note 151 at 1–2.

¹⁵³ Annabelle Cumyn, Adrien Barton, Roxanne Dault et al ‘Meta-consent for the secondary use of health data within a learning health system: A qualitative study of the public’s perspective’ (2021) 22 *BMC Med Ethics* 2.

¹⁵⁴ Ploug & Holm op cit note 151 at 1–2.

¹⁵⁵ Cumyn et al op cit note 153 at 2.

¹⁵⁶ Neil C Manson ‘The biobank consent debate: Why “meta-consent” is not the solution?’ (2018) 45 (5) *J Med Ethics* 1.

(h) *Open consent*

Although meta consent has not yet been explored in South Africa, open consent has received recent attention.¹⁵⁷ Until the publication of two articles by Gooden and Thaldar,¹⁵⁸ open consent (as defined by the PGP) had not been explored in the South African genomics research context. Open consent has been examined in Chapter 1, but to briefly summarise: Open consent was developed by the PGP,¹⁵⁹ and it is a model where participants provide consent for the open and unrestricted sharing and use of their genomics and health data for research purposes.¹⁶⁰ This approach is based on transparency and collaboration, aiming to accelerate scientific discovery while respecting participant autonomy.¹⁶¹ The PGP emphasises the importance of informed decision-making by participants, ensuring that they understand the risks and benefits associated with sharing their data openly.¹⁶² In order to ensure that participant consent is properly informed, the PGP provides potential participants with study material, and they are then required to undergo an assessment, which they must pass with full marks, before being able to enrol in the project.¹⁶³

Open consent is a relatively new concept, but it appears that there has been a tendency to view it as forming part of, or being synonymous with, existing modes of consent. Although blanket consent has sometimes also been referred to as ‘open’ or ‘open-ended’ consent,¹⁶⁴ this is not the same as the concept of open consent – specifically that pioneered by the PGP. The PGP’s concept of open consent has its own features and nuances that are absent from other modes of consent.

¹⁵⁷ Amy Gooden & Donrich Thaldar ‘Towards an open access database of South Africans: Ethical considerations’ (2023) 14 *Front Genet* 1–7; Donrich Thaldar, Amy Gooden & Dusty-Lee Donnelly ‘Toward an open access genomics database of South Africans: Legal considerations’ (2023) 119 (7/8) *S Afr J Sci* 1–4.

¹⁵⁸ Gooden & Thaldar op cit note 157 at 1–7.

¹⁵⁹ The Harvard Personal Genome Project ‘About’ available at <https://pgp.med.harvard.edu/about>, accessed on 22 September 2020.

¹⁶⁰ Jeantine E Lunshof, Jason Bobe, John Aach et al ‘Personal genomes in progress: From the Human Genome Project to the Personal Genome Project’ (2010) 12(1) *Dialogues Clin Neurosci* 56.

¹⁶¹ Lunshof et al op cit note 112 at 5.

¹⁶² Lunshof et al op cit note 160 at 56; Isabelle Budin-Ljøsne, Harriet JA Teare, Jane Kaye et al ‘Dynamic consent: A potential solution to some of the challenges of modern biomedical research’ (2017) 18(4) *BMC Med Ethics* 8.

¹⁶³ Misha Angrist ‘Eyes wide open: The Personal Genome Project, citizen science and veracity in informed consent’ (2009) 6(6) *Per Med* 5.

¹⁶⁴ Mahomed et al op cit note 8 at 32.

V THE CONFLATION OF OPEN CONSENT WITH OTHER MODES OF CONSENT

It is not only broad consent and blanket consent that have been seen as synonymous – several authors conflate open consent with blanket consent,¹⁶⁵ and even refer to open consent as synonymous with broad consent or general consent.¹⁶⁶ This is because they define open consent as ‘a research subject’s affirmative agreement to participate in a population genetic database and in research projects that use tissue and data from that database’.¹⁶⁷ However, one aspect that seems amiss in these definitions of open consent is that data is made publicly available, and privacy is not guaranteed. Unlike broad consent, where there may be emphasis on the de-identification or anonymisation of data, open consent – specifically in terms of the definition and the model developed by the PGP – makes no such promises.

Although the difference between open consent and other types of consent – such as broad consent or blanket consent – has not been explicitly stated in the literature, it appears that the distinction lies in the guarantee of privacy and anonymity. While broad consent, like open consent, entails participants agreeing to the current and future use of their samples and data in any number of unidentified studies, broad consent seems to make assurances regarding the privacy of samples and data – whether it is through measures like de-identification or anonymisation – as well as operating within a framework of certain limitations,¹⁶⁸ such as ethical review and the option for withdrawal.¹⁶⁹ Although few definitions of blanket consent explicitly refer to privacy,¹⁷⁰ De Vries et al recognise that because data used in research is often de-identified and because all potential future uses are unknown, this supports the use of ‘blanket, broad, or general consent’.¹⁷¹ Further, in terms of withdrawal from research, Thompson and McNamee highlight the difficulties associated with withdrawing anonymised and linked data, and add that blanket consent may be justified where there is minimal risk, provided that adequate anonymity protections have been implemented.¹⁷² The mention of

¹⁶⁵ Kegley op cit note 5 at 33; B Hofmann ‘Broad consent – And diluting ethics?’ (2009) 35 *J Med Ethics* 126; Gabriella Foe ‘Biobanks and informed consent’ (2014-2015) 1 *Voices in Bioethics* 2; Dara Hallinan & Michael Friedewald ‘Open consent, biobanking and data protection law: Can open consent be “informed” under the forthcoming data protection regulation?’ (2015) 11(1) *Life Sciences, Society and Policy* 5.

¹⁶⁶ Hallinan & Friedewald op cit note 165 at 5; Timothy Caulfield & Blake Murdoch ‘Genes, cells, and biobanks: Yes, there’s still a consent problem’ (2017) 15(7) *PLoS Biol* 1.

¹⁶⁷ Ants Nõmper *Open Consent – A New Form of Informed Consent for Population Genetic Databases* (Doctor Juris, University of Tartu, 2005) 197. See also, Hallinan & Friedewald op cit note 165 at 5.

¹⁶⁸ Mikkelsen et al op cit note 3 at 2.

¹⁶⁹ Steinsbekk, Myskja & Solberg op cit note 5 at 897; Cheung op cit note 114 at 27; Mahomed et al op cit note 8 at 32; Thorogood & Zawati op cit note 114 at 694; Kaye et al op cit note 114 at 101; Zawati op cit note 114 at 108; Wendler op cit note 110 at 3.

¹⁷⁰ De Vries et al op cit note 107 at 3; Thompson & McNamee op cit note 111 at 53.

¹⁷¹ De Vries et al op cit note 107 at 2.

¹⁷² Thompson & McNamee op cit note 111 at 53.

blanket consent and anonymity suggests that data used in research that adopts blanket consent is anonymised, or at least de-identified.

What distinguishes open consent from other modes of consent is the fact that no assurances are made regarding privacy, nor are there attempts to de-identify data before it is publicised. Open consent was developed specifically for genomics research and, as such, it takes into account the inherently identifiable nature of genomic data.¹⁷³ This means that although steps can be taken to protect participant data, the public release of personal samples and data carries risks, such as re-identification and other potential dangers linked to its uncontrolled sharing. Therefore, no guarantees regarding privacy and anonymity are made.¹⁷⁴ Given this, open consent cannot be equated with broad consent or blanket consent.

The mode of consent that can be seen to most closely resemble open consent – and which has been erroneously conflated with open consent in the literature – is blanket consent. Hofmann,¹⁷⁵ as well as Foe,¹⁷⁶ merge blanket consent with open consent by indicating that the two concepts are interchangeable and denote consent to ‘an unlimited range of options’.¹⁷⁷ However, blanket consent and open consent are distinct.

Some authors in the literature affirm that open consent is neither broad consent nor blanket consent.¹⁷⁸ Hallinan and Friedewald explicitly state that open consent is ‘clearly not’ blanket consent.¹⁷⁹ The reason for this is that the purpose of open consent is not to require justification for every conceivable future use of data, but rather to establish justification for the future use of personal data specifically *in research*.¹⁸⁰ This is unlike blanket consent which is not limited to research, and covers all future studies. Although Hallinan and Friedewald’s reasoning does highlight the fact that open consent was specifically developed for genomics research, their understanding of open consent does not mention the fact that information will be publicly available, as is the approach adopted by the PGP. In this regard, Hallinan and

¹⁷³ Angrist op cit note 163 at 2; Henry T Greely ‘The uneasy ethical and legal underpinnings of large-scale genomic biobanks’ (2007) 8 *Annu Rev Genomics Hum Genet* 352; Elizabeth R Pike ‘Securing sequences: Ensuring adequate protections for genetic samples in the age of big data’ (2015) 37 *Cardozo L Rev* 2018; Cheung op cit note 114 at 26.

¹⁷⁴ Personal Genomes ‘Personal Genome Project study material’ *Personal Genome Project* 30 April 2012, available at <https://www.personalgenomes.org.uk/assets/docs/uk/v20120430-study-guide.pdf>, accessed 16 September 2022 page 5.

¹⁷⁵ Hofmann op cit note 165 at 126.

¹⁷⁶ Foe op cit note 165 at 2.

¹⁷⁷ Hofmann op cit note 165 at 126.

¹⁷⁸ Steinsbekk, Myskja & Solberg op cit note 5 at 897; Hallinan & Friedewald op cit note 165 at 5; Steinsbekk, Myskja & Solberg op cit note 5 at 897.

¹⁷⁹ Hallinan & Friedewald op cit note 165 at 5.

¹⁸⁰ Ibid at 5.

Friedewald's definition of open consent is akin to that of broad consent. This is also evidenced by the fact that the authors, while referring to other modes of consent in their article, do not mention broad consent.

Based on the above, I suggest that referring to open consent as being synonymous with broad consent or blanket consent is incorrect. Open consent, although sharing similarities with other types of consent, is a separate concept. Because open consent does not make any guarantees regarding privacy, confidentiality, and anonymity, it is vital that participants understand what the process entails and what they are consenting to, given the high risks involved. In the case of the PGP, this is assessed through a determination of participants' objective understanding. Open consent may be viewed as a sub-species of broad consent or blanket consent, but it is a distinct concept and one that is catered to the realities of genomics research.

VI IS OPEN CONSENT RECONCILABLE WITH EXISTING MODES OF CONSENT?

The question that must now be considered is whether open consent can be reconciled with any of the existing modes of consent currently used in genomics research in South Africa. First, because open consent entails consenting to countless indefinite and unknown research projects with numerous different researchers and institutions, as well as unlimited access to participant data, open consent cannot be reconciled with specific consent – which entails knowledge of, and consent to, each use of data. However, there is a distinction to be made between POPIA consent and ethics consent (discussed above), and this could have a bearing on the applicability of open consent. POPIA requires consent for a specific purpose – such as health research. Given that genomics research is the envisioned purpose for which the data uploaded by the PGP would be used,¹⁸¹ this could be seen to constitute a specific purpose in terms of section 13(1) of POPIA. However, given that the genetic, health, and trait data uploaded by the PGP (and in terms of the open consent model) is freely available online for anyone to download and use for any purpose, I suggest that this falls outside of POPIA's requirement of a specific purpose. Therefore, regardless of whether POPIA consent or ethics consent is adopted, open consent is too broad to fit within either of these definitions.

Second, although broad consent permits the wide use of samples and/or data for various research projects, broad consent does operate within defined limits – for example, by requiring

¹⁸¹ The Harvard Personal Genome Project 'The PGP is not a traditional research study' available at <https://pgp.med.harvard.edu/about>, accessed on 6 June 2022.

‘a description of the governance framework for access to the samples by third parties, including the need for further ethics review and approval for the proposed further use’.¹⁸² Open consent entails no such requirements and data can be freely access and shared. Third, while tiered consent allows research participants to decide which aspects of a research project to consent to and whether to allow the further sharing and storage of their data, open consent offers no such option. Open consent offers a once-off consent to the open access and sharing of research participants’ data without the option of tailoring this consent to suit the participant.

I suggest that open consent is most closely equated with blanket consent as this mode of consent is ‘all-encompassing consent’,¹⁸³ relating to the unlimited and unrestricted current and future use and sharing of data.¹⁸⁴ However, where open consent and blanket consent differ is that open consent takes extra steps to ensure that consent is informed through requiring participants to undergo (and pass) an examination. The possible reconciliation of open consent in South Africa is the fact that although blanket consent is not *recommended* by the DoH Ethics Guidelines, this mode of consent is not *prohibited*. The reasoning behind this is because there are challenges in upholding primarily respect for persons. Further, complete anonymisation of biological materials is not possible, which affects consent insofar as it relates to participant understanding and what is requested.¹⁸⁵ However, I suggest that open consent addresses these issues. Through transparency, ongoing communication, and objective assessment, the rights of participants can be upheld. Although total anonymisation of samples and data cannot be achieved, by alerting participants to this, they enter into the research without any false pretences and based on full and proper understanding.

VII CONCLUSION

This Chapter has examined various modes of consent – both those that are used and referred to in the South African research context, but also more novel modes of consent, like meta consent and open consent. This Chapter has showed how consent in research is addressed in several relevant statutes, as well as how specific consent, broad consent, blanket consent, tiered consent, and dynamic consent are approached in research in South Africa. It has also addressed issues in distinguishing different modes of consent, specifically broad consent and blanket consent. This Chapter has further probed into the concept of open consent as defined by the

¹⁸² ASSAf op cit note 16 at 51.

¹⁸³ ASSAf op cit note 16 at 52.

¹⁸⁴ Ibid at 52.

¹⁸⁵ Department of Health op cit note 17 at 31.

PGP, and has differentiated it from other modes of consent with which it is commonly conflated, namely broad consent and blanket consent.

This Chapter has differentiated open consent from other modes of consent with which it is commonly conflated, namely broad consent and blanket consent. Although open consent cannot be reconciled with several modes of consent currently used in South Africa – namely specific consent, broad consent, and tiered consent – there is a possibility for open consent to address the issues that blanket consent cannot, and which is the reason why blanket consent is not recommended by the DoH Ethics Guidelines. Open consent's focus on autonomy, transparency, assessment, and no assurances regarding anonymity or privacy, thwarts the concerns raised against the use of blanket consent.

Having critically examined the various modes of consent relevant to genomics research in South Africa, including the novel concept of open consent, it becomes clear that underlying these consent models are deeper philosophical and ethical considerations. Central to these is the principle of autonomy, which shapes how consent is understood and operationalised. However, in the South African context, autonomy does not exist in isolation but is intertwined with collective values, notably Ubuntu, which emphasises relationality and communal well-being. The following chapter thus turns to a thorough exploration of autonomy and Ubuntu, investigating how these concepts intersect and how they inform the ethical and constitutional dimensions of open consent in genomics research in South Africa.

CHAPTER 3

AUTONOMY AND UBUNTU

I INTRODUCTION

Autonomy refers to the ability and freedom of individuals to make their own decisions and act independently, without undue influence or external control.¹ Respect for autonomy is a central idea in contemporary bioethics, initially framed in the Belmont Report as part of respect for persons.² Beauchamp and Childress expanded and popularised this concept in *Principles of Biomedical Ethics*.³ Alongside beneficence, non-maleficence, and justice, autonomy remains a cornerstone of medical ethics, yet its exact meaning and significance continue to spark significant debate.⁴

A primary consideration in genomics research is the autonomy of participants. It upholds respect for persons and promotes rational, informed, and uncoerced decisions.⁵ However, the fact that various decisions are made during the genomics research process that the individual is not part of, may impede autonomy – although this is a common practice within the healthcare landscape.⁶ Autonomy is predominant in the literature on genomics research and the term is commonly known. But what does autonomy actually mean and entail? There are various definitions of autonomy, and its conceptions differ depending on the country and context.

In South Africa, where collective values rooted in Ubuntu – a philosophy emphasising the interconnectedness of individuals within a community⁷ – are integral, the notion of autonomy may not be purely individualistic. Ubuntu prioritises relational values, mutual

¹ PD Motloba & NL Makwakwa ‘Respecting autonomy (part 2)’ (2018) 73(7) *SADJ* 460.

² Office of the Secretary Ethical Principles and Guidelines for the Protection of Human Subjects of Research & The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *The Belmont Report* (1979).

³ Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 1 ed (1979).

⁴ Carlos Gómez-Virseda, Yves de Maeseneer & Chris Gastmans ‘Relational autonomy: What does it mean and how is it used in end-of-life care? A systematic review of argument-based ethics literature’ (2019) 20(76) *BMC Med Ethics* 2.

⁵ Mary Kasule, Mogomotsi Matshaba, Erisa Mwaka et al ‘Considerations of autonomy in guiding decisions around the feedback of individual genetic research results from genomics research: Expectations of and preferences from researchers in Botswana’ (2022) 2022 *Global Health, Epidemiology and Genomics* 2.

⁶ Rachel Horton & Anneke Lucassen ‘Consent and autonomy in the genomics era’ (2019) 7 *Curr Genet Med Rep* 88.

⁷ C Roederer & D Moellendorf *Jurisprudence* (2004) 441; Academy of Science of South Africa (ASSAf) *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (2018) 25.

respect, and the well-being of the community.⁸ This offers a broader lens through which to consider autonomy, as it balances individual freedoms with the recognition of shared responsibilities. For the purposes of this thesis, it is important to consider autonomy from a South African perspective, taking constitutional rights and values, including Ubuntu, into account.

II CHAPTER OVERVIEW

This Chapter considers autonomy, and its meaning, from a constitutional perspective in order to determine whether it can be reconciled with open consent for genomics research in South Africa. This Chapter begins with a broad and general overview of the meaning of autonomy that has been provided in the literature in order to place the term in context. Following this, various philosophical conceptions of autonomy are explored in order to provide an outline for the subsequent analysis. This Chapter then explores and analyses autonomy jurisprudence in South African case law in order to ascertain what autonomy means and how the courts have interpreted this concept. This is done in an attempt to ascertain the meaning of autonomy and which conception of autonomy has been adopted in South Africa, and whether the courts' interpretation of autonomy fits the definition of the conceptions.

In addition to autonomy, this Chapter delves into the principle of Ubuntu and its application to open consent and autonomy. Ubuntu presents a unique lens through which to understand autonomy, particularly in a South African constitutional context. The relationship between autonomy, Ubuntu, and other constitutional rights, such as privacy and freedom, is explored to assess how these principles intersect. Finally, this Chapter examines whether open consent can be reconciled with autonomy from a constitutional perspective, considering both individual freedoms and the collective values inherent in Ubuntu, and how these concepts should be applied in genomics research in South Africa.

III THE MEANING OF AUTONOMY

While, at a glance, autonomy is deemed to be a rather simple concept encompassing self-determination and freedom, upon closer inspection the meaning of this term is complex and vague. Autonomy has been subject to multiple definitions and interpretations. What makes

⁸ Bonginkosi Shoji *An Afrocentric Approach to CRISPR-Cas9: Analysing the Use of Genetic Technologies in Human Reproduction Through the Lens of Human Rights and African Values* (unpublished PhD thesis, University of KwaZulu-Natal, 2021) 44.

determining the meaning of autonomy propounding more challenging is that it does not have a set definition, and its meaning varies depending on context and circumstances. Furthermore, autonomy contains a subjective component, making the bestowing of a universal and objective definition problematic.

Autonomy comes from the Greek ‘auto’ (self) and ‘nomos’ (law), which means to be one’s own law.⁹ Autonomy means acknowledging an individual’s right and ability to think, decide, and act according to their own principles and beliefs.¹⁰ Autonomy refers to the capacity to be one’s own person,¹¹ and to live one’s own life in accordance with reasons and motives that one deems relevant, and is not the product of any distorting external or internal forces. Autonomy refers to an individual’s self-rule,¹² free from external interference.¹³ The essence of self-rule is that individuals have the freedom to live their lives as they choose, provided they do not harm others.¹⁴ According to Jordaan, autonomy means that each individual should be able to pursue their idea of the ‘good life’.¹⁵ Simply, autonomy can be understood as self-determination.¹⁶ In terms of individual human rights, autonomy and freedom often overlap.¹⁷ Freedom comprises political freedom,¹⁸ and individual or personal freedom.¹⁹ In its current utilisation, autonomy commonly resembles individual or personal freedom, but it also encompasses a wider definition denoting an individual’s personal psychological capacity for self-determination.²⁰

Autonomy and self-governance are central to both Kantian moral philosophy and Mill’s utilitarian liberalism.²¹ Dworkin frames autonomy as the key concept by which paternalism is

⁹ Donrich W Jordaan ‘Autonomy as an element of human dignity in South African case law’ (2009) 9(3) *Journal of Philosophy, Science & Law* 4.

¹⁰ R Gillon *Philosophical Medical Ethics* (1986); Alice K Hawkins & Anita Ho ‘Genetic counseling and the ethical issues around direct to consumer genetic testing’ (2012) 21 *J Genet Counsel* 369.

¹¹ John Christman ‘Autonomy in moral and political philosophy’ *Stanford Encyclopaedia of Philosophy* 29 June 2020, available at <https://plato.stanford.edu/entries/autonomy-moral/>, accessed on 12 July 2020.

¹² Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 4 ed (1994).

¹³ Mappes and DeGrazia define an autonomous person as someone who can make ‘rational and unconstrained decisions and being able to act accordingly’. Beauchamp & Childress op cit note 12 at 27; Dain van der Reyden ‘The right to respect for autonomy’ (2008) 38(1) *South African Journal of Occupational Therapy* 27.

¹⁴ John Stuart Mill *On Liberty* (1859) 13.

¹⁵ DW Jordaan ‘Human dignity and the future of the voluntary active euthanasia debate in South Africa’ (2017) 107(5) *SAMJ* 384; *Ferreira v Levin NO*; *Vryenhoek v Powell NO (Ferreira)* 1996 (1) SA 984 (CC).

¹⁶ Jordaan op cit note 9 at 4.

¹⁷ Ibid at 4.

¹⁸ This includes the Roman *libertas*, which encompasses several rights concerning participation in political processes. Ibid at 4.

¹⁹ This is the right to personal self-determination – choosing and pursuing one’s own ends in life, as expanded on in Mill’s essay, *On Liberty*. John Stuart Mill *On Liberty* 4 ed (1999) cited in Jordaan op cit note 9 at 4.

²⁰ Jordaan op cit note 9 at 4.

²¹ Christman op cit note 11.

to be limited. The individualistic core that many popular conceptions of autonomy have, increasingly come under challenge by other schools of thought, such as specific feminist critiques of autonomy.²² What separates autonomy from freedom is the idea of identity and authenticity. Many scholars identify autonomy as not only self-governance, but with authenticity – the ability to identify aspects of oneself independently and formulate actions that serve that identity. Autonomy is important because it is a value that is linked to, and underlies, various rights such as human dignity, freedom, privacy, and equality.

There are various conceptions of autonomy, and the term can be understood in different ways depending on the context, with each interpretation focusing on distinct aspects of the concept.²³ Feinberg suggests that autonomy in moral and political philosophy can be understood in four distinct ways: (1) the ability to self-govern; (2) the state of actually governing oneself; (3) a personal ideal; and (4) a collection of rights that reflect one's authority over oneself.²⁴ It may be argued that central to these various meanings is the idea of an individual who can act, think, and decide based on factors that are genuinely their own. However, developing a 'theory' of autonomy involves more than just defining the essential details of the concept because autonomy, like many concepts central to contentious moral and political debates, is inherently disputed. Therefore, a theory of autonomy serves as a conceptual framework aimed at encompassing the general notion of 'self-rule' or 'self-governance' (concepts that inherently involve ambiguity), and which can be used to support the principles or policies the theory seeks to justify.²⁵

IV SELECTED PHILOSOPHICAL CONCEPTIONS OF AUTONOMY

Since a basic definition of autonomy has been provided, it is necessary at this point to explore several of the many conceptions of autonomy as a background to the analysis, which is to follow. Autonomy is complex and consists of numerous philosophical conceptions that have been developed over the years from a variety of different contexts. While distinct, some of these conceptions may overlap to a certain extent. Although it would be beneficial to explore each conception of autonomy in detail, this thesis is limited to only those conceptions that I believe are most relevant to a constitutional analysis of open consent for genomics research in

²² Gerald Dworkin *The Theory and Practice of Autonomy* (1988).

²³ Nomy Arpaly *Unprincipled Virtue* (2004); Christman op cit note 11.

²⁴ Joel Feinberg 'Autonomy' in John Christman (ed) *The Inner Citadel: Essays on Individual Autonomy* (1989) 27–53; Christman op cit note 11.

²⁵ Christman op cit note 11.

South Africa. Therefore, this section explores various philosophical conceptions of autonomy, mainly based on their relevance to the topic of this thesis, as a first step in understanding the basis of each conception in order to determine which are most relevant and which can be most usefully applied to open consent for genomics research in South Africa. The significant conceptions of autonomy have been split into two main headings, namely (1) atomistic streams of autonomy; and (2) integrated autonomy. Within these, the most relevant conceptions of autonomy are discussed – namely individual autonomy, moral autonomy, personal autonomy, hierarchical autonomy, Beauchamp and Childress’ autonomy, Razian autonomy, rational autonomy, feminist autonomy, and relational autonomy.

(a) *Atomistic streams of autonomy*

(i) *Individual autonomy*

In Western ethics and philosophy, autonomy refers to self-governance. The theory of autonomy is typically associated with Enlightenment scholars, and is central to both Kantian moral philosophy and Mill’s utilitarian liberalism.²⁶ Such conceptions of autonomy are often viewed as individualistic or atomistic. Central to these conceptions is reason or rationality. The capacity for reason is what gives rise to an individual’s autonomy and personhood. Gerald Dworkin frames autonomy as the key concept by which paternalism is to be limited. The individualistic core that many popular conceptions of autonomy have, increasingly come under challenge by other schools of thought, such as specific feminist critiques of autonomy.²⁷

Individualistic notions of autonomy emphasise decision-making capacity, which predicts competence and thus the right to act autonomously. An autonomous choice is one which is in line with an individual’s own desires. The individual is paramount and, once deemed to be competent, may make their own decisions provided that they do not harm others. This focus on consent assesses an individual’s competence, rather than mechanisms that engage the person to assess the background psychological aspects that assure information is complete enough to enable an informed and autonomous decision. Thus, ‘shared decision-making’ is side-lined. Instead, a formulaic approach to consent predominates, assuming that patients can be given

²⁶ In terms of the Millian conception of autonomy, an individual is autonomous ‘to the extent that he directs his actions in accordance with his own values, desires, and inclinations’. Christman op cit note 11; James Stacey Taylor ‘Autonomy: Ethics and political philosophy’ *Encyclopaedia Britannica* 20 June 2017, available at <https://www.britannica.com/topic/autonomy>, accessed on 16 June 2020.

²⁷ Dworkin op cit note 22.

information and then make an independent decision based on this information.²⁸ Individual autonomy tends to focus on who is autonomous and has the right to make a decision and the procedural aspects regarding how a decision is made, rather than what is decided or what is deemed to be a ‘good’ decision. Provided that certain necessary conditions on the decision-making process are present, the choice is deemed to be autonomous. Thus, individual autonomy focuses on the chooser, who must be competent to make autonomous decisions. In this context, consent is viewed as a decision to be given only by one person.²⁹ This conception of autonomy gave rise to various disclosure and consent models which emphasise ensuring that the individual makes choices that are in accordance with his true self – disclosing enough valuable information to enable him to be competent to make a decision, and thereafter obtaining his consent.

(ii) *Moral autonomy*

Moral autonomy, commonly linked to Kant, denotes the capacity to deliberate and impose the moral law on oneself³⁰ – or to have authority over one’s actions³¹ – instead of observing rules imposed by others.³² In terms of Kantian autonomy, an individual is autonomous if his actions and choices are not influenced by unnecessary or external elements such as peer pressure, convention, legal or religious authority, emotions, or his own desires.³³ According to Kant, individual actions are directed by maxims – subjective principles which one chooses to abide by. When these maxims are ‘universal’, in that any rational being would accept them and they do not stem from the specific experience of an individual, such maxims may become objective laws of morality.³⁴

According to Kant, rationality is central to the self – an individual’s choices and actions are autonomous if they are guided exclusively by his rationality. However, if an individual acts in a rational manner in order to attain an external end, he is not autonomous as this is driven by desires – known as a ‘hypothetical imperative’. To be rational and autonomous, an

²⁸ Edward S Dove, Susan E Kelly, Federica Lucivero et al ‘Beyond individualism: Is there a place for relational autonomy in clinical practice and research?’ (2017) 12(3) *Clinical Ethics* 152.

²⁹ Ibid at 153.

³⁰ Christman op cit note 11.

³¹ Jane Dryden ‘Autonomy’ *Internet Encyclopaedia of Philosophy* available at <https://iep.utm.edu/autonomy/>, accessed on 5 June 2020.

³² Ibid.

³³ Kant argued that moral autonomy is a combination of freedom and responsibility, whereby a person submits to the laws that he has made for himself. This for Kant, is the basis of morality. Taylor op cit note 26; Christman op cit note 11; Raphael Cohen-Almagor ‘On the philosophical foundations of medical ethics: Aristotle, Kant, JS Mill and Rawls’ (2017) *Ethics, Medicine and Public Health* 5; Dryden op cit note 31.

³⁴ Dryden op cit note 31.

individual must act in line with the ‘categorical imperative’ – a rule that, irrespective of their desires, all rational agents should obey.³⁵ As rational agency does not differ among individuals, an autonomous agent is required to recognise his intrinsic value as a rational being, as well as that of others. Therefore, due to their capacity for reason, all individuals possess a moral worth that entitles them to equal treatment – individuals should be treated as ends in themselves (as intrinsically valuable), rather than as means to an end (as instrumentally valuable).³⁶ In contrast to Kant, Mill’s view of autonomy does not prevent autonomous individuals from being influenced by desires, as long as such desires are their own.³⁷

(iii) *Personal autonomy*

Personal autonomy refers to the ability to make one’s own decision and follow a course of action, notwithstanding moral content.³⁸ Dworkin contends that personal autonomy is understood as a state or trait of an individual which exhibits itself to all aspects of his life – not just in aspects of morality.³⁹ Central to personal autonomy is authenticity – one is autonomous if they are able to make decisions in line with their authentic self. Therefore, personal autonomy consists of two groups of capacities: (1) authenticity conditions, which aim to identify one’s authentic nature or preferences; and (2) competency conditions, which focus on the ability to live according to these, in light of external influences.⁴⁰ Personal autonomy can be distinguished from moral autonomy in that it does determine autonomous action based on it being embedded in universal principles; rather it focuses on aspects of the action and decision-making process that are specific to the individual.⁴¹

Contemporary accounts of personal autonomy utilise a content-neutral approach which rejects the development of criteria, values, or principles in order to determine whether an action is autonomous. Under this account, an action is autonomous if supported by a process of critical reflection. Such an approach neither considers whether an individual is acting in line with moral

³⁵ This is conveyed generally in Kant’s ‘categorical imperative’, a version of which states: ‘Act only according to that maxim by which you can at the same time will that it should become a universal [moral] law’. Taylor op cit note 26.

³⁶ Ibid. See, Immanuel Kant *Groundwork of the Metaphysics of Morals: A German-English Edition* (2011).

³⁷ Taylor op cit note 26.

³⁸ Dryden op cit note 31; Mark Piper ‘Autonomy: Normative’ *Internet Encyclopaedia of Philosophy* available at <https://iep.utm.edu/aut-norm/#SH2c>, accessed on 4 June 2020.

³⁹ Dworkin op cit note 22.

⁴⁰ Several theories of personal autonomy necessitate the existence of external enabling conditions – such as social, legal, or familial factors that are largely beyond an individual’s control, but which must exist for autonomy to be realised. Piper op cit note 38.

⁴¹ Dryden op cit note 31.

laws, nor does it place limitations on autonomous action; it aims to determine whether an individual is acting for his own reasons.⁴²

(iv) *The hierarchical or split-level view of autonomy*

The popular theory of autonomy, based on the hierarchical account, was developed by Dworkin and Harry Frankfurt in the 1970s, but has been subject to much criticism since its conception.⁴³ Dworkin and Frankfurt, in exploring the type of individual freedom that should be protected, found that decisions are worthy of protection when entrenched in one's values, commitments, and objectives.⁴⁴

Dworkin explores the relationship between acting freely and doing as one pleases. As Dworkin states, '[w]e only consider ourselves as being interfered with, as no longer acting on our own free will, when we find acting for certain reasons painful'.⁴⁵ By differentiating between what encourages one to do something and one's attitude toward such motivation, Dworkin introduced the hierarchical, or split-level, view of the self. Subsequently, Frankfurt examined this hierarchical view in more depth.⁴⁶ Although Frankfurt occasionally referred to autonomy in his work on free will, in 'Autonomy and behavior control',⁴⁷ Dworkin found that there are two conditions necessary for autonomy, namely: (1) authenticity; and (2) independence.⁴⁸ Authenticity occurs whereby an individual, on their first-order desires, identifies with their second-order desires. Independence is the state in which this identification in authenticity takes place without interference or influences, such as manipulation.⁴⁹

According to the hierarchical account, commitments (such as desires, values, and beliefs) are validated by individuals, as their own, through a process of 'reflective endorsement'.⁵⁰ Based on this, individuals are seen to have first-order desires and second-order desires.⁵¹ First-order desires are what one wants (various objects), while second-order desires refer to what

⁴² Such an approach is neutral regarding what an individual may perceive as good or may be attempting to achieve. Dryden op cit note 31.

⁴³ Christman op cit note 11; Maartje Schermer 'Philosophical and ethical perspectives on autonomy' in Maartje Schermer (ed) *The Different Faces of Autonomy: Patient Autonomy in Ethical Theory and Hospital Practice* (2002) 5.

⁴⁴ Dryden op cit note 31.

⁴⁵ Gerald Dworkin 'Acting freely' (1970) 9 *Nous* 379 cited in Lawrence Haworth 'Review: Dworkin on autonomy' (1991) 102(1) *Ethics* 129.

⁴⁶ Harry Frankfurt *The Importance of What We Care About* (1988) cited in Lawrence Haworth 'Review: Dworkin on autonomy' (1991) 102(1) *Ethics* 129.

⁴⁷ Gerald Dworkin 'Autonomy and behavior control' (1976) 6 *Hastings Center Report* 23–8.

⁴⁸ Ibid at 24.

⁴⁹ Christman op cit note 11.

⁵⁰ Piper op cit note 38.

⁵¹ Ibid.

one wants to want.⁵² First-order desires are authentic when they accord with second-order desires. Thus, an individual is autonomous when they can determine their first-order desires by their second-order desires, or when they are able to produce authentic desires and live according to them.⁵³

(v) *Beauchamp and Childress three condition test for autonomy*

Beauchamp and Childress composed their own analysis of whether a choice is autonomous or not.⁵⁴ This evaluation involves three considerations; (1) intentionality;⁵⁵ (2) understanding; and (3) non-control. Understanding requires an individual to have a ‘substantial’ degree of understanding and freedom from constraint. Constraints⁵⁶ in this regard includes mental incapacities such as mental illness or mental immaturity, irrationality, and other restrictions on the requisite cognitive function of an individual. Non-control requires that an individual must be free of control exerted on them by external sources or by internal states that would hamper their self-directedness. External influences include duress, coercion, and manipulation, whilst internal states include conditions such as mental illness.⁵⁷

This conception includes mental incapacities such as mental immaturity and irrationality. Irrationality deserves greater interrogation, as any irrational decision-making would undermine

⁵² Lawrence Haworth ‘Review: Dworkin on autonomy’ (1991) 102(1) *Ethics* 129-130; Piper op cit note 38.

⁵³ The central idea of this theory is that people can have desires on two distinct levels: lower-order desires (first-order desires), which pertain directly to actions; and higher-order desires (second-order desires), which pertain directly to those lower-order desires. A lower-order desire is the desire to act in a certain way, whereas a higher-order desire is the desire to have a certain lower-order desire. The theory contends that a person’s choice is only autonomous if higher-order desires endorses their lower-order desires (Dworkin refers to this as the point where these two orders meet). Higher-order desires are the desires and wishes of a person that are inferred to be superior to the lower-order desires, which are described as instinctive desires. For example, a person who is overweight craves ice cream on a specific day, however, also desires to lose weight and live a healthier lifestyle. According to this model, the first-order desire, is the craving for ice cream, something which the agent experiences. The second-order desire is the goal of the person to lose weight and live a healthier lifestyle, and hence the desire to not want the ice cream to give effect to that goal. In this scenario, the two desires do not correlate, and should said person make the decision to purchase and eat ice cream, those decisions would not be autonomous, as the first-order desire does not match the second-order desire. Dworkin regards autonomy as the higher-order capacity to accept, repudiate, and/or change a lower order desire – hence the person needs to also be in possession of the ability to critically assess their desires in accordance with their higher-order desires, failing which they are not autonomous. Christman op cit note 11; Schermer op cit note 43 at 5; Piper op cit note 38.

⁵⁴ Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 7 ed (2013) 104.

⁵⁵ Intentionality involves ‘plans in the form of representations of the series of events proposed for execution of an action’. This means that the choice or action must be intentional and not accidental and it must correspond to the actor’s conception of said act/decision. The planned outcome may not actually materialise. Ibid at 104.

⁵⁶ Beauchamp and Childress do not advocate for the idea that a decision is only fully autonomous if there is a complete lack of constraint, or if there is a full understanding of an act by an agent. They argue that this is not practical, and in reality, decisions are made under non-ideal conditions. As such, they advocate that a decision can still be autonomous, even if there is not a complete understanding of the decision, or a complete lack of constraint. Ibid at 105.

⁵⁷ Ibid at 105.

understanding and hence render a decision non-autonomous. The questions are then: (1) what is considered irrational; and (2) who decides the content of irrationality? This condition is similar to the rationalist autonomy approach, which has also been criticised for allowing the possibility of paternalistic interventions. Ironically, any interventions on decisions that are deemed irrational would not be an infringement on autonomy however, as the decision itself would not be an autonomous one.

(vi) *Razian autonomy*

The Razian conception of autonomy requires that: (1) an individual possess sound mental capacities; (2) there must be a suitable range of options for an individual to choose from; and (3) there must be an independence from others.⁵⁸ Razian autonomy views an individual as being a ‘part-author’ of their own life, by making life-shaping decisions.⁵⁹ In order for an individual to make these decisions, he must have sufficient mental abilities to form these complex intentions and to execute those intentions.⁶⁰ This includes the requisite rationality and ability to comprehend and synthesise knowledge so as to realise these goals. In order to make these choices, there must be adequate options from which to choose.⁶¹ What sets Razian autonomy apart from other conceptions of autonomy is the requirement of a suitable variety of options which are also morally acceptable.⁶² Raz argues that the value attributed to autonomy partially stems from these variable options from which individuals can choose freely.⁶³ Important to this conception of autonomy is that an individual’s autonomy can be enhanced simply by providing them with ‘morally worthwhile’ options.⁶⁴

By requiring an ‘adequate range of options’ which are ‘morally acceptable’, Vayena notes that Razian autonomy diverges from the common understanding of autonomy in bioethical literature, which centres on an individual’s ability to make choices, which are informed and uncoerced⁶⁵ – in that the Razian conception of autonomy requires that there be a

⁵⁸ Razian autonomy also requires that he must be free from coercion and manipulation. Effy Vayena ‘Direct-to-consumer genomics on the scales of autonomy’ (2015) 41(4) *J Med Ethics* 311.

⁵⁹ Ibid at 311.

⁶⁰ Ibid at 311.

⁶¹ Ibid at 311.

⁶² Ibid at 310–4.

⁶³ Raz argues that one cannot realise personal autonomy should their only options be short term and trivial, or should all be driven towards a choice, despite the multiplicity of valuable options. Joseph Raz *The Morality of Freedom* (1986) 372 cited in Vayena op cit note 58 at 311.

⁶⁴ Conversely, autonomy is not enhanced should a person be presented with options that are morally worthless. Vayena op cit note 58 at 311.

⁶⁵ Ibid at 311.

certain quality to the choices that are presented to an individual.⁶⁶ This stricter requirement for autonomy is underpinned by ideals of ‘the good life’. Not all options will further the interests of an individual, and those that fail to do so fail to enhance autonomy.⁶⁷

(vii) *Rational autonomy*

Many advocate for the view that a patient’s autonomy triumphs over medical paternalism – even if that decision is seemingly unwise or detrimental to their wellbeing.⁶⁸ This view implies that individuals are only afforded the right of choice in terms of decisions relating to their affairs if they do not suffer from any mental incapacities. The basic idea of rational autonomy is that autonomous decision-making requires making decisions based on what one believes one has reason to do.⁶⁹ Objections to rational conceptions of autonomy argue that it leaves the door open to paternalistic interventions as it allows the overriding of a patient’s will, if they are deemed to be acting irrationally (and non-autonomously).

As stated, rationality in this form is based on reason. Reason is to be defined as an accurate connection between one’s values and available options.⁷⁰ One can draw a distinction between theoretical rationality and decision-making rationality. Theoretical rationality relates to the set of norms that govern how we come to form and sustain our beliefs.⁷¹

(b) *Integrated autonomy*

(i) *Feminist autonomy and Ethics of Care*

The individualistic core of many popular conceptions of autonomy has increasingly come under challenge by other schools of thought, such as feminist critiques of autonomy.⁷² Many feminist scholars took issue with individualistic conceptions of autonomy, rather than with autonomy itself, for overlooking values like cooperation, mutual responsibility, and care towards others – central values in decision-making for things such as research and healthcare.⁷³ A humanist approach underpins the Ethics of Care literature. In a medical setting, this involves inculcating humanist virtues such as the importance of relationships, communication, empathy,

⁶⁶ Common conceptions of autonomy refer to informed consent, which is often seen as central to autonomy. However, Vayena states that this only covers one aspect of autonomy: independent choice. Ibid at 311.

⁶⁷ Ibid at 311.

⁶⁸ Jonathan Pugh *Autonomy, Rationality, and Contemporary Bioethics* (2020) 183.

⁶⁹ Ibid at 183.

⁷⁰ Ibid at 22.

⁷¹ Ibid at 22.

⁷² Dworkin op cit note 22.

⁷³ Dove et al op cit note 28 at 152.

and support for patients. This principle finds its origins in feminist conceptions of healthcare and autonomy.⁷⁴ The moral feminist conception of autonomy as framed in feminist literature contains the same value of self-governance or acting on one's own reasons, values, and motivations as the other conceptions do.⁷⁵ Where these conceptions and the feminist view differ, is that the feminist conception of autonomy challenges the ideas of 'personhood' as individualistic or atomistic, which is argued as being damaging, as persons are interdependent social creatures that form, and are affected by, relationships.⁷⁶

(ii) *Relational autonomy*

The kind of autonomy, as proposed by feminist scholars, is commonly referred to 'relational autonomy'. Relational autonomy is a type of autonomy that has begun to feature prominently in healthcare literature. The term 'relational' is a rejection of the individualistic core of autonomy – it serves simply to deny that autonomy requires self-sufficiency. If relationships of care and interdependence are valuable and morally significant,⁷⁷ then any theory of autonomy must be 'relational' in the sense that it must acknowledge that autonomy is compatible with the individual standing in and valuing significant family and other social relationships.⁷⁸

Individualistic conceptions of autonomy were criticised as being removed from the lived experiences of people. However, most relational autonomy theorists do not reject the idea of autonomy, but instead call for its re-conceptualisation.⁷⁹ In this light, relational autonomy seeks to preserve the core idea of autonomy – having control over one's life – while also embracing the understanding that choices and identities are influenced by social connections and environment.⁸⁰ Relational autonomy developed as a conception that places individuals, as social creatures, in a socially embedded *network* of relations with others that impact and

⁷⁴ Hawkins & Ho op cit note 10 at 368.

⁷⁵ Natalie Stoljar 'Feminist perspectives on autonomy' *Stanford Encyclopaedia of Philosophy* 11 December 2018, available at <https://plato.stanford.edu/entries/feminism-autonomy/>, accessed on 5 May 2020.

⁷⁶ The earlier feminist literature identified the popular understanding of autonomy as 'masculine', and contemporary feminists have sought to reconceptualise this notion within the social framework that was argued to be originally characterised as a trait that belonged to women only. Diana Tietjens Meyers 'Personal autonomy and the paradox of feminine socialization' (1987) 84 *Journal of Philosophy* 619–28; P Benson 'Feminist second thoughts about free agency' (1990) 3 *Hypatia* 47–64; Marilyn Friedman 'Autonomy and social relationships: Rethinking the feminist critique' in Diana Tietjens Meyers (ed) *Feminists Rethink the Self* (1997) 40–61; Catriona Mackenzie & Natalie Stoljar (eds) *Relational Autonomy: Feminist Perspectives on Autonomy, Agency and the Social Self* (2000) cited in Stoljar op cit note 75.

⁷⁷ Mackenzie & Stoljar op cit note 76 at 8–10.

⁷⁸ Ibid at 8–10.

⁷⁹ Gómez-Virseda, de Maeseneer & Gastmans op cit note 4 at 9.

⁸⁰ Ibid at 9.

influence their autonomy – social surroundings and relationships enable individuals to flourish and develop a robust capacity for self-determination and identity formation.⁸¹ This account takes into consideration relationships (with family, the community, and society), interdependence (rather than independence), responsibility, care, mutual respect, and maintaining trust and accord.⁸² In terms of relational autonomy, relationships and social surroundings are vital in developing autonomy and encourages individuals to be guided by an ethic of trust and care in their actions.⁸³ Individuals can make their own decisions while being influenced by their relationships with others, who can be affected by decisions. Responsibility to others is an integral component of the decision-making process.⁸⁴

Essentially this means, as opposed to Western conceptions of autonomy, that the external limitations that one would view as reducing autonomy (i.e. family influence on decisions) actually empower autonomy.⁸⁵ The relational view of autonomy impacts: (1) decision-making capacity; (2) informed consent procedures; and (3) disclosure. More people must be consulted regarding consent, negotiations, and disclosure, and must take into account social contexts, such as relations and illiteracy, and an individual's decision-making capacity is interwoven with the community.⁸⁶ In this view, a limitation in the exercise of autonomy is justifiable to prevent harm to the autonomy of others. Furthermore, the integrated nature of relational autonomy requires a holistic view that recognises an individual's intersectionality as part of their autonomy. This would include socio-political factors such as age, race, class, and economic status. Where individuals are more at risk of harm due to higher rates of vulnerability (such as illiteracy or poverty, for example), relational autonomy recognises these conditions and would require an approach that addresses them.⁸⁷

V WHAT IS THE MEANING OF AUTONOMY IN SOUTH AFRICA?

In an open society, such as South Africa, autonomy is paramount.⁸⁸ Personal autonomy means having the freedom to govern oneself without interference from others or internal constraints

⁸¹ Dryden op cit note 31.

⁸² Dove et al op cit note 28 at 153.

⁸³ Ibid at 153.

⁸⁴ Jennifer K Walter & Lainie Friedman Ross 'Relational autonomy: Moving beyond the limits of isolated individualism' (2014) 133(suppl 1) *Pediatrics* 16–23.

⁸⁵ Gómez-Virseda, de Maeseneer & Gastmans op cit note 4 at 9.

⁸⁶ Ibid at 9.

⁸⁷ Jennifer Roest, Busisiwe Nkosi, Janet Seeley et al 'Respecting relational agency in the context of vulnerability: What can research ethics learn from the social sciences?' (2023) 37 *Bioethics* 380.

⁸⁸ Joel C Eissenberg 'Direct-to-consumer genomics: Harmful or empowering?' (2017) 114(1) *Missouri Medicine* 29.

that hinder meaningful decision-making.⁸⁹ Autonomy represents both the legal and mental ability to comprehend and make informed choices. It hinges on understanding available options and determining their suitability for one's purpose. Healthcare professionals have an ethical duty to offer information and support. Legislators establish the legal framework that upholds autonomy. Exercising autonomy also depends on physical ability and a conducive environment. Factors such as age, physical ability, socio-economic status, and personality may limit personal autonomy.⁹⁰ In South Africa, individuals are legally and ethically allowed to freely make informed decisions regarding their healthcare and participation in research. They have the option to choose whether to give consent for treatment or to participate in research.⁹¹

Autonomy has featured predominantly in terms of healthcare and the doctor-patient relationship. Respect for autonomy and self-determination were incorporated into South African law in *Richter v Estate Hammann*,⁹² and reaffirmed in *Castell v De Greef*.⁹³ Patient autonomy necessitates healthcare practitioners respecting patients' freedom and to refrain from interfering with treatment decisions.⁹⁴ It assumes the patient's right and capacity to understand and make informed decisions regarding their life.⁹⁵ McQuoid-Mason defines patient autonomy as meaning that patient decisions must be (1) informed; (2) independent; and (3) respected.⁹⁶ The doctor-patient relationship, and the South African healthcare system in general, traditionally centred on medical paternalism, in terms of which doctor was seen as having expert knowledge that could be utilised to make decisions on behalf of the patient without their consent.⁹⁷ However, in recent times, medical paternalism and the view that 'doctor knows best' has been rejected in South African law, with patient autonomy instead being recognised as a fundamental right.⁹⁸ According to Dhai and McQuoid-Mason, paternalism 'the belief that the healthcare practitioner should protect or advance the interests of the patient even if contrary to

⁸⁹ van der Reyden op cit note 13 at 27.

⁹⁰ Sidney F Engelbrecht 'Can autonomy be limited - An ethical and legal perspective in a South African context?' (2014) 32(1) *JFOS* 35.

⁹¹ ASSAf op cit note 7 at 42.

⁹² 1967 (3) SA 226 (C).

⁹³ 1994 (4) SA 408 (C). The case revolves around the issue of consent for medical treatment and debates whether priority should be given to the patient's autonomy and right to self-determination, or to the medical profession's authority to define what constitutes adequate disclosure. van der Reyden op cit note 89 at 30.

⁹⁴ David McQuoid-Mason 'Medical ethics and the payment of fees before treatment' (2011) 101(11) *SAMJ* 798.

⁹⁵ van der Reyden op cit note 13 at 27–8; Ames Dhai & David McQuoid-Mason *Bioethics, Human Rights and Health Law* 1 ed (2011) cited in Sidney F Engelbrecht 'Can autonomy be limited – An ethical and legal perspective in a South African context?' (2014) 32(1) *JFOS* 35.

⁹⁶ David McQuoid-Mason 'Michael Jackson and the limits of patient autonomy' (2012) 5(1) *SAJBL* 11.

⁹⁷ Dieter Giesen 'From paternalism to self-determination and shared decision making' (1988) 30 *Acta Juridica* 114.

⁹⁸ *Ibid* at 116.

the patient's own immediate desires or freedom of choice, no longer has a place in the healthcare context...the value of autonomy and self-determination have been recognised as paramount'.⁹⁹

In South Africa, the Constitution does not specifically include autonomy as a fundamental right. However, the right to dignity (section 10 of the Constitution) and the right to bodily and psychological integrity (section 12 of the Constitution) in the Bill of Rights have been viewed as recognising and protecting autonomy and self-determination.¹⁰⁰ The NHA and POPIA – whilst not expressly mentioning dignity or bodily and psychological integrity – do recognise that 'the State must respect, protect, promote and fulfil the rights in the Bill of Rights'¹⁰¹ – which is inclusive of the right to dignity and the right to bodily and psychological integrity. Section 8 of the Mental Health Care Act 17 of 2002 deals with respect, human dignity, and privacy, and provides that 'The person, human dignity and privacy of every mental health care user must be respected'.¹⁰² The Regulations Relating to Research with Human Participants (Human Research Participant Regulations)¹⁰³ state that health research involving human participants must inter alia 'respect participants' rights, including but not limited to rights to dignity, privacy, bodily integrity and equality'.¹⁰⁴ Therefore, if autonomy does form part of the rights to dignity and bodily and psychological integrity, then autonomy is recognised and protected under various South African laws.

It is not just the Constitution and various other relevant laws that indirectly mention autonomy. Autonomy also features in various South African policies and guidelines. The Health Professions Council of South Africa (HPCSA) *Guidelines for Good Practice in the Healthcare Professions* provides the following definition of autonomy: 'Healthcare practitioners must honour the right of patients to self-determination, which allows them to make their own informed choices, and to live their lives by their own beliefs, values and preferences'.¹⁰⁵

The South African Medical Research Council (SAMRC) *Guidelines on the Responsible Conduct of Research* promotes the four basic principles of biomedical ethics, namely: (1)

⁹⁹ Dhali & McQuoid-Mason op cit note 95 at 69.

¹⁰⁰ ASSAf op cit note 7 at 42.

¹⁰¹ Preamble of the NHA; Preamble of POPIA.

¹⁰² Section 8(1) of the Mental Health Care Act.

¹⁰³ GN R719 GG 38000 of 19 September 2014.

¹⁰⁴ Regulation 2(h) of the Human Research Participant Regulations.

¹⁰⁵ Health Professions Council of South Africa (HPCSA) *Guidelines for Good Practice in the Healthcare Professions: General Ethical Guidelines for the Healthcare Professions (Booklet 1)* (2021) 2.

autonomy (which denotes respect for persons and human dignity); (2) beneficence; (3) non-maleficence; and (4) justice.¹⁰⁶ As such, all SAMRC researchers must follow these principles as they are central to responsible and ethical research.¹⁰⁷

The DoH Ethics Guidelines define autonomy as ‘the capacity to understand information; to act on it voluntarily; to use own judgement to make decisions about own actions, including whether to participate in research’.¹⁰⁸ Autonomy is included as part of respect for persons, which is one of the ethical principles.¹⁰⁹ It necessitates that individuals capable of considering their choices be treated with respect and allowed to make their own decisions. Respect for persons includes ‘the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy’.¹¹⁰ Autonomy involves both the capacity to reflect on a decision and the ability to act on it.¹¹¹

The NHREC Ethics Guidelines define autonomy as ‘the capacity to understand information; to act on it voluntarily; to use own judgement to make decisions about own actions, including whether to participate in research’.¹¹² The NHREC Ethics Guidelines further contain a heading entitled ‘Respect for persons (dignity and autonomy)’, which implies that it views dignity and autonomy as falling under the concept of respect for persons. It further equates self-determination with autonomy when explaining that respect for persons means treating individuals capable of making decisions with respect and allowing them to make choices for themselves.¹¹³ For those who cannot make decisions or have limited capacity, protections must be put in place to prevent harm from irresponsible choices. Respect for persons acknowledges that the dignity, privacy, confidentiality, well-being, and safety of all research participants are crucial in research involving human participants. Autonomy involves the capacity to think a decision through and to act upon it. Typically, participant recruitment centres on individuals who autonomously decide whether to participate in the research.¹¹⁴

The ASSAf Report places greater emphasis on an African approach to autonomy. Respect for persons requires the recognition and safeguarding of both individual *and* collective

¹⁰⁶ South African Medical Research Council (SAMRC) *The South African Medical Research Council Guidelines on the Responsible Conduct of Research* (2022) 6.

¹⁰⁷ Ibid at 6.

¹⁰⁸ Department of Health *Ethics in Health Research: Principles, Processes and Structures* 2 ed (2015) 53.

¹⁰⁹ Ibid at 14.

¹¹⁰ Ibid at 14.

¹¹¹ Ibid at 14.

¹¹² National Department of Health *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* 3 ed (2024) 102.

¹¹³ Ibid at 8.

¹¹⁴ Ibid at 8–9.

rights and interests, particularly concerning autonomy, privacy, confidentiality, and access to benefits of research. This protection should be balanced, reasonable, and justifiable.¹¹⁵ In Africa, there is a focus on family and community, whose interests are also taken into account when making decisions.¹¹⁶

From the above, it appears that autonomy is generally viewed as being part of human dignity, self-determination, and/or respect for persons. But is this true? Does autonomy actually fit with these concepts? In the headings below, and through South African jurisprudence relating to autonomy, I inter alia determine whether autonomy is, in fact, part of respect for persons and human dignity. This is done in an attempt to understand the meaning afforded to autonomy in South Africa, before proceeding with applying the concept of open consent to genomics research in South Africa.

(a) Autonomy in the broader African context

Beyond South Africa, autonomy has also been discussed in the African context more generally. African philosophy offers ‘a conceptual interpretation and analysis of human problems and human experience in the African context’.¹¹⁷ African philosophy has taken the view that the bioethics discourse has been dominated by Western views and concepts. As such, a new approach to bioethics, based on African values, is required.¹¹⁸ Behrens identifies the most noteworthy African moral perspective as the importance of community¹¹⁹ – highlighting the value of relationality and harmonious relationships in African thought.¹²⁰ In Africa, it is impossible for the individual to exist alone – his existence is based on those around him.¹²¹

African ethics is often described as communitarian, and opposed to Western individualism.¹²² Communitarianism highlights the communal links between individuals.¹²³ This viewpoint acknowledges individual human dignity as well as the social aspect of being human. It emphasises social connections, bonds, common goals, and tradition.¹²⁴ Although the communitarian ethic is more involved than simply placing emphasis on the community, it is

¹¹⁵ ASSAf op cit note 7 at 42.

¹¹⁶ Ibid at 41.

¹¹⁷ Ibid at 25.

¹¹⁸ KG Behrens ‘Towards an indigenous African bioethics’ (2013) 6(1) *S Afr J BL* 33; Cletus T Andoh ‘Bioethics and the challenges to its growth in Africa’ (2011) 1(2) *Open Journal of Philosophy* 74.

¹¹⁹ Behrens op cit note 118 at 33.

¹²⁰ Ibid at 32.

¹²¹ Andoh op cit note 118 at 70.

¹²² Behrens op cit note 118 at 33.

¹²³ Shoji op cit note 8 at 36.

¹²⁴ Andoh op cit note 118 at 70.

clear that there is interdependence and that genuine personhood and individual well-being requires relationships with others.¹²⁵ In terms of communitarianism, there have been two views: (1) radical communitarianism; and (2) moderate communitarianism. Radical communitarianism views the community as paramount.¹²⁶ Communal relations are what make up the individual. The purpose of every individual is to contribute to the greater good of their community. Therefore, only actions that serve the interests of the community are considered 'ethically permissible'.¹²⁷ On the other hand, moderate communitarianism views society as a community of individuals, where each person is both autonomous (possessing rationality, moral sense, and capacity for virtue and free choice) and a communal being.¹²⁸ This is because community's existence and success are contingent upon the existence and success of individuals.¹²⁹ Although the community is central in African thought, the individual also has a separate identity.¹³⁰ Given this, the only time that an individual's interests will not take precedence is when 'doing so will stand in the way of attaining a more highly ranked or preferable goal of the community'.¹³¹ African communitarianism is often thought to be entirely communalistic with an individual's autonomy not being recognised outside of his community. However, this is not the case. A more moderate view of communitarianism views individual interests as important and capable of being independent from the community. It requires the community to enhance the individual's wellbeing, and the individual to enhance the wellbeing of the community. As opposed to Western conceptions, personhood in African communitarianism is a lifelong process that is achieved through societal relations, and being ethical to others.¹³²

African philosophy has attempted to move away from an overtly collectivist view and the idea that individual rights are un-African as it is seen not to be a true representation of African philosophy.¹³³ There is a place for the recognition of individual personhood and legal

¹²⁵ Behrens op cit note 118 at 33.

¹²⁶ Shozi op cit note 8 at 38.

¹²⁷ Ibid at 39; Andoh op cit note 118 at 70.

¹²⁸ GA Ogunbanjo & D Knapp van Bogaert 'Communitarianism and communitarian bioethics' (2005) 47(10) *SA Fam Pract* 51; Andoh op cit note 118 at 70.

¹²⁹ DN Kaphagawani 'African conceptions of a person: A critical survey' in K Wiredu (ed) *A Companion to African Philosophy* (2004) 338; Shozi op cit note 8 at 38.

¹³⁰ GM Kayange *Meaning and Truth in African Philosophy: Doing African Philosophy with Language* (2018) 131–4; M Munyuka & M Mothlabi 'Ubuntu and its socio-moral significance' in MF Murove (ed) *African Ethics: An Anthology of Comparative and Applied Ethics* (2009) 66; Shozi op cit note 8 at 38.

¹³¹ K Gyekye 'Person and community in African thought' in PH Coetzee & APJ Roux (eds) *Philosophy from Africa: A Text with Readings* 2 ed (2002) 308; Shozi op cit note 8 at 38 & 39.

¹³² Shozi op cit note 8 at 36.

¹³³ Ibid at 38; Kaphagawani op ict note 129 at 338; Munyuka & Mothlabi op cit note 130 at 66.

rights in African philosophy.¹³⁴ In that recognition, autonomy is viewed in a different way – an individual is tied to his community, and it is artificial and incoherent to view the individual in an atomistic way. From an African perspective, the individual and the community are almost mutually dependent. Thus, nothing can be in the interests of the individual that is not in the interests of the community and vice versa. An individual does not have inalienable rights to do things even to the detriment of the community, but the scope of individual freedom and individual autonomy must be informed by an understanding that individual actions also impact the community.¹³⁵

From an African perspective, autonomy serves as a pathway to personhood and the ability to act independently. However, the focus remains on choices that contribute to the collective good accepted by the community. This good is defined by harmonious living, strong relationships, solidarity, and the overall well-being of individuals.¹³⁶

Autonomy in the Western view – unlike in Africa – promotes respect for individual rights and does not take others, such as family and the community, into account.¹³⁷ In healthcare, the good of the individual patient – rather than the common good – is central. Conversely, the African view focuses on relationships and connectedness with others in the community.¹³⁸ Communitarian bioethics supports ideas of public health, equal access to healthcare, distributive justice as solidarity, family involvement in decision-making, and shared consensus on public policies.¹³⁹ Therefore, collaborative decision-making takes priority over individual autonomy or consent.¹⁴⁰

Based on the individualistic nature of autonomy in the West, there have been calls to alter the principle of autonomy for the African context. The four principles of autonomy, beneficence, non-maleficence, and justice developed by Beauchamp and Childress,¹⁴¹ are viewed as central to bioethics and moral decision-making.¹⁴² However, these principles have

¹³⁴ Bernard Matolino *The Concept of Person in African Political Philosophy: An Analytical and Evaluative Study* (unpublished PhD thesis, University of KwaZulu-Natal, 2008) 145.

¹³⁵ Shozi op cit note 8 at 39.

¹³⁶ Polycarp Ikuenobe 'African communal basis for autonomy and life choices' (2018) 18 *Developing World Bioeth* 213.

¹³⁷ Francis Akpa-Inyang & Sylvester C Chima 'South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: A cross-cultural qualitative study' (2021) 22 *BMC Med Ethics* 2.

¹³⁸ Ibid at 2.

¹³⁹ Andoh op cit note 118 at 70–1.

¹⁴⁰ Akpa-Inyang & Chima op cit note 137 at 2.

¹⁴¹ Beauchamp & Childress op cit note 3.

¹⁴² S Holm 'Not just autonomy – The principles of American biomedical ethics' (1995) 21 *J Med Ethics* 332–8; Behrens op cit note 118 at 34.

limitations when applied to the African context – especially in terms of respect for autonomy, as it is seen as being too individualistic with a large focus on autonomous decision-making.¹⁴³ As such, Behrens proposes that respect for autonomy be amended to ‘respect for persons’ – as it appeared in the Belmont Report.¹⁴⁴ This is thus inclusive of respecting autonomous decisions without suggesting that autonomy should always be paramount.¹⁴⁵

VI AUTONOMY IN SOUTH AFRICAN CASE LAW

At the outset, it should be clarified that South Africa has adopted a purposive approach to statutory interpretation, which is recognised by courts.¹⁴⁶ Unlike the literal approach to statutory interpretation or ordinary meaning rule – where a statute’s language is understood based on its ordinary, grammatical meaning¹⁴⁷ and is only deviated from when it would lead to absurd outcomes or when it conflicts unreasonably with other provisions of a statute¹⁴⁸ – a purposive approach is required by the Constitution,¹⁴⁹ particularly section 39(2) of the Constitution, where legislation must be interpreted in a way that advances the ‘spirit, purport and objects of the Bill of Rights’.¹⁵⁰ *Jaga v Dönges NO; Bhana v Dönges NO*¹⁵¹ expresses this as follows:

¹⁴³ Behrens op cit note 118 at 34.

¹⁴⁴ Ibid at 34; Office of the Secretary Ethical Principles op cit note 2.

¹⁴⁵ Behrens op cit note 118 at 34.

¹⁴⁶ Annette Singh *The Impact of the Constitution on Transforming the Process of Statutory Interpretation in South Africa* (unpublished PhD thesis, University of KwaZulu-Natal, 2014) 47.

¹⁴⁷ *Union Government (Minister of Finance) v Mack* 1917 (AD) at 739. In the case of *Mpisi v Trebble* 1994 (2) SA 136 (AD) at 9, it was held that ‘[t]he primary rule of statutory interpretation is to arrive at the intention of the Legislature having regard to the ordinary, grammatical meaning of the words of the enactment under consideration within their contextual setting’. This rule has been recognised in case law. See, *HMBMP Properties (Pty) Ltd v King* 1981 (1) SA 906 (N) at 909A; *Nyembezi v Law Society, Natal* 1981 (2) SA 752 (A) at 757H. LM Du Plessis ‘Statute law and interpretation’ in LM Du Plessis (ed) *The Law of South Africa* 2 ed 25(1) (2011) para 349.

¹⁴⁸ *Venter v R* 1907 TS 910 (TS) at 913. The position in South Africa that the plain meaning of words in a statute should be followed was reflected in the case of *Poswa v MEC for Economic Affairs, Environment and Tourism, Eastern Cape* 2001 (3) SA 582 (SCA) para 10 citing *Bhyat v Commissioner for Immigration* 1932 AD 125 at 129: ‘In construing a provision of an Act of Parliament the plain meaning of its language must be adopted unless it leads to some absurdity, inconsistency, hardship or anomaly which from a consideration of the enactment as a whole a court of law is satisfied the Legislature could not have intended’. In *Union Government (Minister of Finance) v Mack* supra note 147 at 739, it was stated that the rule that ‘the language of the Legislature should be read in its ordinary sense’ assists in limiting the innumerable conceivable meanings that can be gleaned from an instrument’s language. See also, *Volschenk v Volschenk* 1946 TPD 486 at 487; *Norden v Bhanki* 1974 (4) SA 647 (AD) at 510. Du Plessis op cit note 147 at para 349; Lourens Du Plessis ‘Interpretation’ in Stuart Woolman, Michael Bishop & Jason Brickhill (eds) *Constitutional Law of South Africa* 2 ed (2008) 32–161.

¹⁴⁹ *Bertie Van Zyl (Pty) Ltd v Minister for Safety and Security (Bertie Van Zyl)* 2010 (2) SA 181 (CC) para 21.

¹⁵⁰ *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism (Bato Star)* 2004 (4) SA 490 (CC) para 91 cited in *Bertie Van Zyl* para 21.

¹⁵¹ 1950 (4) SA 653 (A).

‘Certainly no less important than the oft repeated statement that the words and expressions used in a statute must be interpreted according to their ordinary meaning is the statement that they must be interpreted in the light of their context. But it may be useful to stress two points in relation to the application of this principle. The first is that ‘the context’, as here used, is not limited to the language of the rest of the statute regarded as throwing light of a dictionary kind on the part to be interpreted. Often of more importance is the matter of the statute, its apparent scope and purpose, and within limits, its background’.¹⁵²

The Constitutional Court, in *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism (Bato Star)*,¹⁵³ held that statutory interpretation requires one ‘to have regard to the context within which the words occur, even where the words to be construed are clear and unambiguous’.¹⁵⁴

(a) *Autonomy as a right or a value?*

There has been confusion and misinterpretation in South Africa regarding whether autonomy is a right or a value. Before proceeding further in my analysis, this must be clarified. Whether it is an error or a mere omission, South African case law is inconsistent when referring to autonomy. Some cases refer to it as a value,¹⁵⁵ while others deem it to be a right.¹⁵⁶ In *NM v Smith*¹⁵⁷ O’Regan J, in her dissenting judgment, expanded on autonomy and held as follows:

‘Recognising the role of freedom of expression in asserting the moral autonomy of individuals demonstrates the close links between freedom of expression and other constitutional rights such as human dignity, privacy and freedom. Underlying all these constitutional rights is the constitutional celebration of the possibility of morally autonomous human beings independently able to form opinions and act on them...Our Constitution seeks to assert and promote the autonomy of individuals...’¹⁵⁸

Autonomy is not included in the list of ‘other constitutional rights’. Further, autonomy is referred to as ‘underlying’ these constitutional rights. This indicates that, in South African case

¹⁵² *Jaga v Dönges NO; Bhana v Dönges NO* 1950 (4) SA 653 (A) at 662. Also cited in *Bato Star* supra note 150 at para 89 and *Bertie Van Zyl* supra note 149 at para 21.

¹⁵³ 2004 (4) SA 490 (CC).

¹⁵⁴ *Bato Star* supra note 150 at para 91.

¹⁵⁵ *Barkhuizen v Napier (Barkhuizen)* 2007 (5) SA 323 (CC) para 150; *AB v Minister of Social Development (AB I)* 2016 (2) SA 27 (GP) para 67; *Ferreira* supra note 15 at para 251; *Bernstein v Bester NO (Bernstein)* 1996 (2) SA 751 (CC) para 150; *S v Jordan* 2002 (6) SA 642 (CC) para 52.

¹⁵⁶ *National Coalition for Gay and Lesbian Equality v Minister of Justice (National Coalition)* 1999 (1) SA 6 (CC) para 117; *S v Jordan* supra note 155 at para 53; *AB I* supra note 155 at paras 8 & 76.

¹⁵⁷ 2007 (5) SA 250 (CC).

¹⁵⁸ *NM v Smith* 2007 (5) SA 250 (CC) paras 145–6. This was also cited with approval in the High Court case of *AB I* supra note 155 at paras 65–6, as well as being quoted by the Supreme Court of Appeal (SCA) in *British American Tobacco South Africa (Pty) Ltd v Minister of Health* [2012] 3 All SA 593 (SCA) para 13.

law, autonomy is recognised as a constitutional value that underlies various rights such as human dignity, freedom, and privacy. The Constitutional Court in *Barkhuizen v Napier* (*Barkhuizen*)¹⁵⁹ explicitly recognised ‘self-autonomy’¹⁶⁰ as ‘the ability to regulate one’s own affairs, even to one’s own detriment’.¹⁶¹ This asserts autonomy as a value underlying the Constitution.

In *AB v Minister of Social Development (AB I)*, the respondent agreed that autonomy is a constitutional value, but disputed attempts by the second applicant to ‘elevate a value to a right’.¹⁶² Basson J did not agree with this contention,¹⁶³ but provided no reasoning for this conclusion, besides that autonomy, as a constitutional value, should be taken into account in this case.¹⁶⁴ It appears that the respondent misinterpreted *S v Jordan*,¹⁶⁵ and took the reference to ‘rights’ in terms of dignity, privacy, and freedom of the person, which are generally grouped under autonomy, as meaning that autonomy would be given the status of a right.¹⁶⁶ However, it is expressly stated in *S v Jordan*¹⁶⁷ that such rights should fall under the ‘global concept of autonomy’ (my emphasis).¹⁶⁸ It is clear that no rights status is afforded to autonomy in this context as a concept cannot be equated with a right. However, the respondent may have a point in terms of the subsequent sentence in *S v Jordan*,¹⁶⁹ which states ‘it is the experience of autonomy that matters, the *right* to make decisions rather than the content of these decisions’ (my emphasis).¹⁷⁰ It appears that autonomy in this context may have been inferred as a right – it is implied that autonomy refers to the right to make decisions. Despite the above, *S v Jordan*¹⁷¹ does in fact specifically hold that an independent right to autonomy would neither be useful for constitutional analysis, nor would it be suitable to found a constitutional analysis on a right excluded from the Constitution.¹⁷² Although this shows that an independent right to autonomy is unsuitable, the Court once again (perhaps mistakenly) refers to autonomy as a

¹⁵⁹ 2007 (5) SA 323 (CC).

¹⁶⁰ I agree with the views of Thaldar and Steytler who state that the term ‘self-autonomy’, as used by the Constitutional Court in *Barkhuizen* supra note 155 at para 57, is an ‘unnecessary tautology’ and does not differ from the term ‘autonomy’. Donrich W Thaldar & Michaela Steytler ‘Time for Cinderella to go to the ball: Reflections on the right to freedom of scientific research’ (2020) 138(2) *SALJ* 273.

¹⁶¹ *Barkhuizen* supra note 155 at para 57.

¹⁶² *AB I* supra note 155 at para 67.

¹⁶³ *Ibid* at para 68.

¹⁶⁴ *Ibid* at para 67.

¹⁶⁵ 2002 (6) SA 642 (CC).

¹⁶⁶ *S v Jordan* supra note 155 at para 52.

¹⁶⁷ 2002 (6) SA 642 (CC) para 52.

¹⁶⁸ *S v Jordan* supra note 155 at para 52.

¹⁶⁹ 2002 (6) SA 642 (CC) para 52.

¹⁷⁰ *S v Jordan* supra note 155 at para 52.

¹⁷¹ 2002 (6) SA 642 (CC) para 53.

¹⁷² *S v Jordan* supra note 155 at para 53 cited in *AB I* supra note 155 at para 67.

right in the context of autonomy not being present in the Constitution – the Court refers to ‘a *right* not expressly included within the Constitution’ (my emphasis).¹⁷³

I suggest that autonomy is a value and not a right as it is not expressly included in the Constitution. Rather, it is a *value* that underlies and informs many constitutional *rights*. Although autonomy is not an express right contained in the Constitution, it has been defined as a value that underlies many fundamental human rights including human dignity, freedom, privacy, and equality. Although in the past, the nature of the relationship between autonomy and other fundamental human rights was inexact, the legislature has sought to clarify this relationship through case law.

(b) *Autonomy and other rights and values*

Autonomy has been associated with several constitutional rights, including human dignity, freedom, and privacy.¹⁷⁴ To understand their meaning and the possible relationship that these rights share with autonomy, in the sub-headings below I explore how autonomy links to (1) human dignity; (2) freedom; (3) bodily and psychological integrity; and (4) privacy. These four rights have been chosen as they primarily feature in South African case law relevant to autonomy, and they are also relevant to genomics research – which is a central aspect of this thesis.

(i) *Autonomy and human dignity*

Dignity as autonomy closely links to Kant – treating individuals with dignity is to treat them as autonomous and with the ability to choose their destiny.¹⁷⁵ Before proceeding, it is perhaps necessary to differentiate between ‘dignity’ and ‘human dignity’, a conceptual distinction which was made by Jordaan.¹⁷⁶ First, although dignity is challenging to define, the Constitutional Court, in *National Coalition for Gay and Lesbian Equality v Minister of Justice* (*National Coalition*),¹⁷⁷ held that ‘it is clear that the constitutional protection of dignity requires us to acknowledge the value and worth of all individuals as members of our society’.¹⁷⁸ More recently, in the case of *VJV v Minister of Social Development*,¹⁷⁹ it was held that dignity ‘is

¹⁷³ *S v Jordan* supra note 155 at para 53.

¹⁷⁴ Jordaan op cit note 9 at 4–5.

¹⁷⁵ Christopher McCrudden ‘Human dignity and judicial interpretation of human rights’ (2008) 19(4) *EJIL* 659–60.

¹⁷⁶ Jordaan op cit note 15 at 383–5.

¹⁷⁷ 1999 (1) SA 6 (CC).

¹⁷⁸ *National Coalition* supra note 156 at para 28. This was also cited in *Qwelane v South African Human Rights Commission* (*Qwelane*) 2021 (6) SA 579 (CC) para 66.

¹⁷⁹ 2023 (6) SA 87 (CC).

about acknowledging the value and worth of individuals. It is about agency – the ability to make meaningful choices about your life’.¹⁸⁰ Human dignity denotes a particular ‘species’ of dignity, which refers to the fundamental worth that every individual naturally possesses.¹⁸¹ Human dignity is central to South Africa’s constitutional dispensation and has been referred to as the ‘touchstone of the new political order’.¹⁸² The Constitution recognises human dignity as one of its founding provisions.¹⁸³ Further, section 10 of the Constitution deals with human dignity and provides that ‘[e]veryone has inherent dignity and the right to have their dignity respected and protected’.¹⁸⁴ In the literature, autonomy has been equated with dignity – but does this hold true in terms of South African case law?

Autonomy is significant in South Africa because it forms a central element of dignity, which has been described as ‘the fountain of all rights’.¹⁸⁵ *Ferreira v Levin NO; Vryenhoek v Powell NO (Ferreira)*¹⁸⁶ was the first case to implicitly refer to autonomy as part of human dignity:

‘Human dignity cannot be fully valued or respected unless individuals are able to develop their humanity, their “humanness” to the full extent of its potential. Each human being is uniquely talented...An individual’s human dignity cannot be fully respected or valued unless the individual is permitted to develop his or her unique talents optimally. Human dignity has little value without freedom; for without freedom *personal development and fulfilment* are not possible’¹⁸⁷ (my emphasis).

As stated in the concurring opinion of Ackermann J in *Ferreira*,¹⁸⁸ terms such as ‘personal development’ and ‘own conception of the good life’ – which are associated with autonomy – are used.¹⁸⁹ In quoting with approval part of the minority judgment of Ackermann J in

¹⁸⁰ *VJV v Minister of Social Development* 2023 (6) SA 87 (CC) para 60.

¹⁸¹ Jordaan also provides other species of dignity in Western philosophy, namely: (1) dignity can be seen as a personal sense of worth; (2) dignity can be understood behaviourally, where an individual’s composure and noble conduct contribute to their perceived value; and (3) dignity can be aspirational, linked to an individual’s life achievements. Regarding the Constitutional Court’s stance, Jordaan notes that while it has not provided a precise definition of human dignity, its rulings have shaped a nuanced understanding. This includes seeing individuals as inherently valuable, deserving equal consideration, and entitled to opportunities for self-fulfilment and autonomy. Additionally, there is a collective responsibility to create conditions where individuals can exercise their agency effectively. Jordaan op cit note 15 at 383–4.

¹⁸² *S v Makwanyane (Makwanyane)* 1995 (3) SA 391 para 329.

¹⁸³ Section 1 of the Constitution states that ‘The Republic of South Africa is one, sovereign, democratic state founded on the following values:...(a) Human dignity, the achievement of equality and the advancement of human rights and freedoms’.

¹⁸⁴ Section 10 of the Constitution.

¹⁸⁵ *Makwanyane* supra note 182 at para 308 (concurring judgment by Mokgoro J); Jordaan op cit note 9 at 7.

¹⁸⁶ 1996 (1) SA 984 (CC).

¹⁸⁷ *Ferreira* supra note 15 at para 49.

¹⁸⁸ 1996 (1) SA 984 (CC).

¹⁸⁹ *Ferreira* supra note 15 at para 50; Jordaan op cit note 9 at 5.

Ferreira,¹⁹⁰ the Constitutional Court in *Member of the Executive Council for Education: KwaZulu-Natal v Pillay (Pillay)*¹⁹¹ recognised two elements of autonomy, personal development and fulfilment, and linked them to human dignity. In O'Regan J's dissenting opinion in *NM v Smith*,¹⁹² autonomy was made explicit as a constitutional value underlying human dignity, freedom, and privacy¹⁹³ – and was referred to as moral agency. Moral agency was also referred to in the minority judgment in *S v Manamela*,¹⁹⁴ which held that '[o]ur society asserts individual moral agency and it does not flinch from recognising the responsibilities that flow from it'.¹⁹⁵

*Barkhuizen*¹⁹⁶ held that autonomy is 'the very essence of freedom and a vital part of dignity'.¹⁹⁷ The position in *Barkhuizen*¹⁹⁸ was repeated in *Pillay*.¹⁹⁹ In this case, the majority of the Constitutional Court held that 'an entitlement to respect for the unique set of ends that the individual pursues' is a 'necessary element of freedom and of dignity of any individual'.²⁰⁰ Jordaan applies the liberal view that autonomy 'is a *conditio sine qua non*' for the pursuit of a 'unique set of ends', and deems autonomy as an element of dignity.²⁰¹ In the High Court case of *AB 1*,²⁰² Basson J expressly stated that autonomy is 'a vital part of human dignity'.²⁰³ Further, in *AB 1*,²⁰⁴ by accepting the view of an expert, Basson J implies that autonomy forms part of human dignity. The opinion of an expert stated that infertility negatively affects 'some of the core elements of a person's being, such as self-worth, sense of identity and autonomy', which Basson J referred to as 'human dignity'.²⁰⁵ In the majority judgment of *AB v Minister of Social Development (AB 2)*,²⁰⁶ the view of the applicants that autonomy forms a core element of human dignity was not contested by the Constitutional Court.²⁰⁷ *South African Breweries*

¹⁹⁰ 1996 (1) SA 984 (CC) para 49.

¹⁹¹ 2008 (1) SA 474 (CC) para 63.

¹⁹² 2007 (5) SA 250 (CC).

¹⁹³ Jordaan op cit note 9 at 6.

¹⁹⁴ (*Director-General of Justice Intervening*) 2000 (3) SA 1 (CC).

¹⁹⁵ *S v Manamela* 2000 (3) SA 1 (CC) para 100 (per O'Regan J and Cameron AJ) cited in *NM v Smith* supra note 158 at para 132.

¹⁹⁶ 2007 (5) SA 323 (CC).

¹⁹⁷ *Barkhuizen* supra note 155 at para 57.

¹⁹⁸ 2007 (5) SA 323 (CC).

¹⁹⁹ 2008 (1) SA 474 (CC).

²⁰⁰ *Member of the Executive Council for Education: Kwazulu-Natal v Pillay (Pillay)* 2008 (1) SA 474 (CC) para 64.

²⁰¹ Jordaan op cit note 9 at 7.

²⁰² 2016 (2) SA 27 (GP).

²⁰³ *AB 1* supra note 155 at para 89.

²⁰⁴ 2016 (2) SA 27 (GP).

²⁰⁵ *AB 1* supra note 155 at para 74.

²⁰⁶ 2017 (3) SA 570 (CC).

²⁰⁷ *AB v Minister of Social Development (AB 2)* 2017 (3) SA 570 (CC) para 261.

*Proprietary Limited v President of the Republic of South Africa*²⁰⁸ held that ‘when the right to self-autonomy is infringed, the right to dignity is compromised’.²⁰⁹ Although incorrectly referring to self-autonomy as a ‘right’, it does show the link between autonomy and dignity.

In the recent case of *Qwelane v South African Human Rights Commission (Qwelane)*,²¹⁰ the Constitutional Court referred to Chaskalson, who stated that ‘in a broad and general sense, respect for dignity implies respect for the autonomy of each person’.²¹¹ Here, dignity *implies* respect for autonomy more broadly. From the above, it is clear that autonomy is a crucial aspect of human dignity. Autonomy protects human dignity and worth by allowing individuals to exercise self-determination and control over their own lives. Therefore, I suggest that autonomy does indeed form part of dignity.

(ii) *Autonomy and freedom*

Section 1 of the Constitution provides that South Africa is founded on the values of inter alia ‘[h]uman dignity, the achievement of equality and the advancement of human rights and *freedoms*’ (own emphasis).²¹² Furthermore, section 7(1) of the Constitution states that the Bill of Rights ‘enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and *freedom*’ (own emphasis).²¹³ Section 12(1) of the Constitution also grants all individuals the right to freedom and security of the person.²¹⁴

As mentioned above, the concepts of autonomy and freedom are often seen to overlap. Although initially implicit, it has now been widely accepted that a central aspect of autonomy is freedom. In *S v Jordan*,²¹⁵ while the Constitutional Court did not posit an independent right to autonomy – as argued for by the applicants – its omission regarding the relationship between autonomy and the rights to human dignity, freedom, and privacy can be seen to implicitly confirm this.²¹⁶ However, the view that autonomy underlies human dignity, freedom, and privacy was made explicit in *NM v Smith*,²¹⁷ where O’Regan J held that ‘[u]nderlying all these

²⁰⁸ [2022] 3 All SA 514 (WCC).

²⁰⁹ *South African Breweries Proprietary Limited v President of the Republic of South Africa* [2022] 3 All SA 514 (WCC) para 409.

²¹⁰ 2021 (6) SA 579 (CC).

²¹¹ Arthur Chaskalson ‘Human dignity as a foundational value of our constitutional order’ (2000) 16 *SAJHR* 203. This was cited in *Qwelane* supra note 178 at para 65.

²¹² Section 1(a) of the Constitution.

²¹³ Section 7(1) of the Constitution.

²¹⁴ Section 12(1) of the Constitution.

²¹⁵ *Sex Workers Education and Advocacy Task Force as Amici Curiae* 2002 (6) SA 642 (CC).

²¹⁶ *Jordaan* op cit note 9 at 6.

²¹⁷ 2007 (5) SA 250 (CC).

constitutional rights [human dignity, freedom, and privacy] is the constitutional celebration of the possibility of morally autonomous human beings independently able to form opinions and act on them'.²¹⁸ In *NM v Smith*, freedom of expression was seen as 'asserting the moral autonomy of individuals',²¹⁹ which showed the connection between freedom of expression and inter alia freedom. If freedom of expression affirms autonomy, and given that freedom of expression links to freedom, then it follows that there is a connection between freedom and autonomy. Following this, *Barkhuizen*,²²⁰ confirmed that autonomy is part of freedom when it held that autonomy 'the very essence of *freedom* and a vital part of dignity' (own emphasis).²²¹ Similarly, in *Pillay*²²² the Constitutional Court held that an 'entitlement to respect for the unique set of ends that the individual pursues' is a 'necessary element of freedom...'²²³ Therefore, from the above case law, it is clear that freedom is a constitutional right that forms part of the value of autonomy.

However, it is not just the recognition of freedom as part of autonomy that has been considered by the courts, but also the balancing of protecting individual autonomy and recognising interdependence in achieving freedom. Along these lines, the Constitutional Court, in *Ferreira*,²²⁴ held that:

'The reality is that meaningful personal interventions and abstinences in modern society depend not only on the state refraining from interfering with individual choice, but on the state helping to create conditions within which individuals can effectively make such choices. Freedom and personal security are thus achieved both by protecting human autonomy on the one hand, and by acknowledging human interdependence on the other. The interdependence is not a limitation on freedom, but an element of it. It follows that the definition of freedom requires not the exclusion of inter-dependence, but its embodiment, bearing in mind that such incorporation should be accomplished in a manner which reinforces rather than undermines autonomy and upholds rather than reduces the value of maximising effective personal choice'.²²⁵

²¹⁸ *NM v Smith* supra note 158 at para 145.

²¹⁹ *NM v Smith* supra note 158 at paras 145–6. This was also cited with approval in the High Court case of *AB I* supra note 155 at paras 65–6, as well as being quoted by the Supreme Court of Appeal (SCA) in *British American Tobacco South Africa (Pty) Ltd v Minister of Health* supra note 158 at para 13.

²²⁰ 2007 (5) SA 323 (CC).

²²¹ *Barkhuizen* supra note 155 at para 57; *Pillay* supra note 200 at para 64.

²²² 2008 (1) SA 474 (CC).

²²³ *Pillay* supra note 200 at para 64.

²²⁴ 1996 (1) SA 984 (CC).

²²⁵ *Ferreira* supra note 15 at para 251.

In *Bernstein v Bester NO (Bernstein)*,²²⁶ it was held that the democratic society envisioned by the Constitution does not define freedom as meaning that any invasion on an individual's ability to act is automatically a violation of their constitutional freedom.²²⁷ This overlooks the reality that individuals exist within a society and rely on one another. The idea of freedom in the Constitution must acknowledge this interdependence while valuing individual autonomy. It should recognise the essential role of the state and others in promoting individual autonomy and the enjoyment of rights and freedoms.²²⁸

The relationship between autonomy and freedom is clear from South African jurisprudence. While autonomy is closely linked to freedom, the courts have emphasised that freedom involves not just individual choice, but also the recognition of interdependence between individuals in society. This interdependence enriches the concept of freedom, highlighting the role of the state in fostering conditions that allow individuals to make meaningful choices.

(iii) Autonomy and the right to bodily and psychological integrity

Individuals have the right to make decisions about their own bodies without unnecessary interference from others.²²⁹ Section 12 of the Constitution deals with freedom and security of the person. Section 12(2) of the Constitution states that:

- ‘(2) Everyone has the right to bodily and psychological integrity, which includes the right—
- (a) to make decisions concerning reproduction;
 - (b) to security in and control over their body; and
 - (c) not to be subjected to medical or scientific experiments without their informed consent’.²³⁰

Of relevance is the right to bodily and psychological integrity which, like dignity, has been seen as forming part of autonomy. The law has always emphasised the importance of safeguarding bodily and psychological integrity, a principle now strengthened by constitutional

²²⁶ 1996 (2) SA 751 (CC).

²²⁷ *Bernstein* supra note 155 at para 150.

²²⁸ *Bernstein* supra note 155 at para 150 This was also questioned in *Coetzee v Government of the Republic of South Africa, Matiso v Commanding Officer Port Elizabeth Prison* 1995 (4) SA 631 (CC) para 44.

²²⁹ Nienaber and Bailey refer to this as the right to ‘physical integrity’. A Nienaber & KN Bailey ‘The right to physical integrity and informed refusal: Just how far does a patient’s right to refuse medical treatment go?’ (2016) 9(2) *SAJBL* 74.

²³⁰ Section 12(2) of the Constitution.

protections.²³¹ Section 12(2)(b) of the Constitution, relating to the right to bodily and psychological integrity, consists of two elements: ‘security in’, and ‘control over’, one’s body.²³² The former represents protecting bodily integrity against external intrusions, whilst the latter indicates the protection of ‘bodily autonomy or self-determination against interference’.²³³ It forms part of the right to be left alone in having the freedom to live as one chooses.²³⁴ The courts have recognised that bodily *and* psychological integrity are two distinct concepts.²³⁵ Bodily integrity is the right of each individual to have control over their own body, including the ability to make decisions autonomously.²³⁶ Violations of psychological integrity are more subjective given that individuals may have differing mental and emotional responses.²³⁷

The Court, in *British American Tobacco South Africa (Pty) Ltd v Minister of Co-operative Governance and Traditional Affairs (British American Tobacco)*,²³⁸ held that the right to bodily and psychological integrity – which includes the right to security in, and control over, one’s body – is the right of individuals ‘to make autonomous decisions regarding how they want to maintain their bodily and psychological integrity’.²³⁹

The right to bodily and psychological integrity has also featured in case law dealing with medical information and records. In *NM v Smith*,²⁴⁰ it was held that:

‘Private and confidential medical information contains highly sensitive and personal information about individuals. The personal and intimate nature of an individual’s health information, unlike other forms of documentation, reflects delicate decisions and choices relating to issues pertaining to bodily and psychological integrity and personal autonomy’.²⁴¹

The distinction between bodily and psychological integrity and autonomy indicates that the Court views these concepts as separate. However, it goes without saying that autonomy and

²³¹ *AB 2* supra note 207 at para 66.

²³² The right to security in one’s body prohibits undesirable interference of bodily integrity (such as forced medical treatment), while the right to control over one’s body refers to the ability to make independent and autonomous decisions concerning one’s body. Nienaber & Bailey op cit note 229 at 74.

²³³ Iain Currie & Johan De Waal *The Bill of Rights Handbook* 6 ed (2013) 287.

²³⁴ *Ibid* at 287.

²³⁵ *AB 2* supra note 207 at para 81.

²³⁶ Nienaber & Bailey op cit note 229 at 74; CRIN ‘Bodily integrity’ 2018 available at <https://archive.crin.org/en/home/what-we-do/policy/bodily-integrity.html>, accessed on 14 April 2021.

²³⁷ *AB 2* supra note 207 at para 82.

²³⁸ 2021 (7) BCLR 735 (WCC).

²³⁹ *British American Tobacco South Africa (Pty) Ltd v Minister of Co-operative Governance and Traditional Affairs* 2021 (7) BCLR 735 (WCC) para 145.

²⁴⁰ 2007 (5) SA 250 (CC) para 40.

²⁴¹ *NM v Smith* supra note 158 at para 40.

bodily and psychological integrity are linked. Exercising the right to bodily and psychological integrity is an act of autonomy.

To add to this, the Constitutional Court held that section 12(2) of the Constitution should be understood generously to cover all occasions where an individual's bodily or psychological integrity is harmed.²⁴² Such violations may appear in various forms, but should be considered under the broader concept of 'freedom and security of the person'.²⁴³ Given this, if freedom is central to autonomy and if infringements of bodily and psychological integrity should be interpreted within *freedom* and security of the person, then it follows that autonomy has a bearing on the right to bodily and psychological integrity.

It has also been recognised that part of the right to bodily and psychological integrity in the Constitution includes the right not to be subjected to medical or scientific experiments without informed consent.²⁴⁴ Because one of the reasons for the existence of informed consent is the promotion of autonomy,²⁴⁵ one of the underlying values that the right to bodily and psychological integrity can be seen to serve is autonomy.

(iv) *Autonomy and privacy*

Chapter 5 deals with privacy and it would therefore be imprudent to discuss the link between autonomy and privacy in depth in this Chapter. Therefore, this sub-heading briefly considers the link between autonomy and privacy. Section 14 of the Constitution grants individuals the right to privacy:

'Everyone has the right to privacy, which includes the right not to have –

- (a) their person or home searched;
- (b) their property searched;
- (c) their possessions seized; or
- (d) the privacy of their communications infringed'.²⁴⁶

Like freedom (discussed above), privacy has often been seen as one of the constitutional rights which falls under the concept of autonomy.²⁴⁷ *National Coalition*²⁴⁸ confirmed that privacy acknowledges that individuals have a right to a 'sphere of private intimacy and autonomy'

²⁴² *AB 2* supra note 207 at para 66.

²⁴³ *AB 2* supra note 207 at para 66.

²⁴⁴ Section 12(2)(c) of the Constitution. This was recognised in *AB 2* supra note 207 at para 66.

²⁴⁵ Basil Varkey 'Principles of clinical ethics and their application to practice' (2021) 30 *Med Princ Pract* 17.

²⁴⁶ Section 14 of the Constitution.

²⁴⁷ *S v Jordan* supra note 155; *NM v Smith* supra note 158 at para 145.

²⁴⁸ 1999 (1) SA 6 (CC).

where they can develop and maintain relationships without external interference.²⁴⁹ However, privacy has been closely linked to identity and it is contended that the right to privacy is based on what is essential for an individual to maintain their own autonomous identity and not on the idea of the unencumbered self.²⁵⁰ As such, in *National Coalition*²⁵¹ it was held that:

‘[A]utonomy must mean far more than the right to occupy an envelope of space in which a socially detached individual can act freely from interference by the state. What is crucial is the nature of the activity, not its site. While recognising the unique worth of each person, the Constitution does not presuppose that a holder of rights is as an isolated, lonely and abstract figure possessing a disembodied and socially disconnected self. It acknowledges that people live in their bodies, their communities, their cultures, their places and their times’.²⁵²

The right to privacy is essential for individuals to cultivate their autonomy and develop meaningful relationships without outside interference. However, privacy is not merely about having personal space, but is integral to maintaining one’s identity and autonomy within the context of community. Ultimately, privacy supports a deeper understanding of autonomy that acknowledges the interconnectedness of individuals in society.

(c) *The meaning of autonomy based on South African case law*

What makes determining the meaning of autonomy profoundly more challenging is that it does not have a set definition, and its meaning varies depending on context and circumstances. Furthermore, autonomy contains a subjective component, making the bestowing of a universal and objective definition problematic.

Barkhuizen explicitly recognised ‘self-autonomy’²⁵³ as ‘the ability to regulate one’s own affairs, even to one’s own detriment’.²⁵⁴ This definition shows that autonomy links to personal self-determination or individual freedom.²⁵⁵ Ngcobo J also made reference to the judgment of the Supreme Court of Appeal,²⁵⁶ which highlighted dignity and autonomy, which ‘find expression in the liberty to regulate one’s life by freely engag[ing] [in] contractual arrangements’.²⁵⁷

²⁴⁹ *National Coalition* supra note 156 at para 32.

²⁵⁰ *Bernstein* supra note 155 at para 65. This was also cited in *National Coalition* supra note 156 at para 117.

²⁵¹ 1999 (1) SA 6 (CC).

²⁵² *National Coalition* supra note 156 at para 117.

²⁵³ *Thaldar & Steytler* op cit note 160 at 273.

²⁵⁴ 2007 (5) SA 323 (CC) para 57.

²⁵⁵ *Jordaan* op cit note 9 at 7.

²⁵⁶ *Barkhuizen* supra note 155 at para 12.

²⁵⁷ *Napier v Barkhuizen* 2006 (4) SA 1 (SCA) para 12.

In line with Jordaan,²⁵⁸ O'Regan J in *NM v Smith*²⁵⁹ offers two explanations of autonomy. Firstly, O'Regan J held that 'the constitutional conception of being a human being asserts and seeks to foster the possibility of human beings choosing how to live their lives within the overall framework of a broader community'.²⁶⁰ This protection of autonomy stems from the acknowledgment of 'individual human worth'.²⁶¹ The first part of this definition ('human beings choosing how to live their lives') is comparable to the *Barkhuizen*²⁶² definition, while the second part of the definition ('within the overall framework of a broader community') embeds autonomy in a broader social context.²⁶³ The first definition in *NM v Smith*²⁶⁴ explicitly endorses the socially integrated nature of autonomy – important to the interpretation and application of autonomy. Further, such a socially integrated conception of autonomy is reconcilable with *Barkhuizen*,²⁶⁵ which deals with autonomy in the socially interdependent context of contractual relations.²⁶⁶

In *NM v Smith*,²⁶⁷ it was held by O'Regan J in her dissenting opinion that allowing individuals to develop through forming and sharing opinions enhances human dignity and autonomy (in relation to freedom of expression). Autonomy was made explicit as a constitutional value underlying human dignity, freedom, and privacy.²⁶⁸ This was also cited with approval in *AB I*.²⁶⁹

'Recognising the role of freedom of expression in asserting the moral autonomy of individuals demonstrates the close links between freedom of expression and other constitutional rights such as human dignity, privacy and freedom. Underlying all these constitutional rights is the constitutional celebration of the possibility of *morally autonomous human beings independently able to form opinions and act on them*' (my emphasis).²⁷⁰

Although there is mention of moral autonomy in the paragraph above, no description of its meaning is given leaving it open to interpretation. Following the first definition, the dissenting

²⁵⁸ Jordaan op cit note 9 at 7.

²⁵⁹ 2007 (5) SA 250 (CC).

²⁶⁰ *NM v Smith* supra note 158 at para 131.

²⁶¹ Ibid at para 131.

²⁶² 2007 (5) SA 323 (CC).

²⁶³ Jordaan op cit note 9 at 7.

²⁶⁴ 2007 (5) SA 250 (CC).

²⁶⁵ 2007 (5) SA 323 (CC).

²⁶⁶ Jordaan op cit note 9 at 9.

²⁶⁷ 2007 (5) SA 250 (CC).

²⁶⁸ Jordaan op cit note 9 at 6.

²⁶⁹ 2016 (2) SA 27 (GP) paras 65–6.

²⁷⁰ *NM v Smith* supra note 158 at para 145.

opinion of O'Regan J in *NM v Smith*,²⁷¹ also defines autonomy through a quote from Scanlon, which states that an autonomous individual:²⁷²

“...cannot accept without independent consideration the judgment of others as to what he should believe or what he should do. He may rely on the judgment of others, but when he does so he must be prepared to advance independent reasons for thinking their judgment likely to be correct, and to weigh the evidential value of their opinion against contrary evidence”.²⁷³

Our Constitution seeks to assert and promote the autonomy of individuals in the sense contemplated by Scanlon’.²⁷⁴

The second definition in *NM v Smith*²⁷⁵ (the Scanlon quote) departs from the definition in *Barkhuizen*²⁷⁶ as it allows an autonomous individual to ‘rely on the judgment of others’,²⁷⁷ but they *must* ‘be prepared to advance independent reasons for thinking their judgment likely to be correct’.²⁷⁸ However, many individual values rarely form the subject of rational evaluation. From a liberal viewpoint, an individual must be able to question obtained knowledge and make a decision, as stated in the definition in *Barkhuizen*.²⁷⁹ The ability to regulate one’s own affairs (or choose one’s own life) suggests that an individual may make decisions without having to rationalise them – meaning that an individual does *not* need to possess rational awareness in such regulation (or choice). While useful, O'Regan J did not necessarily have the technical meaning of moral autonomy in philosophy in mind when speaking of ‘morally autonomous human beings’.²⁸⁰

In her dissenting judgment in *Pillay*,²⁸¹ O'Regan J held that human dignity emphasises ‘the equal moral worth of human beings and the right of each and every person to choose to live the life that is meaningful to them’.²⁸² Although referring to human dignity, mention of moral worth and choices makes this quote relevant to autonomy. Though in *NM v Smith*,²⁸³ O'Regan J recognised that ‘although human beings live in a community and are in a real sense

²⁷¹ 2007 (5) SA 250 (CC).

²⁷² *NM v Smith* supra note 158 at para 145.

²⁷³ Scanlon ‘A theory of freedom of expression’ (1972) 1 *Philosophy and Public Affairs* 216 cited in *NM v Smith* supra note 158 at para 145.

²⁷⁴ *NM v Smith* supra note 158 at para 146.

²⁷⁵ 2007 (5) SA 250 (CC).

²⁷⁶ 2007 (5) SA 323 (CC).

²⁷⁷ *NM v Smith* supra note 158 at para 145.

²⁷⁸ *Ibid* at para 145.

²⁷⁹ 2007 (5) SA 323 (CC).

²⁸⁰ *NM v Smith* supra note 158 at para 145.

²⁸¹ 2008 (1) SA 474 (CC).

²⁸² *Pillay* supra note 200 at para 150.

²⁸³ 2007 (5) SA 250 (CC).

both constituted by and constitutive of that community’,²⁸⁴ there is an entitlement to a ‘personal sphere’ in which individuals follow their own ends and interests in ways that suit them – and is vital in making life meaningful.²⁸⁵ The term ‘meaningful’ in this quote implies that one does not need rational evaluation because it entails that which has meaning to an individual, which is subjective, and therefore in line with *Barkhuizen*²⁸⁶ and the first definition in *NM v Smith*.²⁸⁷

In *National Coalition*,²⁸⁸ it was held that, at a minimum, dignity necessitates acknowledging ‘the value and worth of all individuals as members of our society’.²⁸⁹ Furthermore, *Teddy Bear Clinic for Abused Children v Minister of Justice and Constitutional Development (Teddy Bear Clinic)*,²⁹⁰ referred to dignity and held that ‘dignity recognises the inherent worth of all individuals (including children) as members of our society, as well as the value of the choices that they make’.²⁹¹ The reference to ‘value and worth’ was utilised in *Pillay*,²⁹² as well as *Stransham-Ford v Minister of Justice and Correctional Services (Stransham-Ford I)*.²⁹³ This was repeated by the Constitutional Court in *AB 2*.²⁹⁴ It is clear that dignity links to the idea of moral worth, and because it is argued that the moral worth (and dignity) of humans stems from our capacity for autonomous choice, moral worth shares links with autonomy. Dignity was developed based on an individual’s capacity for reason.²⁹⁵ Therefore, treating an individual with dignity shows respect for their capacity for autonomous choice. Additionally, the inclusion of ‘as members of society’ in the definition of dignity,²⁹⁶ that has been repeatedly used by South African courts, places individuals in a broader social context, as per the second part of the definition in *NM v Smith*.²⁹⁷

²⁸⁴ *NM v Smith* supra note 158 at para 130.

²⁸⁵ *Ibid* at para 130.

²⁸⁶ 2007 (5) SA 323 (CC).

²⁸⁷ 2007 (5) SA 250 (CC).

²⁸⁸ 1999 (1) SA 6 (CC).

²⁸⁹ *National Coalition* supra note 156 at para 28.

²⁹⁰ 2014 (2) SA 168 (CC).

²⁹¹ *Teddy Bear Clinic for Abused Children v Minister of Justice and Constitutional Development (Teddy Bear Clinic)* 2014 (2) SA 168 (CC) para 52 cited in *AB 1* supra note 155 at para 89.

²⁹² 2008 (1) SA 474 (CC) para 150.

²⁹³ 2015 (4) SA 50 (GP) para 12.

²⁹⁴ 2017 (3) SA 570 (CC) para 108.

²⁹⁵ McCrudden op cit note 175 at 659.

²⁹⁶ *National Coalition* supra note 156 at para 28; *Teddy Bear Clinic* supra note 291 at para 52; *Bhe v Magistrate, Khayelitsha (Commission for Gender Equality as Amicus Curiae)*; *Shibi v Sithole*; *South African Human Rights Commission v President of the Republic of South Africa* 2005 (1) SA 580 (CC) para 163; *Pillay* supra note 200 at para 53.

²⁹⁷ 2007 (5) SA 250 (CC) para 131.

Constitutional rights and values, such as freedom and dignity, have been defined as referring to the ‘worth’ of individuals.²⁹⁸ In *NM v Smith*,²⁹⁹ O’Regan J made a link between autonomy and the broad definition of human dignity as ‘inherent worth’, asserting that the protection of autonomy ‘flows from our recognition of individual human worth’.³⁰⁰ *National Coalition*³⁰¹ defined autonomy and referred to the ‘unique worth of each person’,³⁰² showing that the term ‘worth’ is not just applicable to dignity and freedom, but also to autonomy.

Personal autonomy is specifically mentioned in *Stransham-Ford I*,³⁰³ and, in the context, it is clear that it refers to the responsibility of individuals in terms of their lives.³⁰⁴ The term ‘responsibility’ links to *NM v Smith*.³⁰⁵ In *Stransham-Ford I*,³⁰⁶ Fabricius J goes on to say that the choice of a patient must be in line with an open and democratic society and the values expressed in the Bill of Rights.³⁰⁷

Autonomy was further developed in the case of *AB I*.³⁰⁸ Based on *Barkhuizen*³⁰⁹ and *NM v Smith*,³¹⁰ Basson J concluded that autonomy denotes ‘the ability to independently form opinions and act on them’.³¹¹ An important turning point came in the Constitutional Court case of *AB 2*,³¹² where the minority referred to Dworkin’s *The Theory and Practice of Autonomy* in holding that autonomy possesses numerous conceptions, comprising ‘a tangled net of

²⁹⁸ In *NM v Smith* supra note 158 at para 131, it was held that protecting the autonomy of individuals in choosing how to live their lives ‘flows from our recognition of individual human worth’. Moreover, *Pillay* supra note 200 at para 150 held that human dignity asserts the ‘equal moral worth of human beings’.

²⁹⁹ 2007 (5) SA 250 (CC).

³⁰⁰ *NM v Smith* supra note 158 at para 131.

³⁰¹ 1999 (1) SA 6 (CC).

³⁰² *National Coalition* supra note 156 at para 117 (concurring opinion of Sachs J).

³⁰³ 2015 (4) SA 50 (GP).

³⁰⁴ *Stransham-Ford v Minister of Justice and Correctional Services (Stransham-Ford I)* 2015 (4) SA 50 (GP) para 14 held that ‘Another aspect is that of personal autonomy. The irony is, they say, that we are told from childhood to take responsibility for our lives but when faced with death we are told we may not be responsible for our own passing. There are many other ironic considerations in this context. One can choose one’s education, one’s career, one can decide to get married, one can live according to a lifestyle of one’s choice, one can consent to medical treatment or one can refuse it, one can have children and one can abort children, one can practice birth control, and one can die on the battlefield for one’s country. But one cannot decide how to die. In this context the Commission says, and I agree with it, that belief or moral doubts of third parties is not the main point in this context at all. The choice of a patient such as the present, is consistent with an open and democratic society and its values and norms as expressed in the Bill of Rights. There is of course no duty to live, and a person can waive his right to life’.

³⁰⁵ 2007 (5) SA 250 (CC) para 131.

³⁰⁶ 2015 (4) SA 50 (GP).

³⁰⁷ *Stransham-Ford I* supra note 304 at para 14.

³⁰⁸ *As Amicus Curiae: Centre for Child Law* 2016 (2) SA 27 (GP).

³⁰⁹ 2007 (5) SA 323 (CC) para 57.

³¹⁰ 2007 (5) SA 250 (CC) para 145.

³¹¹ *AB I* supra note 155 at paras 65–6.

³¹² 2017 (3) SA 570 (CC).

intuitions, conceptual and empirical issues, and normative claims’.³¹³ Thereafter, the Constitutional Court referred to the *relational* character of autonomy, that ‘to be autonomous is to be socially and politically connected, rather than an agent of unfettered individual choice’.³¹⁴ This is emphasised by its approval of Ubuntu. Instead of explicitly adopting a relational account of autonomy, the Constitutional Court in *AB 2*,³¹⁵ recognised the relational nature of autonomy, and instead placed reliance on Ubuntu – a separate but similar concept – to emphasise the socially integrated nature of autonomy.

In *AB 2*,³¹⁶ the court also referred to *Pillay*,³¹⁷ where Langa CJ held that ‘an individual human person cannot develop and achieve the fullness of his/her potential without the concrete act of relating to other individual persons’.³¹⁸ Thus, the Constitutional Court recognised that ‘autonomy is a necessary, but socially embedded part of the value of freedom’.³¹⁹ More recently, and adding to this, in *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service*,³²⁰ the majority of the Constitutional Court held that:

‘Individual autonomy and the rights associated with it are important aspects of human development in the modern world...At the same time, and beyond the demands of individual autonomy, the legitimate communal interests and the rights of others must moderate the outer bounds of individual autonomy’.³²¹

This shows that there is room for both individual autonomy and communal interests. While individual autonomy is important, communal interests and the rights of others must keep a check on individual autonomy. I suggest that the crux of determining what autonomy means in South African case law may be found in *AB 2*,³²² where the Constitutional Court used Ubuntu to create a unique South African version of its own form of relational autonomy that is tailored to the country’s cultures and contexts.

³¹³ Dworkin op cit note 22 at 7 cited in *AB 2* supra note 207 at para 51.

³¹⁴ *AB 2* supra note 207 at para 51.

³¹⁵ 2017 (3) SA 570 (CC).

³¹⁶ 2017 (3) SA 570 (CC).

³¹⁷ 2008 (1) SA 474 (CC).

³¹⁸ *Pillay* supra note 200 at para 53.

³¹⁹ In *AB 2* supra note 207 at para 52, it was held that the value of freedom accepts the ability of individuals to ‘understand and act on their own desires and beliefs’. It acknowledges the ‘inherent worth of our capacity to assess our own socially-rooted situations, and make decisions on this basis’. This capacity is seen to give life meaning and allows individuals to take responsibility for who they are, thus improving the community. Thus, freedom is seen to involve understanding and not just making decisions for personal reasons. Assessing one’s own situations and making decisions accordingly implies an underlying consideration for others – showing a move away from the individual to the community. An aptitude to understand means that understanding is necessary.

³²⁰ 2023 (5) SA 319 (CC).

³²¹ *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service* 2023 (5) SA 319 (CC) para 124.

³²² 2017 (3) SA 570 (CC).

In addition, and from an analysis of the case law above, it is clear that autonomy implies a choice.³²³ As stated in *Pillay*,³²⁴ voluntary choice improves the importance of a practice to inter alia autonomy.³²⁵ Additionally, *Volks NO v Robinson*³²⁶ held that respect for autonomy means that the law must recognise and uphold the choices that individuals make.³²⁷ In *Minister of Justice and Correctional Services v Estate Late James Stransham-Ford (Stransham-Ford 2)*,³²⁸ refusing life-prolonging treatment was recognised as a *constitutionally* protected facet of personal autonomy.³²⁹ Such a refusal also implies a choice on the part of the individual. In *AB 1*,³³⁰ Basson J stated that ‘commissioning parent(s) who make the decision to use donor gametes towards the conception of a prospective child for whatever personal reasons are exercising their autonomy’.³³¹ This implies two things: (1) autonomy involves a decision; and (2) autonomy entails any personal reasons for that choice. The use of the term ‘whatever personal reasons’ implies that such reasons are personal to individuals, and they are neither required to give reasons for their choice, nor are they limited to certain reasons within a given context. In the more recent case of *Centre for Child Law v Media 24 Limited*,³³² the Court referred to *NM v Smith* and emphasised the significance of inter alia autonomy – especially given social media, where the instant and broad dissemination of information gives importance to disclosure and the choice to disclose.³³³

It is also apparent that autonomy denotes some level of responsibility on the part of the individual,³³⁴ and often involves some type of ability or capacity.³³⁵ By using the word ‘ability’, the definition of autonomy in *Barkhuizen*³³⁶ suggests individual psychological capacity for

³²³ *Ferreira* supra note 15 at para 251; *Bernstein* supra note 155 at para 151; *NM v Smith* supra note 158 at para 131; *Pillay* supra note 200 at para 150; *AB 1* supra note 155 at para 89; *AB 2* supra note 207 at paras 21 & 51.

³²⁴ 2008 (1) SA 474 (CC).

³²⁵ *Pillay* supra note 200 at para 64.

³²⁶ 2005 (5) BCLR 446 (CC).

³²⁷ *Volks NO v Robinson* 2005 (5) BCLR 446 (CC) para 154. This was also cited in the recent case of *VJV v Minister of Social Development* supra note 180 at para 38.

³²⁸ 2017 (3) SA 152 (SCA).

³²⁹ *Minister of Justice and Correctional Services v Estate Late James Stransham-Ford (Stransham-Ford 2)* 2017 (3) SA 152 (SCA) para 31.

³³⁰ *As Amicus Curiae: Centre for Child Law* 2016 (2) SA 27 (GP).

³³¹ *AB 1* supra note 155 at para 89.

³³² 2020 (4) SA 319 (CC).

³³³ *Centre for Child Law v Media 24 Limited* 2020 (4) SA 319 (CC) para 86.

³³⁴ *Barkhuizen* supra note 155 at para 57; *NM v Smith* supra note 158 at para 131; *Stransham-Ford* supra note 304 at para 14; *AB 2* supra note 207 at para 52. The reference in *Barkhuizen* supra note 155 to ‘one’s own detriment’ implies a level of responsibility.

³³⁵ Besides the cases specifically referred to in this paragraph, various other cases have referred to an ability or capacity. See, *AB 2* supra note 207 at para 52; *Bernstein* supra note 155 at para 150.

³³⁶ 2007 (5) SA 323 (CC) para 57.

self-determination.³³⁷ The meaning of autonomy in *NM v Smith*,³³⁸ and subsequently referred to in *AB 1*,³³⁹ mentions ‘human beings independently able’,³⁴⁰ which also suggests that some ability is required in order to be autonomous. In *Stransham-Ford 2*,³⁴¹ Wallis JA held that all that is required to exercise autonomy is that an individual must possess the mental and legal capacity necessary to make a decision.³⁴²

What is also clear from the case law above is that the courts in South Africa do not only view autonomy in an atomistic and individualistic manner. From as early as the *NM v Smith* judgment in 2007, autonomy was viewed as being socially integrated.³⁴³ While individual autonomy has been referred to, there is room for the community to come into play when making decisions. In line with *NM v Smith* and the reference to the quote by Scanlon,³⁴⁴ individuals can rely on the judgment of others when making decisions, but there will still be an element of individual reasoning when considering whether such judgment is correct. Therefore, there is recognition of an individual sphere where individuals are able to think for themselves and make their own decisions, but it is also clear that individuals exist in the broader context of the community, thus making autonomy *socially integrated*.³⁴⁵

(d) The socially integrated nature of autonomy

Autonomy’s socially integrated nature has come to play an integral role in the Court’s view of this concept.³⁴⁶ Some definitions also specifically mention the community and place autonomy in a social context. Although it has been mentioned in cases as early as *Ferreira*,³⁴⁷ which cited pursuing ‘individual and collective destinies’,³⁴⁸ it has only been given greater emphasis and due recognition in later years.

A focus on interdependence, and its links to autonomy (and freedom) in a more social context, are present in South African case law. There were attempts to separate autonomy and social interdependence so as to distinguish between freedom and autonomy, with the former

³³⁷ Jordaan op cit note 9 at 7.

³³⁸ 2007 (5) SA 250 (CC).

³³⁹ 2016 (2) SA 27 (GP) paras 65-66.

³⁴⁰ *NM v Smith* supra note 158 at para 145.

³⁴¹ 2017 (3) SA 152 (SCA).

³⁴² *Stransham-Ford 2* supra note 329 at para 32.

³⁴³ *NM v Smith* supra note 158 at para 131.

³⁴⁴ Scanlon op cit note 273 at 216 cited in *NM v Smith* supra note 158 at para 145.

³⁴⁵ See, *NM v Smith* supra note 158; *AB 2* supra note 207.

³⁴⁶ Jordaan op cit note 9 at 7.

³⁴⁷ 1996 (1) SA 984 (CC).

³⁴⁸ *Ferreira* supra note 15 at para 250.

being seen as ‘a socially integrated enabler of autonomy’.³⁴⁹ While freedom was viewed as ‘positive freedom’ (requiring state intervention), autonomy denoted ‘negative freedom’. Such an atomistic view of autonomy was illogical as it acknowledged ‘the socially dependent nature of at least the *development* of autonomy’.³⁵⁰ Since then, autonomy has been viewed as underlying ‘the very notion of human rights and *positive* freedom’ (own emphasis).³⁵¹ Therefore, individuals should be permitted to have the freedom to choose and act, rather than having freedom from interference. In *AB 2*,³⁵² the minority emphasised that the value of freedom ‘recognises the inherent worth of our capacity to assess our own socially-rooted situations, and make decisions on this basis’.³⁵³ Interdependence was first mentioned in *S v Makwanyane (Makwanyane)*,³⁵⁴ where Ubuntu was referred to as placing ‘emphasis on communality and on the interdependence of the members of a community’.³⁵⁵ This was also cited in *South African Police Service v Solidarity obo Barnard (Barnard)*³⁵⁶ and *Pillay*.³⁵⁷ However, *Pillay*³⁵⁸ added to this and also held that ‘every individual is an extension of others’.³⁵⁹ This was referred to in *Shoprite Checkers (Pty) Limited v Member of the Executive Council for Economic Development, Environmental Affairs and Tourism, Eastern Cape (Shoprite Checkers)*.³⁶⁰ Interdependence was mentioned by Sachs J in *Ferreira*,³⁶¹ and was endorsed by O’Regan J in *Bernstein*.³⁶²

‘Freedom and personal security are thus achieved both by protecting human autonomy on the one hand, and by acknowledging human interdependence on the other. The interdependence is not a limitation on freedom, but an element of it. It follows that the definition of freedom requires not the exclusion of interdependence, but its embodiment, bearing in mind that such incorporation should be accomplished in a manner which reinforces rather than undermines autonomy and upholds rather than reduces the value of maximising effective personal choice’.³⁶³

³⁴⁹ Jordaan op cit note 9 at 8.

³⁵⁰ Jordaan op cit note 9 at 8.

³⁵¹ *Centre for Child Law v Media 24 Limited* supra note 333 at para 84.

³⁵² 2017 (3) SA 570 (CC).

³⁵³ *AB 2* supra note 207 at para 52. This was also cited in *Centre for Child Law v Media 24 Limited* supra note 333 at para 84.

³⁵⁴ 1995 (3) SA 391.

³⁵⁵ *Makwanyane* supra note 182 at para 224.

³⁵⁶ 2014 (6) SA 123 (CC) para 174.

³⁵⁷ 2008 (1) SA 474 (CC) para 53.

³⁵⁸ 2008 (1) SA 474 (CC).

³⁵⁹ *Pillay* supra note 200 at para 53.

³⁶⁰ 2015 (6) SA 125 (CC) para 47.

³⁶¹ *Bernstein* supra note 155 at para 151.

³⁶² 1996 (2) SA 751 (CC).

³⁶³ *Ferreira* supra note 15 at para 251.

In *Bernstein*,³⁶⁴ O'Regan J, writing for the minority, held that 'any invasion of the capacity of an individual to act' does not necessarily violate an individual's constitutional freedom.³⁶⁵ Such a conception of freedom overlooks the fact that individuals 'live within a society and are dependent upon one another'.³⁶⁶ A constitutional conception of freedom must 'embrace that interdependence without denying the value of individual autonomy'.³⁶⁷ Interdependence was also referred to in the case of *Soobramoney v Minister of Health (Kwazulu-Natal)*.³⁶⁸ In the minority judgment, Sachs J held that healthcare rights must 'be considered not only in a traditional legal context structured around the ideas of human autonomy but in a new analytical framework based on the notion of human interdependence'.³⁶⁹ The words 'not only' show that human autonomy as well as human interdependence must be considered – they are not mutually exclusive. *Affordable Medicines Trust v Minister of Health*³⁷⁰ held that:

'[W]e live in a modern and industrial world of human interdependence and mutual responsibility. Indeed we are caught in an inescapable network of mutuality. Provided it is in the public interest and not arbitrary or capricious, regulation of vocational activity for the protection both of the persons involved in it and of the community at large affected by it, is to be both expected and welcomed'.³⁷¹

Although occurring before *Barkhuizen*³⁷² and *NM v Smith*,³⁷³ *National Coalition*³⁷⁴ placed autonomy in a social, rather than an atomistic, context and rejected the 'independence-interdependence' distinction between autonomy and freedom:³⁷⁵

'[A]utonomy must mean far more than the right to occupy an envelope of space in which a socially detached individual can act freely from interference by the state... While recognising the unique worth of each person, the Constitution does not presuppose that a holder of rights is as an isolated, lonely and abstract figure possessing a disembodied and socially disconnected self. It acknowledges that people live in their bodies, their communities, their cultures, their places and their times'.³⁷⁶

³⁶⁴ 1996 (2) SA 751 (CC).

³⁶⁵ *Bernstein* supra note 155 at para 150.

³⁶⁶ *Ibid* at para 150.

³⁶⁷ *Ibid* at para 150.

³⁶⁸ 1998 (1) SA 765 (CC).

³⁶⁹ *Soobramoney v Minister of Health (Kwazulu-Natal)* 1998 (1) SA 765 (CC) para 54.

³⁷⁰ 2006 (3) SA 247 (CC).

³⁷¹ *Affordable Medicines Trust v Minister of Health* 2006 (3) SA 247 (CC) para 60. This was also cited in *Minister of Health v New Clicks South Africa (Pty) Ltd* 2006 (2) SA 311 (CC) para 659.

³⁷² 2007 (5) SA 323 (CC).

³⁷³ 2007 (5) SA 250 (CC).

³⁷⁴ 1999 (1) SA 6 (CC).

³⁷⁵ *Jordaan* op cit note 9 at 8.

³⁷⁶ *National Coalition* supra note 156 at para 117 (concurring opinion of Sachs J).

This socially integrated conception of autonomy does not indicate that ‘dominant social values’ limit autonomy any more than an atomistic conception; what is different is that a socially integrated conception of autonomy recognises that positive state actions are necessary to enable autonomy in its social context.³⁷⁷ In encouraging a society in which individuals are able to exercise their fundamental rights and freedoms, O’Regan J in *Bernstein*³⁷⁸ agreed with Sachs J’s statement in *Ferreira*³⁷⁹ that the state must not only refrain from interfering with individual choice, but must also assist in establishing conditions that allow individuals to make such choices – thus enhancing autonomy.³⁸⁰

Due to Africa’s focus on communitarianism, there is a need to move away from viewing autonomy in an atomistic manner. Thus, there has been a departure from Kant’s construction of dignity as the moral worth of individuals based on their capacity for reason. In line with this, the Court in *Barnard*³⁸¹ held that:

‘An atomistic approach to individuals, self-worth and identity is not appropriate. This Court has recognised that we are not islands unto ourselves. The individual, as the bearer of the right to dignity, should not be understood as an isolated and unencumbered being. Dignity contains individualistic as well as collective impulses. Its collectivist attributes, including that we are “social beings whose humanity is expressed through...relationships with others” find resonance in the South African idea of Ubuntu, which foregrounds “interdependence of the members of a community”’.³⁸²

The fact that relational autonomy is viewed in a social context does not mean that autonomy is only subject to the collective as it still recognises the individual. Reference to the phrase ‘no man is an island’³⁸³ has been used in terms of relational autonomy. It explains that individuals are not inherently self-sufficient and do not thrive when isolated from others; they need to be part of a community.³⁸⁴ Individuals function in a system of relationships with family, society, cultural, and group affiliations – which impact decision-making.³⁸⁵ There has been a shift away from individual autonomy to relational autonomy, suggesting that individuals are not solitary,

³⁷⁷ Jordaan op cit note 9 at 8.

³⁷⁸ 1996 (2) SA 751 (CC).

³⁷⁹ *Bernstein* supra note 155 at para 151.

³⁸⁰ *Ferreira* supra note 15 at para 251.

³⁸¹ 2014 (6) SA 123 (CC).

³⁸² *South African Police Service v Solidarity obo Barnard (Barnard)* 2014 (6) SA 123 (CC) para 174.

³⁸³ This phrase initially appeared in John Donne *Devotions Upon Emergent Occasions and Seuerall Steps in my Sicknes - Meditation XVII* (1624) and has since gained popularity.

³⁸⁴ Grammarist ‘No man is an island’ available at <https://grammarist.com/phrase/no-man-is-an-island/>, accessed on 13 July 2020.

³⁸⁵ Ian Pieper ‘Considering relational autonomy’ 1.

but exist within a network of relationships.³⁸⁶ South African courts have referred to a derivation of the term ‘no man is an island’ when discussing Ubuntu. In *Port Elizabeth Municipality v Various Occupiers*,³⁸⁷ Sachs J held that:

‘The Constitution and PIE confirm that we are not islands unto ourselves. The spirit of ubuntu, part of the deep cultural heritage of the majority of the population, suffuses the whole constitutional order. It combines individual rights with a communitarian philosophy. It is a unifying motif of the Bill of Rights, which is nothing if not a structured, institutionalised and operational declaration in our evolving new society of the need for human interdependence, respect and concern’.³⁸⁸

South African courts have referred to a derivation of the term ‘no man is an island’ when discussing Ubuntu.³⁸⁹ While this has been reaffirmed in several cases,³⁹⁰ Pillay³⁹¹ specifically mentioned that ‘we are not islands unto ourselves’,³⁹² and proceeded to explain the concept and its meaning in the South African context. Langa CJ, referring to the importance of cultural convictions or practices, made reference to Ubuntu (discussed in more detail below) – commonly expressed as *umuntu ngumuntu ngabantu* – which highlights ‘the inter-dependence of the members of a community’,³⁹³ and that each individual is an extension of others. According to Gyekye, ‘an individual human person cannot develop and achieve the fullness of his/her potential without the concrete act of relating to other individual persons’.³⁹⁴ There is an important link here: Relational autonomy has utilised the phrase ‘no man is an island’ and South African courts have held that ‘we are not islands unto ourselves’, specifically when referring to Ubuntu. Therefore, there is a common link that exists between these concepts, and

³⁸⁶ Ibid at 5.

³⁸⁷ 2005 (1) SA 217 (CC).

³⁸⁸ *Port Elizabeth Municipality v Various Occupiers* 2005 (1) SA 217 (CC) para 37.

³⁸⁹ These include *Union of Refugee Women v Director, Private Security Industry Regulatory Authority* 2007 (4) SA 395 (CC) para 145; *Molusi v Voges NO* 2016 (3) SA 370 (CC) para 40; *Shoprite Checkers (Pty) Limited v Member of the Executive Council for Economic Development, Environmental Affairs and Tourism, Eastern Cape (Shoprite Checkers)* 2015 (6) SA 125 (CC) para 47; *Barnard* supra note 382 at para 174; *City of Johannesburg Metropolitan Municipality v Blue Moonlight Properties 39 (Pty) Ltd* 2012 (2) SA 104 (CC) para 38; *Port Elizabeth Municipality v Various Occupiers* supra note 388 at para 37.

³⁹⁰ These include *Union of Refugee Women v Director, Private Security Industry Regulatory Authority* supra note 389 at para 145; *Molusi v Voges NO* supra note 389 at para 40; *Shoprite Checkers* supra note 389 at para 47; *Barnard* supra note 382 at para 174; *City of Johannesburg Metropolitan Municipality v Blue Moonlight Properties 39 (Pty) Ltd* supra note 389 at para 38.

³⁹¹ 2008 (1) SA 474 (CC).

³⁹² Pillay supra note 200 at para 53.

³⁹³ *Bhe v Magistrate, Khayelitsha (Commission for Gender Equality as Amicus Curiae)*; *Shibi v Sithole*; *South African Human Rights Commission v President of the Republic of South Africa* supra note 296 at para 163 cited in Pillay supra note 200 at para 53.

³⁹⁴ Gyekye op cit note 131 at 321.

it can be concluded that there is significant overlap between relational autonomy and Ubuntu – showing that this approach to autonomy may be in line with South African jurisprudence.

VII THE CONCEPT OF UBUNTU

As mentioned above, Ubuntu comes from the Nguni phrase *umuntu ngumuntu ngabantu*, which can be translated as ‘a person is a person through other persons’.³⁹⁵ Ubuntu ‘represents notions of universal human interdependence, solidarity and communalism which can be traced to small-scale communities in precolonial Africa, and which underlie virtually every indigenous African culture’.³⁹⁶ Ubuntu is a relational ethic that values harmonious relationships and emphasises community, caring, harmony, dignity, and unity.³⁹⁷ Ubuntu is based on the idea that because humans are inherently social creatures, humans require other humans in order to live a good life; hence, individuals in a community owe reciprocal obligations to each other aimed at achieving harmonious relations in society.³⁹⁸ Metz elaborates on Ubuntu as follows: ‘an action is right just insofar as it is a way of living harmoniously or prizing communal relationships, ones in which people identify with each other and exhibit solidarity with one another; otherwise, an action is wrong’.³⁹⁹

Ubuntu not only recognises the relational nature of individuals, but it also values and respects each person’s individuality. This mutual respect enables both personal growth and the flourishing of relationships within communities.⁴⁰⁰ This entails recognising and seeking to balance the interests of the community and the individual, rather than viewing one as more important than the other. However, it is important that, in understanding Ubuntu, communal relations are not over-emphasised at the expense of the individual – this is an inaccurate depiction of how Ubuntu is commonly understood. Although community is important, the value of the individual is recognised.⁴⁰¹ Ubuntu entails respecting individuality as this allows relationships where individuals, as well as communities, are able to thrive.⁴⁰² Thus, the

³⁹⁵ Thaddeus Metz ‘Ubuntu as a moral theory and human rights in South Africa’ (2011) 11(2) *Afr Hum Rights L J* 536; JY Mokgoro ‘Ubuntu and the law in South Africa’ (1998) 1(1) *PER/PELJ* 2.

³⁹⁶ Roederer & Moellendorf op cit note 7 at 441; ASSAf op cit note 7 at 25.

³⁹⁷ Behrens op cit note 118 at 34; ASSAf op cit note 7 at 25.

³⁹⁸ Shoji op cit note 8 at 44; Munyuka & Mothlabi op cit note 130 at 65.

³⁹⁹ Thaddeus Metz ‘African and Western moral theories in a bioethical context’ (2010) 10 *Developing World Bioeth* 51; Andoh op cit note 118 at 70.

⁴⁰⁰ Shoji op cit note 8 at 44.

⁴⁰¹ Ibid at 44.

⁴⁰² Ibid at 50.

individual, as well as the community, are given priority⁴⁰³ – and each have a duty to show Ubuntu to the other.⁴⁰⁴

There is much to be said about Ubuntu, especially in the African context and this concept has been discussed by academics as well as South African courts. While Ubuntu appears to be a simple concept – commonly known to mean ‘I am, because you are’ – its understanding and application seemingly go deeper. It is necessary to examine Ubuntu in relation to autonomy, especially given its centrality to the Constitution.

Ubuntu is a value in the Constitution and courts have interpreted and applied it in South African law, so it has developed in African philosophy. Although ‘difficult to define’,⁴⁰⁵ Ubuntu has featured in South African case law, beginning with *Makwanyane*.⁴⁰⁶ Although Ubuntu may point towards collectivism, it also recognises individual human rights. In *Makwanyane*,⁴⁰⁷ Langa J held that respect for the dignity of each individual is fundamental to Ubuntu, which views the life of another being ‘at least as valuable as one’s own’.⁴⁰⁸ Madala J stated that Ubuntu is a concept that ‘carries in it the ideas of humaneness, social justice and fairness’.⁴⁰⁹ Mokgoro J held that:⁴¹⁰

‘[U]buntu translates as *humaneness*...Metaphorically, it expresses itself in *umuntu ngumuntu ngabantu*, describing the significance of group solidarity on survival issues so central to the survival of communities. While it envelops the key values of group solidarity, compassion, respect, human dignity, conformity to basic norms and collective unity, in its fundamental sense it denotes humanity and morality. Its spirit emphasises respect for human dignity, marking a shift from confrontation to conciliation’.⁴¹¹

Ubuntu was also mentioned in *Dikoko v Mokhatla*.⁴¹² Mokgoro J held that human dignity is closely linked to Ubuntu, ‘an idea based on deep respect for the humanity of another’.⁴¹³ In

⁴⁰³ Ibid at 51.

⁴⁰⁴ Ibid at 51–2.

⁴⁰⁵ *Beadica 231 CC v Trustees for the time being of the Oregon Trust (Beadica)* 2020 (5) SA 247 (CC) para 213.

⁴⁰⁶ 1995 (3) SA 391.

⁴⁰⁷ 1995 (3) SA 391.

⁴⁰⁸ *Makwanyane* supra note 182 at para 225.

⁴⁰⁹ *Makwanyane* supra note 182 at para 237. This was repeated in the dissenting judgment of Victor AJ in *Beadica* supra note 405 at para 210.

⁴¹⁰ *Makwanyane* supra note 182 at para 308.

⁴¹¹ Ibid at para 308.

⁴¹² 2006 (6) SA 235 (CC).

⁴¹³ *Dikoko v Mokhatla* 2006 (6) SA 235 (CC) para 68.

Everfresh Market Virginia (Pty) Ltd v Shoprite Checkers (Pty) Ltd,⁴¹⁴ the Constitutional Court explained the meaning of Ubuntu, which:

‘[E]mphasises the communal nature of society and “carries in it the ideas of humaneness, social justice and fairness” and envelopes “the key values of group solidarity, compassion, respect, human dignity, conformity to basic norms and collective unity”’.⁴¹⁵

In the recent case of *Beadica 231 CC v Trustees for the time being of the Oregon Trust (Beadica)*,⁴¹⁶ Theron J, writing for the majority, held that Ubuntu, which is recognised as a constitutional value, includes the values of ‘fairness, reasonableness and justice’.⁴¹⁷

The fact that Ubuntu has featured in South African jurisprudence shows its position as a fundamental constitutional value. While reference to Ubuntu in case law has not always been explicit, its meaning can be gleaned from comparable terms and phrases. Although often not applied as a legal principle, Ubuntu acts as a value for interpreting and applying human rights.⁴¹⁸ In *Barnard*,⁴¹⁹ by interpreting rights through the lens of Ubuntu, the Constitutional Court recognised that autonomy should not be viewed in an overly individualistic manner.⁴²⁰ While Ubuntu may have a focus on the community, this does not impede the existence and protection of individual human rights.⁴²¹ In *AB 2*,⁴²² the Constitutional Court took cognisance of relational autonomy, but relied on Ubuntu to emphasise autonomy’s socially integrated nature. Ubuntu can therefore be seen as the foundation upon which a South African understanding of autonomy is built.

(a) *What is the difference between relational autonomy and Ubuntu?*

Ideas of interdependence in South African case law, and through the values of autonomy and Ubuntu, link to relational autonomy. Although relational autonomy and Ubuntu may seem similar in theory, and there are several areas of overlap, there are also important points that make the two concepts distinct from one another. As a brief excursus, it is necessary to clarify the difference between relational autonomy and Ubuntu.

⁴¹⁴ 2012 (1) SA 256 (CC).

⁴¹⁵ *Everfresh Market Virginia (Pty) Ltd v Shoprite Checkers (Pty) Ltd* 2012 (1) SA 256 (CC) para 71.

⁴¹⁶ 2020 (5) SA 247 (CC).

⁴¹⁷ *Beadica* supra note 405 at para 72.

⁴¹⁸ Shoji op cit note 8 at 53.

⁴¹⁹ 2014 (6) SA 123 (CC).

⁴²⁰ *Barnard* supra note 382 at para 174.

⁴²¹ Shoji op cit note 8 at 58.

⁴²² 2017 (3) SA 570 (CC).

A relational account of autonomy is an endeavour by scholars to respond to the logical incoherencies of absolute rights for individuals.⁴²³ Although there is a natural overlap between relational autonomy and African autonomy, relational autonomy has a particular goal and agenda, whereas African autonomy is a consequence rather than an agenda-driven theory.⁴²⁴ While relational autonomy follows an outcome-based approach, African autonomy focuses on the process of maintaining social relations by incorporating values such as mutual respect, interdependence, and trust. Whilst these values are shared between relational autonomy and African autonomy, the outcomes may not always be the same. For example, relational autonomy's agenda is to develop a theory of autonomy that makes sense for a certain context, and then determine how to modify it to suit the agenda. On the other hand, African autonomy considers what an individual is and, as a result, determines the concept of autonomy to be followed. In practice, there may be differences that arise because of those nuanced disparities. This is because the African perspective of autonomy is a value-driven process (values, views, and morals tied to those considerations which might influence how we rule certain exercises of autonomy as justifiable). For example, relational autonomy appears to require a scientific approach to determine under what circumstances the community can say that a particular exercise is a justifiable exercise of morality, whereas from the African perspective, it is tied less to an empirical determination of the communal will and more on a general understanding of communal values.⁴²⁵

Given the existence of relational autonomy, there has been a debate regarding whether African philosophy is a worthwhile intellectual endeavour that adds anything new.⁴²⁶ However, these are articulated on the basis of Western principles even though they may overlap with African autonomy. This is defended on the basis that contemporary African philosophy does not claim to necessarily be distinct or produce different answers, but it is simply an endeavour to situate questions on issues of morality and ethics within the African context – making it something that African people can relate to.⁴²⁷ Although sometimes doing this will produce outcomes that are identical to using different value systems, the outcome is not the point – it is about the reasoning process being something that is authentic, that speaks to the African experience, and which can be communicated to people in a way that they can relate to. The African perspective may not produce answers that differ from the Western perspective, but the

⁴²³ Mackenzie & Stoljar op cit note 77 at 8–10.

⁴²⁴ Shozi op cit note 8 at 28.

⁴²⁵ Shozi op cit note 8 at 30.

⁴²⁶ Ibid at 28.

⁴²⁷ Ibid at 28.

aim is to legitimise the reasoning process which allows people to identify with an outcome because it goes through a process that is familiar, makes sense, and is something that they can relate to.⁴²⁸

VIII SYNTHESIS: AUTONOMY AND UBUNTU

From the above analysis of case law, it is clear that autonomy in South Africa has an individual and communal component. Unlike the traditional Western views of autonomy as atomistic, a South African account of autonomy includes a group element – where the interests of the community are also given due consideration.

South Africa's laws and guidelines that mention autonomy largely focus on the individual in the doctor-patient relationship.⁴²⁹ However, the ASSAf Report recognises that the interests of the family and community are taken into account when making decisions.⁴³⁰ Despite being one of the most recent documents dealing with health research in South Africa, the NHREC Ethics Guidelines (and the DoH Ethics Guidelines) make no reference to a more African autonomy, and rather the NHREC Ethics Guidelines define autonomy as 'the capacity to understand information; to act on it voluntarily; to use *own* judgement to make decisions about *own* actions, including whether to participate in research' (own emphasis).⁴³¹ The NHREC Ethics Guidelines base participant recruitment on individuals and make no mention of the community.⁴³² I suggest that this is a missed opportunity for a document that is legally binding on researchers.

Although South African laws and guidelines tend to have a more individualistic approach to autonomy, case law has expanded on the concept and its meaning. Whilst autonomy is not an explicit right in the Constitution, it has the status of a constitutional value that underlies and informs other rights such as human dignity, freedom, and bodily and psychological integrity.

In South African jurisprudence, autonomy has been viewed in an individualistic manner. The term 'self-autonomy' has been used by the courts to denote the ability to make one's own choices and live as one chooses, even if this causes loss or harm.⁴³³ Autonomy has also been

⁴²⁸ Ibid at 28.

⁴²⁹ See, for example, HPCSA op cit note 105 at 2; SAMRC op cit note 106 at 6; National Department of Health op cit note 112 at 102.

⁴³⁰ ASSAf op cit note 7 at 41.

⁴³¹ National Department of Health op cit note 112 at 102.

⁴³² Ibid at 8–9.

⁴³³ *Barkhuizen* supra note 155 at para 57.

seen as allowing ‘human beings choosing how to live their lives’,⁴³⁴ and denotes ‘the ability to independently form opinions and act on them’.⁴³⁵ However, autonomy has also been viewed in a broader social context.⁴³⁶ Significantly, the Constitutional Court has referred to the *relational* character of autonomy, but instead relied on Ubuntu to emphasise autonomy’s socially integrated nature.⁴³⁷ In addition, the analysis of the case law commonly shows that autonomy entails both a choice⁴³⁸ and responsibility,⁴³⁹ which requires ability or capacity.⁴⁴⁰ South African jurisprudence shows that there is room for both individual autonomy and communal interests.

In addition to autonomy, Ubuntu is another important constitutional value that the courts have used *inter alia* in developing a South African version of autonomy. Interpreting rights through the lens of Ubuntu causes the courts to view autonomy in a more communal way.⁴⁴¹ Ubuntu does not have a clear definition, but it has certain features that make it recognisable – such as ideas of harmony, humaneness, fairness, group solidarity, compassion, respect, and human dignity.⁴⁴² Yet, it must be noted that while Ubuntu places greater emphasis on the relational nature of individuals and the community, the value of the individual and their rights is nevertheless recognised and each person’s individuality is respected and protected.⁴⁴³ As the Constitutional Court has used Ubuntu to emphasise the socially integrated nature of autonomy,⁴⁴⁴ I suggest that Ubuntu forms a basis for a South African understanding of autonomy.

Accounts of relational autonomy have referred to the phrase ‘no man is an island’. Similarly, South African courts have used a derivation of ‘no man is an island’ when discussing

⁴³⁴ *NM v Smith* supra note 158 at para 131.

⁴³⁵ *AB 1* supra note 155 at paras 65–6; *NM v Smith* supra note 158 at para 145.

⁴³⁶ *NM v Smith* supra note 158 at para 131.

⁴³⁷ *AB 2* supra note 207 at para 51.

⁴³⁸ *Ferreira* supra note 15 at para 251; *Bernstein* supra note 155 at para 151; *NM v Smith* supra note 158 at para 131; *Pillay* supra note 200 at paras 64 & 150; *AB 1* supra note 155 at para 89; *AB 2* supra note 207 at paras 21 & 51; *Stransham-Ford 2* supra note 329 at para 31; *Centre for Child Law v Media 24 Limited* supra note 333 at para 86.

⁴³⁹ *Barkhuizen* supra note 155 at para 57; *NM v Smith* supra note 158 at para 131; *Stransham-Ford* supra note 304 at para 14; *AB 2* supra note 207 at para 52.

⁴⁴⁰ *AB 2* supra note 207 at para 52; *Bernstein* supra note 155 at para 150; *Stransham-Ford 2* supra note 329 at para 32; *NM v Smith* supra note 158 at para 145; *AB 1* supra note 155 at paras 65–6.

⁴⁴¹ *Barnard* supra note 382 at para 174.

⁴⁴² *Makwanyane* supra note 182 at paras 237 & 308; *Beadica* supra note 405 at paras 72 & 210; *Dikoko v Mokhatla* supra note 413 at para 68; *Everfresh Market Virginia (Pty) Ltd v Shoprite Checkers (Pty) Ltd* supra note 415 at para 71.

⁴⁴³ *Shozi* op cit note 8 at 44.

⁴⁴⁴ 2017 (3) SA 570 (CC).

Ubuntu.⁴⁴⁵ However, the fact that autonomy is viewed in a social context (island) does not mean that autonomy is only subject to the collective – it is still about the individual. Although relational autonomy and Ubuntu share similarities, Ubuntu has developed through local values and cultures. Therefore, it would be incorrect to simply transfer an account of autonomy from the West and apply it, in an identical manner, to South Africa. South Africa has different cultures, customs, beliefs, and views, and all of this impacts the way in which autonomy is viewed and practically applied. I thus suggest that South Africa maintain and develop Ubuntu and, although there may be links between relational autonomy and Ubuntu – Ubuntu is unique to South Africa and should be applied. However, what this does show is that South Africa clearly accepts a more communal view of autonomy – rather than a purely individual one. I suggest that, as mentioned above, a useful determination of the meaning of autonomy in South African case law may be found in *AB 2*,⁴⁴⁶ where the Constitutional Court created a unique version of relational autonomy using Ubuntu.

The meanings of autonomy and Ubuntu in South African case law, as well as interrelated concepts, have been clarified. In the next section, I consider the meanings of autonomy and Ubuntu from South African jurisprudence, and apply them to open consent in order to determine whether open consent is aligned with these constitutional values.

IX AUTONOMY, UBUNTU, AND OPEN CONSENT

From the above analysis, the question now becomes whether – based on South African jurisprudence and various constitutional rights and values – open consent is compatible with the South African context – specifically whether open consent is aligned with autonomy and Ubuntu. What is clear from the case law above is that autonomy recognises the individual, but also views them as connected and socially embedded with others.

Autonomy and Ubuntu are relevant to several aspects of a research project (and the PGP's open consent model), namely: (1) the decision to participate; (2) informed consent; (3) the provision of information; (4) objective assessment; and (5) community engagement. Each of these aspects are discussed in turn under the sub-headings below. They are considered in terms

⁴⁴⁵ *Port Elizabeth Municipality v Various Occupiers* supra note 388 at para 37; *Union of Refugee Women v Director, Private Security Industry Regulatory Authority* supra note 389 at para 145; *Molusi v Voges NO* supra note 389 at para 40; *Shoprite Checkers* supra note 389 at para 47; *Barnard* supra note 382 at para 174; *City of Johannesburg Metropolitan Municipality v Blue Moonlight Properties 39 (Pty) Ltd* supra note 389 at para 38.

⁴⁴⁶ 2017 (3) SA 570 (CC).

of the open consent model, and then applied to a South African context based on the constitutional values of autonomy and Ubuntu.

(a) *The decision to participate*

The first consideration when it comes to research involving human participants, is making the decision to participate. In the West, this is generally done by an individual who makes a decision on their own.⁴⁴⁷ They may consult with family, friends, and other relevant parties, but this is generally not the determining factor on deciding whether or not to participate in a research project.⁴⁴⁸ This is not only relevant to the open consent model, but to genomics research more broadly. Because the PGP consists of a group of projects in different countries, the contents of their documents may vary. However, some of the PGP documents mention discussions regarding participation in the PGP. As the PGP has adopted an open consent model, it may be useful to consider their stance on decisions to participate as this may shed some light on the position when considering whether open consent aligns with South African constitutional rights and values.

The Harvard PGP mini consent document – which must be signed before individuals begin the enrolment process and undergo eligibility screening⁴⁴⁹ – *strongly* encourages individuals to consult with their family on their interest in enrolling in the PGP, as well as the possible risks associated with it.⁴⁵⁰ The Harvard PGP’s full consent document goes into greater detail – not only are individuals strongly encouraged to discuss the PGP and its possible risks with immediate family, but also healthcare professionals and the Principal Investigator.⁴⁵¹ This is also repeated in the consent form of the PGP UK.⁴⁵² However, this is only mentioned in terms of the risks of participation. There is no information provided in the Harvard PGP consent

⁴⁴⁷ Andoh op cit note 118 at 70–1.

⁴⁴⁸ Johns Hopkins Medicine ‘Clinical research: Why take part?’ available at <https://www.hopkinsmedicine.org/research/understanding-clinical-trials/why-take-part>, accessed on 17 July 2023; Australian Clinical Trials ‘Who can participate in a clinical trial’ *Australian Government* 29 January 2024, available at <https://australianclinicaltrials.gov.au/participants/who-can-participate>, accessed 5 May 2024.

⁴⁴⁹ The Harvard Personal Genome Project ‘Participating in the Harvard PGP’ 18 February 2014 available at <https://pgp.med.harvard.edu/participate#consentdocs>, accessed on 17 March 2021.

⁴⁵⁰ Harvard Personal Genome Project ‘Consent form’ 2021 at 3, available at https://my.pgp-hms.org/static/PGP_Mini_Consent-2021-07-12.pdf, accessed on 12 January 2023.

⁴⁵¹ Ibid at 13–4.

⁴⁵² Personal Genome Project UK *Informed Consent for Enrolment in the PGP-UK* (2018) 11.

form relating to discussions with family or healthcare professionals regarding the PGP in general.

In addition to repeating the provision of the Harvard PGP relating to discussing the project and its risks with family, healthcare professionals, and the Principal Investigator,⁴⁵³ the PGP Canada consent form includes a sub-heading that deals with conversations with family members.⁴⁵⁴ It provides that unless an individual is an identical twin, there is no requirement to obtain consent from family members.⁴⁵⁵ Given that the publishing of health information and genome sequences may affect family members, individuals are encouraged to discuss their decision to partake in the PGP with their family.⁴⁵⁶ Following this, the PGP Canada consent form contains a checkbox which requires individuals to select whether or not they have discussed their interest to enrol in the PGP with their parents, siblings, or children, with an optional space to explain why, in the case where they have answered no.⁴⁵⁷ PGP Canada places greater importance on discussions with family members than the Harvard PGP, but it is still not a requirement.

While individuals are urged to discuss their decisions with their family and healthcare professionals, it is not a cultural requirement – as is the case in South Africa. Furthermore, besides healthcare professionals and the Principal Investigator, only family is mentioned as a party that such discussions should occur with. This does not extend to other (potential non-family) members of a community. This position is largely based on a more individualistic conception of autonomy, where the individual and their choices are paramount. However, such a position is unsustainable in South Africa because of the value that is placed on Ubuntu and the focus on communal relations.

The questions then become: Ought it to be a prerequisite that individuals consult with the head of the clan, responsible for keeping the family together, or the community before deciding to become a research participant and enrol in a research project? Who is responsible for making

⁴⁵³ Personal Genome Project Canada ‘Full consent form’ 2017 at 12, available at https://personalgenomes.ca/assets/consent-forms/PGP%20Full%20consent%20form%20revised_July%2025,%202017_CLEAN.pdf, accessed on 12 January 2023.

⁴⁵⁴ Ibid at 5.

⁴⁵⁵ Ibid at 5.

⁴⁵⁶ Ibid at 5.

⁴⁵⁷ Ibid at 5.

the decision on whether or not to participate in a research project? Should it be an individual decision or one that is up to the community?

The issue is that the decision to participate or actual participation in a genomics research project does not only affect the individual, but also those genetically related to them. Genomics research projects generally work with genetic information. While each individual's genetic information is unique, because genes are passed down through generations, it has a familial aspect as well.⁴⁵⁸ Therefore, learning about this genetic information may affect health, lifestyle, and reproductive decisions, as well as insurance and employment opportunities of not only individuals, but their family members too.⁴⁵⁹ The results of genomics research may also disclose previously unknown family relationships, such as unrelated or adopted relatives.⁴⁶⁰ Whereas with other modes of consent, the individual is the gatekeeper of any genetic information and results that they may receive which they can then choose to share with genetic relatives, an open consent model makes these issues more pronounced in that the genomic and trait data information of research participants is freely accessible on the internet.⁴⁶¹

Due to the fact that families in the African context are tied up in diverse ways beyond the simple atomic family,⁴⁶² it is important that any research project is approached in such a way so as to avoid risks associated with the disclosure of certain harmful information to families. There are certain relationships in the African context of family that others might not understand or be aware of that may be impacted by genomics research.⁴⁶³ Thus, an African understanding of autonomy requires that information related to participation in genomics research communicates, and encourages communication, regarding the implications of partaking in such research for the family unit. This should be something that researchers encourage and therefore

⁴⁵⁸ Serra J Schlanger 'Filling in the cracks: Improving the regulation of direct-to-consumer genetic tests' (2011) 14 *Journal of Health Care, Law & Policy* 6.

⁴⁵⁹ Jane Kaye 'The regulation of direct-to-consumer genetic tests' (2008) 17 *Hum Mol Genet* 181–2.

⁴⁶⁰ National Human Genome Research Institute 'Special considerations for genomics research' NIH 2 October 2019, available at <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent/Special-Considerations-for-Genome-Research#families>, accessed on 6 March 2023.

⁴⁶¹ The Harvard Personal Genome Project 'The PGP is not a traditional research study' available at <https://pgp.med.harvard.edu/about>, accessed 6 June 2022.

⁴⁶² Katharine Hall & Zitha Mokomane 'The shape of children's families and households: A demographic overview' (2018) *South African Child Gauge* 32; Racheal Mafumbate 'The undiluted African community: Values, the family, orphanage and wellness in traditional Africa' (2019) 9(8) *Information and Knowledge Management* 8.

⁴⁶³ Hall & Mokomane op cit note 462 at 32; Mafumbate op cit note 462 at 8.

they should be educated and informed of these dynamics in order to avoid disruption within family units.

Requiring a consultation with the head of the clan or the community before partaking in a research project as a legal formality seems difficult to justify in a liberal democracy, but creating strict boundaries delineating what one can and cannot do is not a solution for incorporating consultation or informed consent as a means of integrating the South African account of autonomy. In terms of South African autonomy, an integral part of the consultation process is encouraging individuals to speak to the family head, so that participation in genomics research does not adversely affect certain relations within the family unit. The clan head should be part of the decision-making process, but this does not necessarily need to entail legal requirements.

Due to the complexities inherent in individual and community relations in South Africa, it is important that all parties are properly informed. The head of the clan should be consulted, and the community should be involved in important decisions. However, in line with an understanding of Ubuntu, there is space for the recognition of the individual and their capacity to make their own decisions – provided that harm to the community does not result.⁴⁶⁴ Given that there is potential harm in the open sharing of genomic data, certain precautions need to be taken to ensure that the community properly understands what the research entails. This duty would fall on the researchers conducting the research. As autonomy and relationships in South Africa are unique, this means that researchers must be knowledgeable on the nature of South African communal relations and Ubuntu, and also that communities understand the nature of the research project and what it entails. This requires education from both sides.

The decision to participate in genomics research does not only involve autonomy, but the related right to bodily and psychological integrity (discussed above) comes into play. Individuals have a constitutional right to make decisions regarding their bodies. The court in *NM v Smith* made it clear that, in the context of medical information which includes private and sensitive information about individuals, decisions relating to bodily and psychological integrity and autonomy are important.⁴⁶⁵ In terms of genomics research, genetic data – which is a form of personal and medical information as it contains sensitive health data – is commonly used. This is buttressed by South African law, in that POPIA classifies genetic data as a type

⁴⁶⁴ Metz op cit note 395 at ‘540.

⁴⁶⁵ *NM v Smith* supra note 158 at para 40.

of ‘special personal information’.⁴⁶⁶ However, in terms of the PGP’s open consent model, genomic and trait data are publicised, shared, and used openly. In this context, this would require individuals in South Africa to choose to forgo their right to bodily and psychological integrity in order to participate in genomics research that is undertaken using an open consent model.

(b) Informed consent

Traditionally, informed consent was deemed to be an individual decision and involved an agreement between the researcher and research participant regarding the details of a research project.⁴⁶⁷ However, in terms of a more relational account of autonomy, it is not just the individual, but also other members of the community (such as family), who must be considered.⁴⁶⁸ However, relational autonomy does not mean that an individual cannot make decisions without the support or consent of others. It simply means that autonomous decisions should take into account values such as interdependence, benefit-sharing, respect, and commonality. This impacts informed consent, which was typically seen as something that the individual did as an exercise of their autonomy.⁴⁶⁹ Given that autonomy in South African is viewed in a more socially integrated manner, the nature of informed consent will require certain adjustments.

The issue of informed consent shares links with the sub-heading above relating to the decision to participate in genomics research. In terms of the South African context, it has been questioned whether informed consent must be obtained from the individual or the community. In South Africa, the individual is part of a socially integrated web of relations with family and the community. Given this, obtaining informed consent from research participants (and the community) will require amending the principle,⁴⁷⁰ because without transparency and comprehensive information, consent is not informed. This must also take into account the various cultures and different levels of understanding, as well as issues of illiteracy, lack of

⁴⁶⁶ Section 1 of POPIA defines special personal information as ‘personal information as referred to in section 26’ of POPIA. Section 26(a) of POPIA refers to personal information concerning...health or sex life or biometric information of a data subject’. As special personal information includes biometric information, and as genetic data is a type of biometric information, genetic data therefore also falls under ‘special personal information’ in POPIA. For more information, see Amy Gooden *Unregulated or Not? A Legal Analysis of South Africa’s Legislative Framework Relevant to Direct-to-Consumer Genetic Testing* (unpublished PhD thesis, University of KwaZulu-Natal, 2021) 88.

⁴⁶⁷ Ronald P Strauss, Sohini Sengupta, Sandra Crouse Quinn et al ‘The role of community advisory boards: Involving communities in the informed consent process’ (2001) 91(12) *Am J Public Health* 1938.

⁴⁶⁸ Mackenzie & Stoljar op cit note 77 at 8–10.

⁴⁶⁹ Strauss et al op cit note 467 at 1938.

⁴⁷⁰ Andoh op cit note 118 at 70–1.

education, and language – which all present barriers to informing individuals.⁴⁷¹ In terms of culture, Dhai provides that:⁴⁷²

‘The cultural background of research participants must be understood with regard to how informed consent is obtained. Ethical conflict is quite likely to emerge when researchers and participating patients come from different cultures. In Africa a person does not perceive himself or herself as an individual in his or her own right, but rather as an extension of a family serving as an intermediary between ancestors and future generations. Because of this perception, an insistence on first person informed consent in group-orientated cultures is viewed as morally unacceptable’.⁴⁷³

As such, where individual informed consent is obtained in communal cultures, this has been viewed as a type of ‘medical-ethical imperialism’.⁴⁷⁴ If informed consent is to be given fairly, such imperialism ought to be avoided.

In discussions surrounding informed consent generally, it has been questioned how to ensure that critical information reaches, and is understood by, individuals.⁴⁷⁵ The PGP has taken several steps to mitigate against a lack of understanding, and thereby an absence of informed consent. In terms of the PGP’s open consent model, potential participants are provided with an informed consent document as well as study material.⁴⁷⁶ These documents are openly accessible, comprehensive and substantial, and cover various aspects of genomics research.⁴⁷⁷ Potential participants first undergo eligibility screening which entails them reading and signing a mini consent document and creating an account, and answering an eligibility questionnaire to determine their suitability for the PGP.⁴⁷⁸ Potential participants are then required to study the information provided and are given the opportunity to ask questions.⁴⁷⁹ Thereafter, potential participants undergo an assessment in which they must obtain 100% in

⁴⁷¹ Kirsten Rowe & Keymanthri Moodley ‘Patients as consumers of health care in South Africa: The ethical and legal implications’ (2013) 14(15) *BMC Med Ethics* 1-9 cited in Engelbrecht op cit note 95 at 36; Akpa-Inyang & Chima op cit note 137 at 12.

⁴⁷² Andoh op cit note 118 at 71.

⁴⁷³ Ibid at 70–1.

⁴⁷⁴ Ibid at 70–1; CB Ijsselmuiden & RR Faden ‘Research and informed consent in Africa – Another look’ (1992) 326 *New England Journal of Medicine* 831.

⁴⁷⁵ Nothando Ngwenya, Manono Luthulia, Resign Gunda et al ‘Participant understanding of informed consent in a multidisease community-based health screening and biobank platform in rural South Africa’ (2020) 12 *International Health* 564; H3Africa Consortium *Guideline for Informed Consent* 3 ed (2018) 25; Dorothy Maxwell Kazembe, Tigist Mesfin, Abigiya Abebe et al ‘A review assessing participants’ understanding of informed consent for clinical trials in Africa’ (2022) 10(11) *Medical Research Archives* 2.

⁴⁷⁶ The Harvard Personal Genome Project ‘How it works’ available at <https://pgp.med.harvard.edu/how-it-works>, accessed 4 June 2022.

⁴⁷⁷ Ibid.

⁴⁷⁸ Ibid.

⁴⁷⁹ The Harvard Personal Genome Project op cit note 476.

order to be considered as a research participant in the PGP.⁴⁸⁰ Following this, potential participants undergo pre-enrolment. This encompasses reading and signing the full consent form, naming a proxy, verifying their identity, and then submitting the enrolment application.⁴⁸¹ If their application is accepted, potential participants are then enrolled in the PGP. Once enrolled, research participants have the option to publicly publish their trait data (which is collected through questionnaires and health records) to the PGP's website and database. Research participants also have the option to submit tissue samples and other specimens to the PGP for research purposes – the results of which may be publicly available.⁴⁸² However, is this viable in the South African context?

Because autonomy has traditionally been central in the provision of informed consent, it must now be questioned how this may shift in light of the South African view of autonomy. How will the South African view of autonomy impact informed consent, and what implications will this have for the application of open consent to genomics research in South Africa?

Akpa-Inyang and Chima have discussed the issues inherent in trying to apply informed consent – which is culture dependent and differs among groups – globally.⁴⁸³ There is tension between Western and African views of autonomy and informed consent in research.⁴⁸⁴ Therefore, the informed consent process must be flexible to be able to adapt to a diverse range of cultures.⁴⁸⁵ Adapting informed consent to the South African context would entail the involvement of family or the community in the consent process.⁴⁸⁶ It also means that there should be increased community involvement.⁴⁸⁷ Researchers must be aware of the nuances of South African culture as well as the fact that informed consent is not viewed as a purely individual exercise.⁴⁸⁸ Whilst informed consent may be implemented in genomics research in South Africa, it must take into account the concept of Ubuntu and the local understanding of autonomy.

Given the South African view of autonomy and the importance of Ubuntu, open consent will need to be modified to suit the South African context in terms of obtaining informed

⁴⁸⁰ Ibid.

⁴⁸¹ Ibid.

⁴⁸² It should also be noted that there are procedures in place following enrolment in the PGP and the PGP strives to continuously engage with participants. This includes the returning of specimen analysis to participants, the publishing of reports that interpret data, and safety monitoring. Ibid.

⁴⁸³ Akpa-Inyang & Chima op cit note 137 at 12.

⁴⁸⁴ Ibid at 15.

⁴⁸⁵ Ibid at 12.

⁴⁸⁶ Ibid at 14.

⁴⁸⁷ Strauss et al op cit note 467 at 1939.

⁴⁸⁸ Akpa-Inyang & Chima op cit note 137 at 15.

consent for genomics research. Informed consent is not suited to being a purely individual exercise, where potential participants study the documents and sign their own consent form. Researchers will need to be proactive and work with the community in order to building an understanding of the research and what it entails, as well as inform the community of the consent process.

Linked to the topic of informed consent is the provision of information and the objective assessment – both of which are steps that the PGP takes in order to ensure that consent is informed. Each of these are discussed below.

(c) The provision of information

For autonomy and decision-making to be meaningful, there is a need for information.⁴⁸⁹ Information is inclusive of the objectives, methods, advantages and risks, and other relevant aspects of a research project.⁴⁹⁰ Research documents, containing vital information, must be taken into account throughout the research process.⁴⁹¹ However, there is uncertainty as to whether research participants will understand the information that is provided to them – especially in terms of genomics research, which is complex and ever-changing.⁴⁹² Traditionally, information was provided to the individual who wished to partake in a research project. Given the communal focus in South Africa, it must be questioned whether it is sufficient to merely provide information to the research participant only.

It has been suggested that information regarding the research should be provided to both potential participants and the community. It should inter alia clarify the research and its aim, and seek to lessen uncertainty and apprehension, leading to increased understanding and confidence, the ability to ask questions, veracity, and participant compliance.⁴⁹³ The provision of information enhances community awareness and informed consent.⁴⁹⁴ Regardless of which conception of autonomy is applied, it is imperative that all research projects provide sufficient

⁴⁸⁹ Linda L McCabe & Edward RB McCabe ‘Direct-to-consumer genetic testing: Access and marketing’ (2004) 6(1) *Genet Med* 58.

⁴⁹⁰ Maxwell Kazembe et al op cit note 475 at 2.

⁴⁹¹ Michael McDonald, Anne Townsend, Susan M Cox et al ‘Trust in health research relationships: Accounts of human subjects’ (2008) 3(4) *J Empir Res Hum Res Ethics* 43.

⁴⁹² Maxwell Kazembe et al op cit note 475 at 2; Jennifer GR Kromberg, Elaine B Sizer & Arnold L Christianson ‘Genetic services and testing in South Africa’ (2013) 4(3) *J Community Genet* 419.

⁴⁹³ CS Molyneux, N Peshu & K Marsh ‘Trust and informed consent: Insights from community members on the Kenyan coast’ (2005) 61(7) *Soc Sci Med* 1471.

⁴⁹⁴ Irene Jao, Francis Kombe, Salim Mwalukore et al ‘Research stakeholders’ views on benefits and challenges for public health research data sharing in Kenya: The importance of trust and social relations’ (2015) 10(9) *PLoS One* 15.

information to participants. This allows them to make an informed decision based on transparent and reliable information. This remains unchanged regardless of whether an atomistic or individual account of autonomy is applied, or whether the approach is more relational in nature.

But how can it be ensured that research participants and their communities will understand the information that is provided to them? There is a need for improved explanations of complex terms, using speakers of the local language with knowledge of the research, involving communication professionals in developing material, and employing cognitive testing to check comprehension.⁴⁹⁵ Where literacy is an issue, there have been suggestions that information may be given verbally or visually (such as images or films) in a simple and understandable manner, and in a language that the individual understands.⁴⁹⁶ However, it is not only about the research participants. There is also a duty on the researcher to ensure that research participants understand the information provided to them before deciding to partake in a research project – as well as ongoing comprehension assessments during the research to ensure that research participants continue to understand the nature of the research project.⁴⁹⁷

In terms of the PGP's open consent model, the information provided to participants in both the informed consent documents and the study material is presented in a simple and easy to understand manner.⁴⁹⁸ The informed consent document explains the basics of informed consent, the purpose of the research, the nature and procedures of the research, risks, withdrawal, amongst other things.⁴⁹⁹ However, in the South African context, varying literacy levels as well as the numerous languages that are spoken, must be considered. One of the identified weaknesses of informed consent documents and the provision of information is the fact that many individuals are unwilling to read lengthy and complex texts.⁵⁰⁰ This is made more challenging if the information is in a language that an individual does not understand.

⁴⁹⁵ Ngwenya et al op cit note 475 at 564; Maxwell Kazembe et al op cit note 475 at 8.

⁴⁹⁶ H3Africa Consortium op cit note 475 at 11.

⁴⁹⁷ Maxwell Kazembe et al op cit note 475 at 8.

⁴⁹⁸ Harvard Personal Genome Project op cit note 450 at 13–4; Personal Genome Project Canada op cit note 453 at 5; Personal Genome Project UK op cit note 452.

⁴⁹⁹ Harvard Personal Genome Project op cit note 450.

⁵⁰⁰ Lesley Jean Burgess, Berna Gerber, Kathleen Coetzee et al 'An evaluation of informed consent comprehension by adult trial participants in South Africa at the time of providing consent for clinical trial participation and a review of the literature' (2019) 11 *Open Access Journal of Clinical Trials* 20; Marta S Palmeirim, Amanda Ross, Brigit Obrist et al 'Informed consent procedure in a double blind randomized anthelmintic trial on Pemba Island, Tanzania: Do pamphlet and information session increase caregivers knowledge?' (2020) 21(1) *BMC Med Ethics* 2. See also, Mehmet Özgür Özhan, Mehmet Anıl Süzer, İlker Çomak et al 'Do the patients read the informed consent?' (2014) 31 *Balkan Med J* 132.

Even in the South African context, an individual is capable of making decisions – unless it will result in harm to the community. In terms of genomics research, there is the risk of finding out about one’s genes – and this could include being informed of genetic conditions, diseases, or family relationships.⁵⁰¹ The question then becomes how to align the interest of the individual in partaking in genomics research with the broader interest of the family, community, or ethnic group? A possible solution lies in involving the community in a proactive way, without infringing the interests of the individual. Researchers should undergo training on the provision of information and the research process, but they should also be trained to involve members of the community. A relational account of autonomy, based on Ubuntu, contends that ‘no man is an island’,⁵⁰² hence support and the provision of information from trained researchers is not a limitation to autonomy, but a means of realising it.

(d) *Objective assessment*

Linked to informed consent is the PGP’s model of including an objective assessment. Although it has been mentioned elsewhere, it is worth briefly repeating here. The PGP requires potential participants to review the study material that is provided and then undergo an entrance assessment based on this study material that tests potential participants’ understanding of the project, the use of their samples and data, and risks to their privacy.⁵⁰³ Potential participants are required to obtain 100% for the assessment in order to be considered for the PGP.⁵⁰⁴ However, potential participants are permitted to re-take the enrolment examination as many times as they like until they pass.

The aspect of objective assessment needs to be considered from a practical perspective in the South African context. In terms of the PGP, the examination is done online – requiring both a device and an internet connection. In South Africa, this is not feasible. Many communities do not have access to the internet, and many do not own smart phones, let alone

⁵⁰¹ Hawkins & Ho op cit note 10 at 369.

⁵⁰² Donne op cit note 383; Grammarist op cit note 384; *Port Elizabeth Municipality v Various Occupiers* supra note 388 at para 37; *Pillay* supra note 200 at para 53.

⁵⁰³ Jeremy Walter ‘General FAQ’ 18 April 2019 *GitHub*, available at <https://github.com/PGPHarvard/FAQ/wiki/General-FAQ#why-do-i-have-to-get-100-on-your-eligibility-questionnaire-before-i-can-join>, accessed on 5 May 2022.

⁵⁰⁴ Oscar A Zarate, Julia Green Brody, Phil Brown et al ‘Balancing benefits and risks of immortal data: Participants’ views of open consent in the Personal Genome Project’ (2016) *Hastings Center Rep* 37. See also, Fida K Dankar, Marton Gergely & Samar K Dankar ‘Informed consent in biomedical research’ (2019) 17 *Computational and Structural Biotechnology Journal* 470; Anne SY Cheung ‘Moving beyond consent for citizen science in big data health and medical research’ (2018) 16(1) *Northwest J Technol Intellect Prop* 26–7; Misha Angrist ‘Eyes wide open: The Personal Genome Project, citizen science and veracity in informed consent’ (2009) 6(6) *Per Med* 5.

computers.⁵⁰⁵ This is a significant barrier to implementing the PGP's open consent model for genomics research in South Africa. Thus, are there alternative solutions that can be offered?

While objective assessment remains important to offset the increased risks of open access to data, it should not be the sole focus. In South Africa, autonomy is no longer viewed in a purely individualistic manner – as evidenced in the Constitutional Court case of *AB 2*,⁵⁰⁶ where the minority judgment accepted a relational account of autonomy, emphasised by its approval of Ubuntu – showing that autonomy refers to being ‘socially and politically connected, rather than an agent of unfettered individual choice’.⁵⁰⁷ Therefore, autonomy should not only be understood in a purely intellectual way (of objective understanding), but also in a relational way, that includes involving, and building a relationship with, not only the individual participant, but the community too. Researchers should act in a manner that promotes Ubuntu and includes the community. In countries such as South Africa, where scientific literacy is generally low, there has been a view that research participants will battle to understand the information provided to them.⁵⁰⁸ Linked to the provision of information heading above, by providing sufficient and understandable information and by explaining this information to, and engaging with, both participants and their communities, this will promote the importance of relationships, and will ensure that participants are able to make autonomous decisions that are in line with South Africa's relational view of autonomy and the principles of Ubuntu.

(e) Community engagement

Krogstad et al argue that international guidelines may overemphasise the role of the individual in the consent process, which could conflict with key ethical principles regarding the autonomy of participants.⁵⁰⁹ In sub-Saharan Africa, the consent process should be multi-layered and include input from family and community members.⁵¹⁰ However, there is limited guidance on how to effectively implement this multi-layered approach to consent.⁵¹¹

⁵⁰⁵ Victoria Nembaware, Katherine Johnston, Alpha A Diallo et al ‘A framework for tiered informed consent for health genomic research in Africa’ (2019) 51(11) *Nat Genet* 2.

⁵⁰⁶ 2017 (3) SA 570 (CC).

⁵⁰⁷ *AB 2* supra note 207 at para 51.

⁵⁰⁸ Maxwell Kazembe et al op cit note 475 at 2.

⁵⁰⁹ Donald J Krogstad, Samba Diop, Amadou Diallo et al ‘Informed consent in international research: The rationale for different approaches’ (2010) 83(4) *Am J Trop Med Hyg* 743; Nkosi Busisiwe, Janet Seeley, Ann Strode et al ‘Beyond translations, perspectives for researchers to consider to enhance comprehension during consent processes for health research in sub-Saharan Africa: A scoping review’ (2023) 24 *BMC Med Ethics* 11.

⁵¹⁰ *Ibid* at 11.

⁵¹¹ *Ibid* at 11.

In South Africa, consultation with community representatives is a legal requirement when conducting research involving human participants. Regulation 3(b) of the Human Research Participant Regulations provides that researchers undertaking health research involving human participants must inter alia ‘consult with representatives from the participating community or other relevant research stakeholders, where appropriate’.⁵¹² But what does community consultation entail?

Community consultation falls under the term ‘community engagement’, and is one way to engage with, and involve, communities in research⁵¹³ – although the terms have been used interchangeably.⁵¹⁴ Community engagement is not only beneficial for members of the community in that it enhances community understanding of the research, aids the informed consent process, and lessens possible exploitation,⁵¹⁵ but it can also assist researchers in understanding community preferences and developing communication and research approaches that are tailored to the community.⁵¹⁶ Community engagement should be continuous throughout, and following, the research.⁵¹⁷ There is no one strategy that can be used when engaging with a community, and the most suitable approach depends on the purpose of the research and the community involved.⁵¹⁸

Three important aspects in community engagement are: (1) information sharing; (2) community consultation; and (3) community involvement and collaboration.⁵¹⁹ In terms of (1), the sharing of information is central to all research, but becomes especially important in the context of genomics research, where terminology and processes are often complex. Thus, providing information is central to building rapport and community empowerment. Certain research projects may require educational materials to explain vital parts of a research project.⁵²⁰ In terms of (2), community consultation entails gathering feedback from the

⁵¹² Regulation 3(b) of the Human Research Participant Regulations.

⁵¹³ Neal Dickert & Jeremy Sugarman ‘Ethical goals of community consultation in research’ (2005) 95(7) *Am J Public Health* 1123; Rosemary Musesengwa & Moses J Chimbari ‘Community engagement practices in Southern Africa: Review and thematic synthesis of studies done in Botswana, Zimbabwe and South Africa’ (2017) 175 *Acta Tropica* 21.

⁵¹⁴ Paulina Tindana, Jantina de Vries, Megan Campbell et al ‘Community engagement strategies for genomic studies in Africa: A review of the literature’ (2015) 16(24) *BMC Med Ethics* 5.

⁵¹⁵ Ibid at 1; Syed M Ahmed & Ann-Gel S Palermo ‘Community engagement in research: Frameworks for education and peer review’ (2010) 100(8) *Am J Public Health* 1380; Musesengwa & Chimbari op cit note 513 at 21.

⁵¹⁶ Ahmed & Palermo op cit note 515 at 1380.

⁵¹⁷ Tindana et al op cit note 514 at 2.

⁵¹⁸ H3Africa Community Engagement Working Group for the Human Heredity and Health (H3Africa) Consortium *H3Africa Guidelines for Community Engagement (Version Two)* (2017) 8; Tindana et al op cit note 514 at 2; Dickert & Sugarman op cit note 513 at 1123.

⁵¹⁹ Tindana et al op cit note 514 at 5.

⁵²⁰ Ibid at 6.

community regarding aspects of the research in order to consider the community's interests. Consultation may occur with different groups within the community, including community leaders and representatives, community advisory boards, and research ethics committees, before informed consent is sought from individuals.⁵²¹ In terms of (3), community involvement encourages the formation of genuine and mutually respectful relationships between the researchers and the community.⁵²²

Involving the community entails researchers meeting with, and getting to know, the community and the leaders.⁵²³ Researchers should include participants in the research process, engage with them, learn more about them, enter into a dialogue, and obtain their differing views, beliefs, opinions, and experiences⁵²⁴ – this shows respect for autonomy.⁵²⁵ Community engagement may also include newspapers, educational videos, advocacy groups, and annual feedback.⁵²⁶

Community meetings and focus group discussions can also be used to directly engage with potential participants and their communities.⁵²⁷ These can either consist of larger community gatherings (such as town hall meetings) or small groups within the community such as women's groups or patient associations. These meetings aim to discuss the research and obtain individual's feedback. The outcomes of these meetings can serve to guide the research – for example, in terms of altering informed consent forms or the enrolment process.⁵²⁸

Furthermore, in many African countries, consulting with community gatekeepers is required before being given access to the community.⁵²⁹ This involves meeting with community leaders, such as chiefs and elders in order to get permission to conduct the research and understand any concerns that the community may have.⁵³⁰ This is done prior to undertaking any research and is followed by meetings with the wider community.⁵³¹ These community

⁵²¹ Ibid at 6.

⁵²² Ibid at 7.

⁵²³ Keymanthri Moodley & Shenuka Singh “‘It’s all about trust’: Reflections of researchers on the complexity and controversy surrounding biobanking in South Africa’ (2016) 17(57) *BMC Med Ethics* 6.

⁵²⁴ Ibid at 6; Molyneux, Peshu & Marsh op cit note 493 at 1471; McDonald et al op cit note 491 at 43.

⁵²⁵ McDonald et al op cit note 491 at 43.

⁵²⁶ Moodley & Singh op cit note 523 at 6.

⁵²⁷ Tindana et al op cit note 514 at 8.

⁵²⁸ H3Africa Consortium op cit note 518 at 12.

⁵²⁹ Paulina O Tindana, Linda Rozmovits, Renaud F Boulanger et al ‘Aligning community engagement with traditional authority structures in global health research: A case study from northern Ghana’ (2011) 101(10) *Am J Public Health* 1861; Paulina Tindana, Susan Bull, Lucas Amenga-Etego et al ‘Seeking consent to genetic and genomic research in a rural Ghanaian setting: A qualitative study of the MalariaGEN experience’ (2012) 13(15) *BMC Med Ethics* 4.

⁵³⁰ H3Africa Consortium op cit note 518 at 9; Tindana et al op cit note 529 at 4.

⁵³¹ Tindana et al op cit note 529 at 4; H3Africa Consortium op cit note 518 at 10.

meetings (sometimes known as ‘durbars’) aim to educate the broader community about the proposed research and its implications, and allow discussions on the research purpose, processes, involvement, and anticipated results. Researchers should ensure that scientific information is described, and that complex terminology and concepts are translated and explained to the community in their local language and in lay terms, with suitable comparisons to assist in understanding.⁵³²

Community engagement may have the additional benefit of improving the informed consent process as it can offer insights and assist in designing consent processes that are suited to the local context. Engaging with communities also supports effective communication, which is crucial for demonstrating respect, ensuring individuals grasp the research’s risks and benefits, and valuing participants’ involvement.⁵³³ Community engagement is particularly critical for the consent process because it influences how individuals perceive the risks and benefits of research, thus shaping their ability to make independent decisions during the consent process.⁵³⁴

In terms of the PGP, there is a focus on continuous engagement and it does take its research participants into account in that every three months, the PGP sends out a safety questionnaire to all participants, and every five years (as well as upon withdrawing participation in the PGP) the PGP requests participants to share their views on the PGP – including whether the consent form was sufficient in describing the processes and risks associated with participation.⁵³⁵ However, in the South African context, the provision of a questionnaire every few months is insufficient. Going out into communities and interacting with them promotes and strengthens relationships between researchers and communities, and this goes a long way in ensuring that the researchers take the interests of the community into consideration and act in a manner that promotes Ubuntu. Therefore, given the above, the PGP’s open consent model should be modified for a South African environment. While objective assessment remains important given the increased risk of open access data and obtaining informed consent, it should not be the sole focus and proper community engagement should also be a priority for researchers.

⁵³² Tindana et al op cit note 529 at 4.

⁵³³ Joseph Mumba Zulu, Ingvild Fossgard Sandøy, Karen Marie Moland et al ‘The challenge of community engagement and informed consent in rural Zambia: An example from a pilot study’ (2019) 20 *BMC Med Ethics* 2.

⁵³⁴ Ibid at 8.

⁵³⁵ Harvard Personal Genome Project op cit note 450; Personal Genome Project Canada op cit note 453.

X RECOMMENDATIONS AND CONCLUSION

This Chapter has extensively explored the constitutional value of autonomy. It has also expanded to discuss the related, and important, concept of Ubuntu. This Chapter began by providing a universal definition of autonomy from the literature, as well as defining some of the prominent philosophical conceptions of autonomy, including individual autonomy, moral autonomy, personal autonomy, the split-level view of autonomy, Beauchamp and Childress' three condition test for autonomy, Razian autonomy, rational autonomy, as well as the more integrated feminist autonomy and the ethics of care, and relational autonomy.

Following this, this Chapter explored the meaning of autonomy in South Africa through an examination of definitions in the literature and South African laws and documents. It then broadened the meaning of autonomy to Africa more generally, looking at the concept of communitarianism. The crux of this Chapter was an analysis of the meaning of autonomy based on South African case law. This was done by assessing whether autonomy in South Africa is a right or a value, whether autonomy forms part of human dignity, autonomy and the link to bodily and psychological integrity, and the meaning of autonomy in South African case law. From this, I found that autonomy in South African jurisprudence has been interpreted and understood in a more relational and socially integrated way, which leads onto the next part of this Chapter: Ubuntu. Ubuntu was defined and its meaning was explored through South African case law. Although Ubuntu is difficult to define, its importance in South Africa should not be understated. It is a central value in South African culture and has been used as a tool by the courts when interpreting other constitutional rights and values.

Thereafter, this Chapter applied what had been established in the analysis above and examined autonomy and Ubuntu in relation to open consent. This was divided into five aspects relating to genomics research and open consent: (1) the decision to participate; (2) informed consent; (3) the provision of information; (4) objective assessment; and (5) community engagement. Each of these aspects was discussed and applied to the South African context.

In this Chapter, I have established that the PGP's open consent model should be modified for a South African genomics research environment. Open consent was developed abroad. The concept, as it has been used and defined by the PGP, follows rather individualistic notions. The ideas of autonomy, the decision to participate, informed consent, the provision of information, and objective assessment have typically revolved around the individual. However, as can be seen from the analysis above, South African culture does not place sole focus on the individual

– and the community also plays a central role in decisions. Whilst all of these aspects of open consent (and genomics research projects more generally) all remain valid, they require some adaptation to be more communal in nature. One important modification, and a way in which a more South African understanding of autonomy and Ubuntu can be integrated with open consent, is through community engagement. By engaging with, and consulting, both participants and their communities throughout the research process, this will promote the importance of relationships; and by explaining the research and allowing communities to engage, this will ensure that participants are able to make autonomous decisions that are in line with South Africa’s relational view of autonomy and the principles of Ubuntu.

Additionally, education is an important factor in the success of an open consent model for genomics research in South Africa. Researchers must be educated on the concept of Ubuntu and the nuances of individual and communal relationships in the South African context. Similarly, communities must be educated on the research project and exactly what it will entail. This requires an understanding of the type of data to be collected, how it will be used and shared, feedback on the research, and the benefits and risks of participation.

The South African NHREC Ethics Guidelines adopt a more individualistic approach to autonomy. It refers to autonomy as the ‘ability to deliberate about a decision and to act on that decision’.⁵³⁶ The focus is generally on the individual who decides whether or not to participate in research.⁵³⁷ However, reference is made to Ubuntu and its inclusion of values such as respect, fairness, and justice.⁵³⁸ Social context is mentioned in relation to the fact that research participants decide whether or not to participate in research ‘from within their community context, including consultation with others’.⁵³⁹ Whilst this is a positive inclusion in the NHREC Ethics Guidelines, it could benefit from being given greater recognition. As the NHREC Ethics Guidelines are legally binding on health researchers in South Africa,⁵⁴⁰ I suggest that to the NHREC should incorporate a version of autonomy that is more in line with local contexts and cultures. A more relational form of autonomy that is in line with Ubuntu should be given greater emphasis in the NHREC Ethics Guidelines, as well as the provision of a pathway for achieving this in health research. Furthermore, whereas the DoH Ethics Guidelines do not recommend

⁵³⁶ National Department of Health op cit note 112 at 8.

⁵³⁷ Ibid at 8.

⁵³⁸ Ibid at 8.

⁵³⁹ Ibid at 8.

⁵⁴⁰ This is in terms of regulation 2(a) of the Regulations Relating to Research with Human Participants GN R719 GG 38000 of 19 September 2014. See also, Amy Gooden ‘A pathway to strengthening open science: Comments on the draft South African Ethics in Health Research Guidelines’ (2024) 15 *Front Pharmacol* 2.

blanket consent,⁵⁴¹ it is also not prohibited. I suggest that the NHREC Ethics Guidelines retain the previous provision regarding blanket consent from the DoH Ethics Guidelines. This provides for the possibility of allowing open consent in health research in South Africa.⁵⁴²

This Chapter's exploration of autonomy and Ubuntu has revealed the complex interplay between individual rights and communal values that shape consent practices in South African genomics research. Understanding autonomy in a relational context not only informs ethical consent models but also raises important questions about how these values coexist with the broader constitutional rights that govern scientific inquiry. As such, the next Chapter shifts focus from the individual and community dimensions of decision-making to the constitutional protection of scientific freedom. This transition is critical for assessing how the right to freedom of scientific research supports, constrains, or complements open consent frameworks within genomics research in South Africa, providing a legal and philosophical context for balancing innovation, transparency, and respect for participants.

⁵⁴¹ Department of Health op cit note 108 at 43.

⁵⁴² Gooden op cit note 540 at 5. Although this article was written based on the previous draft of the draft NDoH Ethics Guidelines, the recommendation still applies.

CHAPTER 4

FREEDOM OF SCIENTIFIC RESEARCH

I INTRODUCTION

Science involves seeking and using knowledge about the natural and social world through a structured approach grounded in evidence.¹ Science has been described as ‘knowledge or a system of knowledge covering general truths or the operation of general laws especially as obtained and tested through scientific method’.² The scientific method is ‘principles and procedures for the systematic pursuit of knowledge involving the recognition and formulation of a problem, the collection of data through observation and experiment, and the formulation and testing of hypotheses’.³ It is important to distinguish between opinions that are not based on scientific evidence and findings that have been rigorously verified through scientific methods.⁴ As such, science has a duty to society to share and communicate research findings clearly, transparently, and in a way that is understandable.⁵

Research refers to a systematic investigation or study aimed at generating knowledge that can be broadly applied, adhering to accepted scientific and ethical norms relevant to the field. It encompasses various activities across diverse disciplines, each employing distinct methods and frameworks to expand understanding through rigorous investigation or disciplined inquiry.⁶ Scientific research benefits individuals and society by advancing knowledge.⁷ Research and the freedom to conduct it are essential foundations for the resilience and advancement of society across social, cultural, political, and economic realms.⁸ Freedom of scientific research has been recognised as a ‘universal right and public good’.⁹ In South Africa, freedom of scientific research is enumerated as a right in the Constitution.¹⁰ But how has the right to freedom of scientific research been applied in South Africa? How does the right to

¹ Science Council ‘Our definition of science’ 2015 available at <https://sciencecouncil.org/about-science/our-definition-of-science/>, accessed on 2 June 2024.

² Merriam-Webster ‘Science’ available at <https://www.merriam-webster.com/dictionary/science>, accessed on 2 June 2024.

³ Merriam-Webster ‘Scientific method’ available at <https://www.merriam-webster.com/dictionary/scientific%20method>, accessed on 2 June 2024.

⁴ Bundesministerium für Bildung und Forschung *Bonn Declaration on Freedom of Scientific Research* (2020) 2.

⁵ Ibid at 2.

⁶ National Department of Health *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* 3 ed (2024) 108.

⁷ Bundesministerium für Bildung und Forschung op cit note 4 at 2.

⁸ Ibid at 2.

⁹ Ibid at 2.

¹⁰ Section 16(1)(d) of the Constitution.

freedom of scientific research link to open science? And what does the right to freedom of scientific research mean for open consent in genomics research in South Africa?

II CHAPTER OVERVIEW

In this Chapter, I explore the right to freedom of scientific research. This Chapter begins by examining the right to freedom of scientific research in South African law, as well as what this concept means. It considers where this right has appeared and how it has been applied. This Chapter then examines the link between the right to freedom of scientific research and open science, which can be seen to promote the right to freedom of scientific research. Following this, this Chapter examines the right to freedom of expression – the umbrella right under which the right to freedom of scientific research falls. Through an examination of the history, links to other rights, and the purposes of the right to freedom of expression, this Chapter aims to determine whether there is a link between the right to freedom of expression and the right to freedom of scientific research, and whether this can be applied to the right to freedom of scientific research. Finally, this Chapter determines how open consent may fit in with the right to freedom of scientific research in terms of genomics research in South Africa – from a constitutional perspective.

III THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH

Both scientific freedom and scientific responsibility are crucial for advancing human knowledge for the benefit of society. Scientific freedom encompasses the freedom to conduct research, explore knowledge, and openly share findings.¹¹ It should be noted that research that is free from external control serves to benefit scientific progress.¹² Freedom of research refers to the freedom of the individual conducting the research, not to freedom of science.¹³

Freedom of scientific research is interconnected with various fundamental rights such as freedom of expression, association, movement, and education. It includes the ability to independently formulate research inquiries, develop theories, collect empirical data using rigorous methods, and challenge existing beliefs with innovative ideas. Researchers also have

¹¹ American Association for the Advancement of Science ‘AAAS Statement on Scientific Freedom & Responsibility’ AAAS available at <https://www.aaas.org/programs/scientific-responsibility-human-rights-law/aaas-statement-scientific-freedom#:~:text=Scientific%20freedom%20is%20the%20freedom,in%20accordance%20with%20scientific%20responsibility.>, accessed 20 June 2024.

¹² Giuseppe Tanzella-Nitti ‘The autonomy of the sciences and freedom of research’ *Interdisciplinary Encyclopedia of Religion and Science* 2002, available at <https://inters.org/node/1987>, accessed on 5 May 2024.

¹³ Ibid.

the right to openly share, disseminate, and publish their findings, as well as educate others through training and teaching.¹⁴

Freedom of scientific research extends to all research institutions and fields of study, fostering intellectual creativity and the security of individuals' freedoms. It promotes openness, collaboration, excellence, global cooperation, diversity, equality, integrity, curiosity, responsibility, and self-reflection. As such, it forms a cornerstone of any democratic society.¹⁵ Freedom of scientific research allows researchers to create, share, and transmit knowledge as a public good for the benefit of society.¹⁶ Academic freedom and freedom of scientific research are essential elements of the right to access and benefit from scientific progress (often referred to as the 'right to science') and the right to education. Without intellectual freedom and autonomy, scientists and educators would be limited in their ability to pursue truth and their work's credibility in society would be compromised.¹⁷

Government bodies use scientific evidence to formulate healthcare guidelines for the public. Following this, the public trusts that treatment recommendations are based on solid evidence. Research institutions prioritise research integrity to safeguard against negative outcomes, like ineffective drugs or procedures that could harm the public, which could damage their reputation, funding, and impede scientific progress.¹⁸ However, issues such as the involvement of politics in science, publication bias, outdated evidence, and weak or inaccurate study design or results has caused issues with the integrity of the scientific community.¹⁹ Trust in science is crucial for a society that values inclusivity, openness, and democracy. Upholding rigorous standards of ethical scientific conduct and establishing guidelines and advisory frameworks may help to ensure integrity and responsible research practices.²⁰

In South Africa, the right to freedom of scientific research is a right that is enumerated in section 16(1)(d) of the Constitution, under freedom of expression. It provides that '[e]veryone has the right to freedom of expression, which includes...(d) academic freedom and freedom of scientific research'.²¹ But what does such a right entail? Despite its importance, the right to freedom of scientific research neither features in any South African statutes, nor has it

¹⁴ Bundesministerium für Bildung und Forschung op cit note 4 at 2.

¹⁵ Ibid at 2.

¹⁶ Ibid at 2.

¹⁷ UNESCO 'Academic freedom and freedom of science' *UNESCO* 28 June 2023, available at <https://www.unesco.org/en/articles/academic-freedom-and-freedom-science>, accessed 20 June 2024.

¹⁸ Emma Catterall 'Why research freedom is crucial to science' (2014) 21(3) *Annals of Neurosciences* 83.

¹⁹ Ibid at 83.

²⁰ Bundesministerium für Bildung und Forschung op cit note 4 at 2.

²¹ Section 16(1)(d) of the Constitution.

been discussed in case law. It is also not mentioned in the DSI *Draft National Open Science Policy* (draft Open Science Policy),²² which had the ideal opportunity to express the importance of the constitutional right to freedom of scientific research and its position within the South African research landscape.

An additional government document to consider is the NHREC Ethics Guidelines.²³ Although the previous DoH Ethics Guidelines²⁴ make no mention of the right to freedom of scientific research, this right does feature (although not extensively) in the NHREC Ethics Guidelines. The NHREC Ethics Guidelines recognise ‘academic freedom and freedom of scientific enquiry’ in section 16(1)(d) of the Constitution, and provide that High-quality, scientifically rigorous, and ethically sound research depends on the freedom to conduct, write about, and discuss any topic thoroughly and professionally, without being influenced by bias or fear of repercussions.²⁵ However, exercising these freedoms requires researchers to uphold integrity, respect, fairness, trustworthiness, and transparency in their work and communication.²⁶

Jordaan opines that because the right to freedom of scientific research is linked to human dignity – and because human dignity is connected to autonomy (which is established in Chapter 3) – freedom of scientific research forms part of individual autonomy and self-actualisation.²⁷ This is in terms of both the scientist who exercises this freedom and society who benefits from the results of science given this freedom.²⁸ Science has enabled individual autonomy and self-actualisation through its improvement of the human condition.²⁹ Because the right to freedom of scientific research is connected with autonomy, and because autonomy is an important underlying constitutional value that underlies many other rights, the importance of the right to

²² Department of Science and Innovation (DSI) *Draft National Open Science Policy* (2022).

²³ National Department of Health op cit note 6.

²⁴ The DoH Ethics Guidelines do provide a definition of ‘academic freedom’, which it defines as ‘the collective freedom of researchers, including students, to conduct research and to disseminate ideas or findings without religious, political or institutional restrictions; it includes freedom of inquiry and freedom to challenge conventional thought. Academic freedom does not mean freedom to ignore ethical issues’. This can be seen to share similarities with freedom of scientific research, but the DoH Ethics Guidelines do not mention the right to freedom of scientific research. Department of Health *Ethics in Health Research: Principles, Processes and Structures* 2 ed (2015) 76.

²⁵ National Department of Health op cit note 6 at 3. The NHREC Ethics Guidelines also mention the right to freedom of scientific research under heritable human genome editing, emphasising the need to strengthen ethical oversight, but this is not relevant for the purposes of this thesis.

²⁶ Ibid at 3.

²⁷ Donrich W Jordaan ‘Science versus anti-science: The law on pre-embryo experimentation’ (2007) 124 *S Afr L J* 631–2.

²⁸ Ibid at 631–2.

²⁹ Ibid at 631–2.

freedom of scientific research – and its potential pathway for open consent in South Africa – cannot be understated.

However, in South Africa case law on the right to freedom of scientific research is lacking. There is also an absence of the right in other documents and guidelines. Therefore, in order to understand the right to freedom of scientific research, it needs to be deconstructed, and its meaning, scope, and purpose must be established.³⁰ Before proceeding with the right to freedom of scientific research, it is necessary to situate it within the broader open science movement. This will assist in understanding what the right to freedom of scientific research may entail and how it may serve to aid or hamper open science.

IV FREEDOM OF SCIENTIFIC RESEARCH: A PROMOTER OF OPEN SCIENCE

Although open science was introduced and briefly discussed in Chapter 1, it is given greater attention in the paragraphs that follow. Science is necessary to advance society, stimulate innovation, enhance education, develop policies, and protect wellbeing.³¹ But science is most successful when knowledge is freely available.³² There is growing concern that science has become too secluded to benefit the common good of society. Therefore, open science has emerged as an endeavour to close the science-society gap by democratising scientific knowledge.³³ Scientific data must be accessible and re-usable, taking into account safety and privacy.³⁴

In the past centuries, science was predicated on the open creation and sharing of knowledge.³⁵ Knowledge as a public good, peer-review, the importance of publications, and the focus given to ‘professional recognition and scientific autonomy’ symbolised science in the past three centuries.³⁶ With the aim of democratising knowledge, increased access to literature has been an aim of numerous researchers.³⁷ Open science is not a new phenomenon – it began

³⁰ Donrich W Thaldar & Michaela Steytler ‘Time for Cinderella to go to the ball: Reflections on the right to freedom of scientific research’ (2021) 138 *S Afr L J* 262.

³¹ International Science Council *Open Science for the 21st Century* (2020) Draft ISC Working Paper 3.

³² *Ibid* at 4.

³³ J Britt Holbrook ‘Philosopher’s corner: Open science, open access, and the democratization of knowledge’ *Issues in Science and Technology* 2019, available at <https://issues.org/philosophers-corner-open-science-open-access-and-the-democratization-of-knowledge/>, accessed on 26 February 2022.

³⁴ International Science Council *op cit* note 31 at 5.

³⁵ Sascha Friesike, Bastian Widenmayer, Oliver Gassmann et al ‘Opening science: Towards an agenda of open science in academia and industry’ (2015) 40 *J Technol Transf* 582.

³⁶ Venni V Krishna ‘Open science and its enemies: Challenges for a sustainable science–society social contract’ (2020) 6(61) *J Open Innov Technol Mark Complex* 2.

³⁷ Holbrook *op cit* note 33.

in the 17th century with the emergence of scientific journals,³⁸ peer-review,³⁹ and replicating experiments that appeared in the literature.⁴⁰ The Royal Society's maxim 'nullius in verba', which broadly means 'take nobody's word for it', represented a scientific principle that theories are open to questioning and results must be capable of being replicated.⁴¹ New ideas were revealed and it was a requirement that editors also receive the related evidence for these ideas. This allowed inspection by others of the links between evidence and hypotheses, to duplicate experiments, and to examine predictions arising from hypotheses.⁴² Merton's 'ethos of science' which entailed the principles of communalism,⁴³ universalism,⁴⁴ disinterestedness,⁴⁵ originality, and scepticism⁴⁶ promoted an open scientific environment in the 20th century.⁴⁷

While open science has been variously defined, it is commonly seen as 'the idea that scientific knowledge of all kinds should be openly shared as early as is practical in the discovery process'.⁴⁸ It aims to freely share research methods and results to foster collaboration and transparency for the benefit of the community as a whole.⁴⁹ A common definition of open science, as put forward by Maurer, is that it 'tends to connote (a) full, frank, and timely publication of results, (b) absence of intellectual property restrictions, and (c) radically increased pre- and post-publication transparency of data, activities, and deliberations within

³⁸ International Science Council op cit note 31 at 4; Marcus Hanwell 'What is open science?' *Open Source* available at <https://opensource.com/resources/open-science#:~:text=Open%20science%20arguably%20began%20in,such%20as%20the%20Royal%20Society>, accessed on 26 February 2022.

³⁹ International Science Council op cit note 31 at 4.

⁴⁰ Ibid at 4; Hanwell op cit note 38.

⁴¹ Hanwell op cit note 38.

⁴² International Science Council op cit note 31 at 4.

⁴³ Communalism entails sharing ideas, and should not be owned or subject to property rights. Megan Ristau Baca 'Barriers to innovation: Intellectual property transaction costs in scientific collaboration' (2006) 4 *Duke L & Tech Rev* 2; Krishna op cit note 36 at 2.

⁴⁴ Science should be open to all who are interested. Ristau Baca op cit note 43 at 2; Krishna op cit note 36 at 2.

⁴⁵ Ristau Baca op cit note 43 at 2; Krishna op cit note 36 at 2.

⁴⁶ Organised skepticism entails results undergoing peer-review. Ristau Baca op cit note 43 at 2; Krishna op cit note 36 at 2.

⁴⁷ Ristau Baca op cit note 43 at 2; Arul George Scaria & Rishika Rangarajan 'Fine-tuning the intellectual property approaches to fostering open science: Some insights from India' (2016) 8(1) *WIPOJ* 109; Krishna op cit note 36 at 2; Diana Rhoten & Walter W Powell 'The frontiers of intellectual property: Expanded protection versus new models of open science' (2007) 3 *Annu Rev Law Soc Sci* 347.

⁴⁸ Friesike et al op cit note 35 at 582.

⁴⁹ Adèle Strydom, Juanita Mellet, Jeanne Van Rensburg et al 'Open access and its potential impact on public health – A South African perspective' (2022) 7 *Front Res Metr Anal* 1.

research groups'.⁵⁰ Although the concept of open science is sometimes ambiguous,⁵¹ at the centre of open science is the idea that knowledge must be transparent and accessible and must be shared and developed through collaborative networks.⁵² Open science entails balancing scientific responsibility and scientific freedom.⁵³

Open science is characterised by certain features, such as open data, open access to literature, records, and data; open source; open peer-review; open access to research tools and digital infrastructures; open standards allowing diffusion of science; open engagement between scientists and others; and a means to obtain access.⁵⁴ At the heart of open science is the idea of returning to the central values introduced by early scientists that discoveries are published in order to allow results to be replicated and confirmed. Open science aims to empower all to partake in science, aided by the Internet which allows broad dissemination of knowledge.⁵⁵

Advancements in technology have transformed science by promoting openness. Open science stands apart from older practices where research publications were restricted to journal subscribers after publication.⁵⁶ Open science plays a crucial role in advancing research, innovation, and society by emphasising accessibility, collaboration, and transparency.⁵⁷ Through open science, sharing data, methods, and findings becomes easier, fostering greater accessibility and reproducibility in research.⁵⁸ This enhances scientific discovery, democratises

⁵⁰ Stephen M Maurer 'New institutions for doing science: From databases to open source biology' *European Policy for Intellectual Property Conference on Copyright and database protection, patents and research tools, and other challenges to the intellectual property system* (19 November 2003 University of Maastricht, The Netherlands) 4; Roberto Caso & Rossana Ducato 'Intellectual property, open science and research biobanks' (2014) *Trento Law and Technology Research Group Research Paper* 22 15.

⁵¹ It may be used: (1) as a research ideal, which advances 'transparency, accessibility, and collaboration'; (2) to define a scientific movement which furthers particular values, but primarily creates the structures and policies to bring about openness; or (3) to explain the policies to be applied in order to encourage openness. Manuela Fernández Pinto 'Open science for private Interests? How the logic of open science contributes to the commercialization of research' (2020) 5 *Front Res Metr Anal* 3.

⁵² Ruben Vicente-Saez & Clara Martinez-Fuentes 'Open Science now: A systematic literature review for an integrated definition' (2018) 88 *Journal of Business Research* 11.

⁵³ Holbrook op cit note 33.

⁵⁴ International Science Council op cit note 31 at 2; Krishna op cit note 36 at 3; Hanwell op cit note 38; Ed Levy, Emily Marden, Ben Warren et al 'Patent pools and genomics: Navigating a course to open science' (2010) 16 *BU J Sci & Tech L* 77.

⁵⁵ Hanwell op cit note 38.

⁵⁶ Friesike et al op cit note 35 at 582.

⁵⁷ Virginia Gewin 'Data sharing: An open mind on open data' (2016) 529 *Nature* 118. See also, Michael Nielsen *Reinventing Discovery: The New Era of Networked Science* (2011).

⁵⁸ Benedikt Fecher & Sascha Friesike 'Open science: One term, five schools of thought' in S Bartling (ed) *Opening Science* (2014) 20; Tom E Hardwicke, Maya B Mathur, Kyle MacDonald et al 'Data availability, reusability, and analytic reproducibility: Evaluating the impact of a mandatory open data policy at the journal *Cognition*' (2018) 5(8) *R Soc Open Sci* 15; Erin C McKiernan, Philip E Bourne, C Titus Brown et al 'How open science helps researchers succeed' (2016) 5 *Elife* 1; BA Nosek, G Alter, GC Banks et al 'Promoting an open research culture' (2015) 348 *Science* 1423.

access to knowledge, amplifies research impact, and boosts public trust in science.⁵⁹ However, it is important to distinguish open science from open access. Open access – as a practice of open science – is a set of principles and procedures that ensures research outputs are freely available, without cost or access barriers.⁶⁰ While open access focuses on making published work accessible, open science encompasses the entire scientific process, from data collection and analysis to publication and beyond.⁶¹

Open science has also found importance in health research. Health research has significantly advanced with the evolution of genome sequencing, particularly in genomics research and the utilisation of large datasets. The availability of health research data holds tremendous potential for improving population health outcomes, prompting calls for increased accessibility of datasets, materials, processes, protocols, findings, results, and software.⁶² While the concept of open science has been around for years and initially thrived in university research settings,⁶³ recent developments in intellectual property law and policies have exerted pressure on open science ideals, leading some research to become more commercialised and proprietary.⁶⁴ However, in health research (inclusive of genomics research), there is a strong push towards promoting open science. This is driven by the vast volumes of data generated in genomics research and the necessity for collaborative efforts to effectively analyse it.⁶⁵ Moreover, there is a growing recognition of the importance of reproducibility and transparency,⁶⁶ the potential of precision medicine,⁶⁷ and the opportunities for new discoveries facilitated by broader data access.⁶⁸ The collaborative and data-intensive nature of health and genomics research positions it as a leading advocate for open science.⁶⁹ Open science not only

⁵⁹ Fecher & Friesike op cit note 58 at 20; Hardwicke et al op cit note 58 at 15; McKiernan et al op cit note 58 at 1; Nosek et al op cit note 58 at 1423.

⁶⁰ DSI op cit note 22 at 5.

⁶¹ Christian Heise & Joshua M Pearce ‘From open access to open science: The path from scientific reality to open scientific communication’ (2020) *SAGE Open* 2.

⁶² Bobbie Spellman, Elizabeth Gilbert & Katherine S Corker ‘Open science: What, why, and how’ (2017) *PsyArXiv* 1; Rahul Ramachandran, Kaylin Bugbee & Kevin Murphy ‘From open data to open science’ (2021) 8 *Earth and Space Science* 2; Nishant Chakravorty, Chandra Shekhar Sharma, Kutubuddin A Molla et al ‘Open science: Challenges, possible solutions and the way forward’ (2022) 88 *Proc Indian Natl Sci Acad* 457.

⁶³ Ristau Baca op cit note 43 at 2; Scaria & Rangarajan op cit note 47 at 109; Krishna op cit note 36 at 2; Rhoten & Powell op cit note 47 at 347.

⁶⁴ Ristau Baca op cit note 43 at 2.

⁶⁵ International Human Genome Sequencing Consortium ‘Initial sequencing and analysis of the human genome’ (2001) 409 *Nature* 860–921.

⁶⁶ C Glenn Begley & Lee M Ellis ‘Raise standards for preclinical cancer research’ (2012) 483 *Nature* 532.

⁶⁷ Francis S Collins & Harold Varmus ‘A new initiative on precision medicine’ (2015) 372(9) *N Engl J Med* 793.

⁶⁸ JC Venter, MD Adams, EW Myers et al ‘The sequence of the human genome’ (2001) 291(5507) *Science* 1304–51.

⁶⁹ Martin Hetu, Konstantia Koutouki & Yann Joly ‘Genomics for all: International open science genomics projects and capacity building in the developing world’ (2019) 10 *Front Genet* 6; Ciara Staunton, Carlos Andrés Barragán,

accelerates research progress, but also reduces resource wastage,⁷⁰ allows scrutiny of research outputs,⁷¹ and enhances transparency, research integrity, and responsible use of genomic data.⁷²

(a) *Open science in South Africa*

Open science has been defined in South Africa in several government documents. Open science is referred to as ‘research and development that is collaborative, transparent and reproducible and whose outputs are publicly available’.⁷³ Open science has also been seen to denote ‘an approach to research based on greater access to public research data enabled by information and communications technology (ICT) tools and platforms, broader collaboration in science – including the participation of non-scientists – and the use of alternative copyright tools for diffusing research results’.⁷⁴ The African Open Science Platform (AOSP) acknowledges that while open science often focuses on open data and accessible publishing, this represents just a narrow perspective.⁷⁵ According to AOSP, open science should encompass more than scientists alone; it should be a collaborative effort involving the broader public, private businesses, policymakers, government entities, communities, and citizens. Together, these stakeholders engage with scientists to address societal challenges and explore solutions, emphasising a more inclusive and expansive approach to advancing scientific knowledge and its applications.⁷⁶

Open science has been actively promoted by the AOSP through various strategies and reports.⁷⁷ Additionally, open science is the focus of the DSI draft Open Science Policy,⁷⁸ which aims to democratise access to scientific knowledge. The draft Open Science Policy seeks to enhance the research landscape by making research outputs accessible, fostering economic development, and encouraging research collaboration.⁷⁹ The draft Open Science Policy is

Stefano Canali et al ‘Open science, data sharing and solidarity: Who benefits?’ (2021) 43(4) *Hist Philos Life Sci* 3.

⁷⁰ Rachel T Buxton, Elizabeth A Nyboer, Karine E Pigeon et al ‘Avoiding wasted research resources in conservation science’ (2021) 3 *Conservation Science and Practice* 8.

⁷¹ Lonni Besançon, Nathan Peiffer-Smadja, Corentin Segalas et al ‘Open science saves lives: Lessons from the COVID-19 pandemic’ (2021) 21 *BMC Med Res Methodol* 11.

⁷² Sean Grant, Kathleen E Wendt, Bonnie J Leadbeater et al ‘Transparent, open, and reproducible prevention science’ (2022) 23 *Prev Sci* 702; Tamarinde Haven, Gowri Gopalakrishna, Joeri Tjeldink et al ‘Promoting trust in research and researchers: How open science and research integrity are intertwined’ (2022) 15 *BMC Res Notes* 1.

⁷³ DSI op cit note 22 at 5.

⁷⁴ Department of Science and Technology (DST) *White Paper on Science, Technology and Innovation* (2019) vii.

⁷⁵ African Open Science Platform (AOSP) *The Future of Science and Science for the Future* (2023) 6.

⁷⁶ Ibid at 6; Amy Gooden ‘A pathway to strengthening open science: comments on the draft *South African Ethics in Health Research Guidelines*’ (2024) 15 *Front Pharmacol* 2.

⁷⁷ AOSP op cit note 75; Academy of Science of South Africa (ASSAf) *African Open Science Platform – Part 1: Landscape Study* (2019).

⁷⁸ DSI op cit note 22.

⁷⁹ Ibid at 9.

guided by principles such as findability, accessibility, reusability, transparency, responsibility, flexibility, and sustainability.⁸⁰ Moreover, open science is highlighted in the Department of Science and Technology (DST) *White Paper on Science, Technology and Innovation* (STI White Paper),⁸¹ where concepts like inclusivity, innovation culture, and policy coherence are introduced. These ideas are intended to advance science, technology, and innovation while tackling global challenges such as those posed by the Fourth Industrial Revolution.⁸² Open science is recognised as a means to promote collaborative, transdisciplinary approaches to knowledge development and to facilitate the dissemination of ideas and research findings.⁸³

Open science and related concepts, like open access and open data, are referenced in various government policies and strategies, presenting opportunities for the open sharing of information. Many of these policies and strategies do not provide specific guidance on open science, but instead advocate for the development of policies or frameworks to govern the field.⁸⁴ However, some documents offer more detailed objectives and principles concerning open science, including its facets of open access and open data. Below I examine five key government documents: (1) the Department of Telecommunications and Postal Services *National Integrated ICT Policy White Paper* (ICT Policy White Paper);⁸⁵ (2) the *National Policy on Data and Cloud*;⁸⁶ (3) the AOSP; (4) the STI White Paper; and (5) the draft Open Science Policy.⁸⁷ These documents provide varying levels of guidance and commitment to promoting open science principles within the broader context of national policies and strategies.

(i) *Department of Telecommunications and Postal Services National Integrated ICT Policy White Paper*

The ICT Policy White Paper aims to leverage Information and Communication Technologies (ICTs) as tools to combat poverty and inequality in South Africa.⁸⁸ A significant component of the ICT Policy White Paper is the promotion of open government and open data. This involves

⁸⁰ Ibid at 13.

⁸¹ DST op cit note 74.

⁸² Ibid at 40.

⁸³ Ibid at 52.

⁸⁴ Department of Telecommunications and Postal Services *National Integrated ICT Policy White Paper* (2016); Department of Science and Innovation (DSI) *Synthesis Report: South Africa Foresight Exercise for Science, Technology and Innovation 2030* (2019); DST op cit note 74.

⁸⁵ Department of Telecommunications and Postal Services op cit note 84.

⁸⁶ Department of Communications and Digital Technologies *National Policy on Data and Cloud* GG 50741 (2024).

⁸⁷ DSI op cit note 22.

⁸⁸ Department of Telecommunications and Postal Services op cit note 84 at 10.

ensuring that essential data is freely accessible while safeguarding privacy, confidentiality, and security.⁸⁹ The key principles for open data include: (1) making data openly accessible should be the standard practice, with due consideration to protecting individuals' rights to privacy and security; (2) data that is personal and confidential must be securely protected; (3) identified data should be freely available for redistribution, use, and re-use under specified conditions, including identification of the data source and redistribution under the same terms and conditions; (4) data must be available in the public domain without restriction and published in machine-readable formats that are non-proprietary; and (5) all data should be easily accessible and searchable to ensure transparency and usability.⁹⁰

(ii) *Department of Communications and Digital Technologies National Policy on Data and Cloud*

Recently, the Department of Communications and Digital Technologies released their final version of the National Policy on Data and Cloud,⁹¹ which replaced the 2021 draft version.⁹² The National Policy on Data and Cloud aims to foster conditions that support the use and supply of data and cloud services, aiming to drive socio-economic progress and ensure inclusiveness for all through inter alia: (1) promoting access to data and cloud services; (2) tackling government's long-term data storage and processing needs; (3) establishing governance frameworks for data and cloud services; and (4) supporting research, innovation, and human capital development.⁹³ One of the principles of the National Policy on Data and Cloud is the promotion of open data and data interoperability.⁹⁴ 'Open data' is defined as 'data that is made freely available to everyone for use, re-use and republishing as they wish, subject to ensuring the protection of privacy, confidentiality and security in line with the Constitution'.⁹⁵ The National Policy on Data and Cloud recognises that in order to benefit from the digital economy, it is essential to invest in broadband infrastructure, data centres, and related technologies like cloud computing. These investments must be backed by robust information technology (IT) security protocols, cybersecurity measures, and a structured data governance framework that upholds principles of open data.⁹⁶ Whereas the previous Draft National Policy on Data and

⁸⁹ Ibid at 115.

⁹⁰ Ibid at 116.

⁹¹ Department of Communications and Digital Technologies op cit note 86.

⁹² Department of Communications and Digital Technologies *Draft National Policy on Data and Cloud* GN 306 GG 44389 (2021).

⁹³ Department of Communications and Digital Technologies op cit note 86 at 16.

⁹⁴ Ibid at 5.

⁹⁵ Ibid at 42.

⁹⁶ Ibid at 7.

Cloud recognised a need for an open data strategy in South Africa, guided by principles like ‘Data for Good’, to ensure data accessibility is maximised,⁹⁷ the current National Policy on Data and Cloud simply mentions that an open data framework will be established to ensure that small and medium-sized enterprises (SMMEs), startups, citizens, and industry participants can access government data that is timely, accurate, complete, consistent, and valid. Access to this data will adhere to current data protection laws and regulations to safeguard privacy and security.⁹⁸

(iii) The African Open Science Platform

The AOSP recognises the imperative for the shift towards open science.⁹⁹ To support this transition, the AOSP proposes establishing an African Open Science Platform, aimed at equipping African scientists with resources and principles for embracing open science. This initiative seeks to promote scientific excellence and facilitate the practical application of scientific knowledge across various sectors. The AOSP envisions a platform that encourages data-driven research focused on solving real-world problems, fostering collaboration among scientists and non-scientists through open networks. Through such collaboration, the AOSP aims to generate practical knowledge, enhance the credibility and relevance of scientific endeavours, and elevate their socio-political impact in Africa.¹⁰⁰ The AOSP outlines three main objectives: (1) to map existing data and science initiatives across Africa; (2) to establish a Pan-African community dedicated to open science; and (3) to develop frameworks that will guide the operations of the Platform.¹⁰¹ Recognising that successful scientific communities require diversity and collaboration on a large scale, the AOSP advocates for a Pan-African approach. It emphasises Africa’s diversity as a strength that should be leveraged to realise its full scientific potential. According to the AOSP, pursuing individualistic approaches to science in Africa, particularly where scientific communities are small and underfunded, would be a missed opportunity.¹⁰²

(iv) Department of Science and Technology White Paper on Science, Technology and Innovation

⁹⁷ Department of Communications and Digital Technologies op cit note 92 at 21.

⁹⁸ Department of Communications and Digital Technologies op cit note 86 at 23.

⁹⁹ AOSP op cit note 75 at 6.

¹⁰⁰ Ibid at 7.

¹⁰¹ Ibid at 2.

¹⁰² Ibid at 8.

One of the main goals outlined in the STI White Paper is to ensure that South Africa's knowledge system is open, diverse, and adaptable.¹⁰³ The STI White Paper recognises the value of transdisciplinary knowledge and emphasises the importance of data-driven research. The STI White Paper identifies open science as a means to increase access to existing information and facilitate collaborative, transdisciplinary approaches to knowledge development.¹⁰⁴ However, transitioning to open science requires the establishment of appropriate regulatory frameworks and the development of data skills.¹⁰⁵ To promote open science in South Africa, the STI White Paper outlines several measures. These include: (1) promoting incentives for open science through educational initiatives and career development programs for researchers; (2) identifying (and removing) barriers to open science, and ensuring that legislation and practices support open science principles; (3) reviewing policies and institutional frameworks governing access to research data and publications, and encouraging researchers to share their data in public repositories and publish in open access journals; (4) establishing a licensing system for depositing and using open data; (5) respecting data providers by defining who can access the data, and under what conditions; (6) re-evaluating intellectual property laws to align with the FAIR (Findable, Accessible, Interoperable, and Reusable) principles for managing and storing data; (7) developing a model for data storage and cloud computing; and (8) harmonising data repositories.¹⁰⁶ The STI White Paper intends to develop a framework containing guidelines and principles for open science in South Africa.¹⁰⁷ This resulted in the Draft Open Science Policy.

(v) *The Department of Science and Innovation Draft National Open Science Policy*

The Draft Open Science Policy outlines essential principles to guide the practice of open science in South Africa.¹⁰⁸ These principles are grounded in the following core values: (1) ensuring quality and integrity through transparency, critique, and reproducibility; (2) promoting equity, fairness, and collective benefits from scientific endeavours; and (3) fostering diversity, collaboration, and inclusiveness in research practices.¹⁰⁹ Moreover, the Draft Open Science Policy provides specific guidelines for implementing open science in South Africa. These include: (1) ensuring that publicly funded data and research results adhere to the FAIR

¹⁰³ DST op cit note 74 at 45.

¹⁰⁴ Ibid at 16.

¹⁰⁵ Ibid at 52.

¹⁰⁶ Ibid at 52.

¹⁰⁷ Ibid at 53.

¹⁰⁸ DSI op cit note 22 at 12–3.

¹⁰⁹ Ibid at 12–3.

principles – making them findable, accessible, interoperable, and reusable; (2) applying the CARE principles (cognisance of collective benefit, authority to control, responsibility, and ethics) – emphasising ethical considerations and responsible research conduct that benefit society and avoid exploitation; (3) upholding the TRUST principles (transparency, responsibility, user community, sustainability, and technology) when evaluating, developing, and maintaining the trustworthiness of data repositories; (4) adopting a flexible approach to open science that considers local contexts; (5) establishing financial and operational sustainability for long-term viability of the open science model; and (6) following the principle of ‘as open as possible, as closed as necessary’, where research outputs are openly accessible unless justified by significant risks.¹¹⁰

Based on the above, it is essentially only the Draft Open Science Policy that explicitly provides guidelines for open science in South Africa. Considering the importance of open science, it would be reasonable to assume it is prominently addressed in government documents. However, in South Africa there has been a noticeable absence of emphasis on open science in several recent and pertinent publications. For example, the National Policy on Data and Cloud,¹¹¹ the proposed *POPIA Code of Conduct for Research*,¹¹² the draft POPIA Compliance Framework,¹¹³ the Bio-Economy Strategy,¹¹⁴ and the NHREC Ethics Guidelines¹¹⁵ do not include substantial discussions or provisions related to open science.¹¹⁶ This reflects a gap in acknowledging and integrating open science principles into these important policy and strategy frameworks in the country.

(b) Open science and the right to freedom of scientific research

Freedom of scientific research has been seen to represent inter alia openness, diversity, integrity, exchange, equality and responsibility¹¹⁷ – all terms that align it with open science. According to the United Nations (UN), open science is integral to the right to science in today’s

¹¹⁰ Ibid at 13.

¹¹¹ Department of Communications and Digital Technologies op cit note 92.

¹¹² Academy of Science of South Africa (ASSAf) *POPIA [proposed] Code of Conduct for Research* (2023) GG 48589 of 12 May 2023.

¹¹³ Academy of Science of South Africa (ASSAf) *POPIA Compliance Framework for Researchers and Research Institutions* [draft] (2024).

¹¹⁴ Department of Science and Technology (DST) *Bio-Economy Strategy* (2013).

¹¹⁵ National Department of Health op cit note 6.

¹¹⁶ Gooden op cit note 76 at ‘3.

¹¹⁷ Bundesministerium für Bildung und Forschung op cit note 4 at 2.

digital age.¹¹⁸ Given this, the right to freedom of scientific research can be seen to be facilitated by open science.

Open science not only upholds the freedom to conduct scientific research by making knowledge more accessible and transparent, but it also relies on this freedom for its own existence. Restricting the sharing of research findings would violate the right to freedom of scientific research and undermine the principles of open science.¹¹⁹ However, it is also imperative that, when exercising their right to freedom of scientific research, researchers and scientists uphold their standards of research in order to ensure that open science is promoted in a fair and accurate way.¹²⁰

But because the right to freedom of scientific research has received little attention in South Africa, is there a possibility of relying on other related rights to determine its meaning and purpose? The answer may be found in the right to freedom of expression.

V FREEDOM OF EXPRESSION

The right to freedom of scientific research falls under the ambit of the broader right to freedom of expression in terms of section 16 of the Constitution.¹²¹ Thus, freedom of expression is inclusive of the right to freedom of scientific research. Although there is a lack of guidance in South African jurisprudence regarding the right to freedom of scientific research, the right to freedom of expression has appeared in case law. Therefore, it is worth examining South African case law on freedom of expression in order to guide the purpose of the right to freedom of scientific research. Examining the meaning and purpose of the right to freedom of expression may shed some light on the purpose of the right to freedom of scientific research.

(a) *The history of the right to freedom of expression*

Prior to the Constitution, the right to freedom of expression existed in the common law.¹²² However, under the apartheid regime in South Africa, freedom of expression was severely

¹¹⁸ Raffaella Kunz & Monika Plozza 'Claiming open science via human rights? An analysis of General Comment No. 25 on science and human rights' *Frontiers Policy Labs* available at <https://policylabs.frontiersin.org/content/commentary-claiming-open-science-via-human-rights>, accessed on 24 May 2024; United Nations (UN) Committee on Economic, Social and Cultural Rights *General Comment No. 25 on Science and Economic, Social and Cultural Rights (Article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights)* (67th session, 2020).

¹¹⁹ Donrich Thaldar, Amy Gooden & Michaela Steytler 'Open science and human genetic data: Recommendations on South Africa's *Draft National Open Science Policy*' (2023) 14 *Front Genet* 3.

¹²⁰ Bundesministerium für Bildung und Forschung op cit note 4 at 2.

¹²¹ Section 16(1) of the Constitution.

¹²² *Phillips v Director of Public Prosecutions* 2003 (3) SA 345 (CC) para 27.

restricted. This was done in order to achieve a degree of thought control, which helped to maintain apartheid and enforce a value system created by a minority on all South Africans.¹²³ Various laws severely restricted expression, particularly political and artistic expression. These restrictions not only undermined democracy, but also worsened the effects of other human rights abuses in South Africa.¹²⁴ The Constitutional Court, in *Economic Freedom Fighters v Minister of Justice and Correctional Services*,¹²⁵ summarises it as follows:

‘[E]xpression was so extensively and severely circumscribed that a person could be arrested, banned, banished or even killed by the apartheid regime for labelling as unjust, what everyone now accepts is unjust. Inciting people to protest against apartheid – a crime against humanity – or to break its unjust laws, was not only criminalised but could also attract untold consequences. Thought control or enforced conformity was virtually institutionalised. Free expression is thus a right or freedom so dear to us and critical to our democracy and healing the divisions of our past, that it ought not to be interfered with lightly – especially where no risk of serious harm or danger exists’.¹²⁶

With the rise of South Africa’s new democracy, freedom of expression is a constitutional right that is viewed as being worthy of protection:

‘Those restrictions would be incompatible with South Africa’s present commitment to a society based on a “constitutionally protected culture of openness and democracy and universal human rights for South Africans of all ages, classes and colours”’.¹²⁷

Section 16(2) of the Constitution – which contains the right to freedom of expression – has been viewed as defining the instances in which the right to freedom of expression is protected. In this way, section 16(2) of the Constitution ‘defines the boundaries beyond which the right to freedom of expression does not extend’.¹²⁸ Where expression is ‘repulsive, degrading,

¹²³ Ibid at para 23.

¹²⁴ Ibid at para 27.

¹²⁵ 2021 (2) SA 1 (CC).

¹²⁶ *Economic Freedom Fighters v Minister of Justice and Correctional Services* 2021 (2) SA 1 (CC) para 42.

¹²⁷ *Phillips v Director of Public Prosecutions* supra note 122 at para 27.

¹²⁸ *Islamic Unity Convention v Independent Broadcasting Authority (Islamic Unity Convention)* 2002 (4) SA 294 (CC) para 30. Also cited in *Economic Freedom Fighters v Minister of Justice and Correctional Services* supra note 126 at para 31.

offensive or unacceptable’,¹²⁹ or it ‘has the potential to impinge adversely on the dignity of others and cause harm’,¹³⁰ then such expressions are not worthy of constitutional protection.¹³¹

Although the meaning of freedom of expression has not been explicitly provided, several cases have attempted to define it for the purpose of providing clarity to the term. In *S v Mamabolo*,¹³² freedom of expression was defined as ‘the free and open exchange of ideas’.¹³³ *Print Media South Africa v Minister of Home Affairs*¹³⁴ expanded on the right to freedom of expression as follows:

‘Embraced by the right is the liberty to express and to receive information or ideas freely. The right also encompasses the freedom to form one’s own opinion about expression received, and in this way both promotes and protects the moral agency of individuals. Whether expression lies at the right’s core or margins, be it of renown or notoriety, however essential or inconsequential it may be to democracy, the right cognises an elemental truth that it is human to communicate, and to that fact the law’s support is owed’.¹³⁵

From the above, it is clear that the right to freedom of expression is central in South Africa’s democracy. The right to freedom of expression should not be undermined and, as such, it should only be used where a serious risk of harm is present. The right to freedom of expression allows ideas to be shared openly. The right to freedom of expression allows both the unhampered expression and receiving of ideas and thoughts, as well as the liberty to form individual opinions on such ideas and thoughts. This freedom to independently form opinions shares links with autonomy (as discussed in Chapter 3), and it can thus be said that the right to freedom of expression allows for the promotion and protection of autonomy.

(b) The link between the right to freedom of expression and other rights

The right to freedom of expression is not a standalone right. It is informed by various other constitutional rights and values, including human dignity, equality, and freedom. In line with

¹²⁹ *Phillips v Director of Public Prosecutions* supra note 122 at para 17.

¹³⁰ *Islamic Unity Convention* supra note 128 at para 30. Also cited in *Economic Freedom Fighters v Minister of Justice and Correctional Services* supra note 126 at para 31.

¹³¹ *Islamic Unity Convention* supra note 128 at para 30. Also cited in *Economic Freedom Fighters v Minister of Justice and Correctional Services* supra note 126 at para 31.

¹³² 2001 (3) SA 409 (CC).

¹³³ *S v Mamabolo* 2001 (3) SA 409 (CC) para 37.

¹³⁴ 2012 (6) SA 443 (CC).

¹³⁵ *Print Media South Africa v Minister of Home Affairs* 2012 (6) SA 443 (CC) para 53.

this, in *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International (Laugh It Off)*,¹³⁶ the Constitutional Court held that:

‘[F]reedom of expression is a vital incidence of dignity, equal worth and freedom. It carries its own inherent worth and serves a collection of other intertwined constitutional ends in an open and democratic society’.¹³⁷

In *South African National Defence Union v Minister of Defence*,¹³⁸ the Constitutional Court referred to *Case*, where Mokgoro J purportedly referred to freedom of expression as ‘one of a “web of mutually supporting rights” in the Constitution’.¹³⁹ While Mokgoro J did indeed mention in *Case* a ‘web of mutually supporting rights enumerated in the Constitution’,¹⁴⁰ this was in reference to section 15 of the Constitution, which deals with freedom of religion, belief, and opinion – and not section 16 of the Constitution, which concerns freedom of expression. Therefore, the Constitutional Court, in *South African National Defence Union v Minister of Defence*,¹⁴¹ is incorrect in referring to freedom of expression as being part of a “web of mutually supporting rights” in the Constitution’.¹⁴² As such, it is technically incorrect to refer to this ‘web of mutually supporting rights’ in relation to the right to freedom of expression, and it should rather be referred to in terms of freedom of religion, belief, and opinion. However, the Constitutional Court went on to hold that freedom of expression:

‘...is closely related to freedom of religion, belief and opinion (section 15), the right to dignity (section 10), as well as the right to freedom of association (section 18), the right to vote and to stand for public office (section 19) and the right to assembly (section 17)...The rights implicitly recognise the importance, both for a democratic society and for individuals personally, of the

¹³⁶ 2006 (1) SA 144 (CC).

¹³⁷ *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International (Laugh It Off)* 2006 (1) SA 144 (CC) para 45. This was also cited in *South African Broadcasting Corporation Limited v National Director of Public Prosecutions (SABC v NDPP)* 2007 (1) SA 523 (CC) para 121.

¹³⁸ 1999 (4) SA 469 (CC).

¹³⁹ *South African National Defence Union v Minister of Defence* 1999 (4) SA 469 (CC) para 8.

¹⁴⁰ *Case v Minister of Safety and Security, Curtis v Minister of Safety and Security (Case)* 1996 (3) SA 617 (CC) para 27.

¹⁴¹ 1999 (4) SA 469 (CC).

¹⁴² *South African National Defence Union v Minister of Defence* supra note 139 at para 8.

ability to form and express opinions, whether individually or collectively, even where those views are controversial'.¹⁴³

Despite the apparent error made in *South African National Defence Union v Minister of Defence*,¹⁴⁴ it does seem that the right to freedom of expression links to other constitutional rights and values – such as the right to dignity,¹⁴⁵ the right to freedom of religion, belief, and opinion, the right to assembly, the right to freedom of association, and the right to vote and stand for public office.¹⁴⁶

Although much importance has been placed on the right to freedom of expression in South Africa's democracy, the courts have recognised that the right to freedom of expression is not supreme¹⁴⁷ – 'freedom of expression does not enjoy superior status in our law'.¹⁴⁸ Instead, it 'must be construed in the context of the other values enshrined in our Constitution'.¹⁴⁹ However, the way in which the courts have defined the right to freedom of expression underscores its crucial importance to democracy. Without the right to freedom of expression, other rights may be compromised or diminished.¹⁵⁰

It is now clear that the right to freedom of expression links to other constitutional rights and values and plays an important role in South Africa's democracy. But what possible purposes does the right to freedom of expression serve? In the headings below, I examine South African case law relating to the right to freedom of expression in order to determine the purposes of the right to freedom of expression.

(c) *The search for truth and the exercise of autonomy*

One of the earliest references to the right to freedom of expression in South African case law is *Case v Minister of Safety and Security*, *Curtis v Minister of Safety and Security (Case)*.¹⁵¹ In

¹⁴³ *South African National Defence Union v Minister of Defence* supra note 139 at para 8. This was also cited in *Islamic Unity Convention* supra note 128 at para 24 and *Phillips v Director of Public Prosecutions* supra note 122 at para 23.

¹⁴⁴ 1999 (4) SA 469 (CC).

¹⁴⁵ *South African National Defence Union v Minister of Defence* supra note 139 at para 8. See also, *The Citizen 1978 (Pty) Ltd v McBride (Citizen v McBride)* 2011 (4) SA 191 (CC) para 143.

¹⁴⁶ *South African National Defence Union v Minister of Defence* supra note 139 at para 8.

¹⁴⁷ *Khumalo v Holomisa* 2002 (5) SA 401 (CC) para 25. This was also cited in *Democratic Alliance v African National Congress* 2015 (2) SA 232 (CC) para 46. See also, *S v Mamabolo* supra note 133 at para 41; *Citizen v McBride* supra note 145 at para 148.

¹⁴⁸ *S v Mamabolo* supra note 133 at para 41. This was also cited in *Citizen v McBride* supra note 145 at para 148.

¹⁴⁹ *Khumalo v Holomisa* supra note 147 at para 25. This was also cited in *Democratic Alliance v African National Congress* supra note 147 at para 46.

¹⁵⁰ *Mail and Guardian Media Ltd v Chipu NO* 2013 (6) SA 367 (CC) para 51.

¹⁵¹ 1996 (3) SA 617 (CC).

this case, the Constitutional Court expressly referred to the ‘foundational purposes for the existence of the right to freedom of expression’,¹⁵² and held that:

‘The most commonly cited rationale is that the search for truth is best facilitated in a free “marketplace of ideas.” That obviously presupposes that both the supply and the demand side of the market will be unfettered. But of more relevance here than this “marketplace” conception of the role of free speech is the consideration that freedom of speech is a sine qua non for every person’s right to realise her or his full potential as a human being, free of the imposition of heteronomous power. Viewed in that light, the right to receive others’ expressions has more than merely instrumental utility, as a predicate for the addressee’s meaningful exercise of her or his own rights of free expression. It is also foundational to each individual’s empowerment to autonomous self-development’.¹⁵³

From this paragraph, two important purposes of the right to freedom of expression can be extracted. The first is the search for truth. The second, and more important, is the exercise of autonomy.¹⁵⁴

(i) *The search for truth*

According to Thaldar and Steytler, ‘[f]reedom of expression is indispensable for the attainment of truth’.¹⁵⁵ In South African jurisprudence, the search for truth has been recognised as one of the purposes of the right to freedom of expression.¹⁵⁶ In the concurring judgment of Van Der Westhuizen J in *Print Media South Africa v Minister of Home Affairs*,¹⁵⁷ one of the reasons as to why freedom of expression is worthy of protection is the search for truth.¹⁵⁸ Additionally, in the recent case of *United Democratic Movement v Lebashe Investment Group (Pty) Ltd*,¹⁵⁹ it was held that the right to freedom of expression is crucial in helping both individuals and society to discover the truth.¹⁶⁰ The idea that the right to freedom of expression is vital in

¹⁵² *Case* supra note 140 at para 26.

¹⁵³ *Ibid* at para 26.

¹⁵⁴ *Ibid* at para 26.

¹⁵⁵ Thaldar & Steytler op cit note 30 at 276.

¹⁵⁶ *Case* supra note 140 at para 26; *SABC v NDPP* supra note 137 at para 23; *Citizen v McBride* supra note 145 at para 82; *Print Media South Africa v Minister of Home Affairs* supra note 135 at para 93; *Democratic Alliance v African National Congress* supra note 147 at paras 122–3; *Economic Freedom Fighters v Minister of Justice and Constitutional Development*; *Economic Freedom Fighters v Minister of Justice and Constitutional Development (EFF v Minister of Justice and Constitutional Development)* 2019 (2) SACR 297 (GP) para 36; *United Democratic Movement v Lebashe Investment Group (Pty) Ltd* 2023 (1) SA 353 (CC) para 65; *Reddell v Mineral Sands Resources (Pty) Ltd* 2023 (2) SA 404 (CC) para 103.

¹⁵⁷ 2012 (6) SA 443 (CC).

¹⁵⁸ *Print Media South Africa v Minister of Home Affairs* supra note 135 at para 93.

¹⁵⁹ 2023 (1) SA 353 (CC).

¹⁶⁰ *United Democratic Movement v Lebashe Investment Group (Pty) Ltd* supra note 156 at para 65. This was also provided for in *Democratic Alliance v African National Congress* supra note 147 at para 122.

‘facilitating the search for truth by individuals and society generally’ has been repeated in many judgments¹⁶¹— this emphasis shows the importance of this phrase in a democratic South Africa. Individuals must be allowed to freely listen to, create, and air views and opinions on a range of matters.¹⁶²

From this, it follows that censorship hinders the pursuit of truth. When individuals are prevented from expressing their opinions, it affects not only them but also their opponents, as well as present and future generations. This is because if the silenced opinion is accurate, opponents miss the chance to correct their mistakes. Conversely, if the silenced opinion is incorrect, its holders lose the opportunity to discover the truth through counter-arguments. Therefore, restricting freedom of expression disrupts the search for truth.¹⁶³ This idea was recognised in *Democratic Alliance v African National Congress*,¹⁶⁴ where it held that ‘[i]f society represses views, it considers unacceptable, they may never be exposed as wrong’.¹⁶⁵

Open and unrestricted debate has been viewed by the courts as a means to enhance truth-finding,¹⁶⁶ as it allows for the critical examination of political arguments and the consideration of social values.¹⁶⁷ In *The Citizen 1978 (Pty) Ltd v McBride*,¹⁶⁸ the Constitutional Court cited in the United States Supreme Court case of *Whitney v California*,¹⁶⁹ in providing for the constitutional recognition of the right to freedom of expression:

‘[F]reedom to think as you will and to speak as you think are means indispensable to the discovery and spread of political truth;...that the greatest menace to freedom is an inert people;

¹⁶¹ For example, see *South African National Defence Union v Minister of Defence* supra note 139 at para 7; *Islamic Unity Convention* supra note 128 at para 24; *SABC v NDPP* supra note 137 at para 23; *Democratic Alliance v African National Congress* supra note 147 at paras 122–3; *United Democratic Movement v Lebashe Investment Group (Pty) Ltd* supra note 156 at para 65; *Reddell v Mineral Sands Resources (Pty) Ltd* supra note 156 at para 103.

¹⁶² *SABC v NDPP* supra note 137 at para 23; *United Democratic Movement v Lebashe Investment Group (Pty) Ltd* supra note 156 at para 65.

¹⁶³ Thaldar & Steytler op cit note 30 at 276.

¹⁶⁴ 2015 (2) SA 232 (CC).

¹⁶⁵ *Democratic Alliance v African National Congress* supra note 147 at paras 122–3. This was also cited in *Reddell v Mineral Sands Resources (Pty) Ltd* supra note 156 at para 103.

¹⁶⁶ *Citizen v McBride* supra note 145 at para 82; *Democratic Alliance v African National Congress* supra note 147 at paras 122–3; *EFF v Minister of Justice and Constitutional Development* supra note 156 at para 36; *Reddell v Mineral Sands Resources (Pty) Ltd* supra note 156 at para 103.

¹⁶⁷ *Citizen v McBride* supra note 145 at para 82; *Democratic Alliance v African National Congress* supra note 147 at paras 122–3; *EFF v Minister of Justice and Constitutional Development* supra note 156 at para 36; *Reddell v Mineral Sands Resources (Pty) Ltd* supra note 156 at para 103.

¹⁶⁸ 2011 (4) SA 191 (CC).

¹⁶⁹ 274 US 357 (1927).

that public discussion is a political duty; and that this should be a fundamental principle of [our] government'.¹⁷⁰

The right to freedom of expression is also seen as central in political debate.¹⁷¹ It plays a vital role in safeguarding democracy by keeping citizens informed, fostering debate, and uncovering incompetence and poor governance.¹⁷² Democracy flourishes when both political figures and the public can express themselves without restraint.¹⁷³ This openness fosters the debate of ideas, including those that are contentious, unpopular, or challenge the interests of those in power.¹⁷⁴ The suppression of robust political debate would infringe, amongst others, the right to freedom of expression¹⁷⁵ – and this would, in turn, affect the search for truth.

From these judgments, it is clear that the truth is important in a democracy and is one of the purposes underlying the right to freedom of expression. Given that the search for truth (through the right to freedom of expression) positively benefits both individuals and society, it follows that limiting the right to freedom of expression compromises the search for truth.¹⁷⁶

(ii) *The exercise of autonomy*

As autonomy has already been dealt with extensively in Chapter 3, it would be redundant to repeat information here. However, where autonomy is relevant to the right to freedom of expression, it is highlighted. Autonomy is seen to be promoted by the right to freedom of expression. In *Khumalo v Holomisa*,¹⁷⁷ it was recognised that freedom of expression is 'constitutive of the dignity and autonomy of human beings'.¹⁷⁸ Moreover, having the ability to speak freely forms part of what it is to be individually human, as well as acknowledges and safeguards 'the moral agency of individuals in our society'.¹⁷⁹

The right to freedom of expression is important to democracy, but also to individual development as it allows the formation and sharing of opinions, which strengthens autonomy and human dignity.¹⁸⁰ Understanding how freedom of expression supports individual moral

¹⁷⁰ *Whitney v California* 274 US 357 (1927) at 375 cited in *Citizen v McBride* supra note 145 at para 142.

¹⁷¹ See, *EFF v Minister of Justice and Constitutional Development* supra note 156 at para 36.

¹⁷² *Democratic Alliance v African National Congress* supra note 147 at para 122.

¹⁷³ *EFF v Minister of Justice and Constitutional Development* supra note 156 at para 36.

¹⁷⁴ *Ibid* at para 36.

¹⁷⁵ *Ibid* at para 36.

¹⁷⁶ Thaldar & Steytler op cit note 30 at 276.

¹⁷⁷ 2002 (5) SA 401 (CC).

¹⁷⁸ *Khumalo v Holomisa* supra note 147 at para 21. This was also cited in *Qwelane v South African Human Rights Commission (Qwelane)* 2021 (6) SA 579 (CC) para 54.

¹⁷⁹ *Democratic Alliance v African National Congress* supra note 147 at para 123.

¹⁸⁰ *NM v Smith* 2007 (5) SA 250 (CC) para 145.

autonomy highlights its strong connection with other constitutional rights like human dignity, privacy, and freedom.¹⁸¹ Significantly, in *NM v Smith*,¹⁸² it was held that ‘[u]nderlying all these constitutional rights is the constitutional celebration of the possibility of morally autonomous human beings independently able to form opinions and act on them’.¹⁸³ Following this, O’Regan J quoted,¹⁸⁴ with approval, Scanlon’s essay on freedom of expression,¹⁸⁵ where it was stated that an autonomous person:

‘[C]annot accept without independent consideration the judgment of others as to what he should believe or what he should do. He may rely on the judgment of others, but when he does so he must be prepared to advance independent reasons for thinking their judgment likely to be correct, and to weigh the evidential value of their opinion against contrary evidence’.¹⁸⁶

Following this, O’Regan J held that freedom of expression is crucial to the promotion of the autonomy of individuals as viewed by Scanlon.¹⁸⁷

In South African jurisprudence, it is clear that autonomy is an important purpose that underlies the right to freedom of expression. Interestingly, when autonomy is discussed in relation to the right to freedom of expression, it is often done so through the lens of the individual – and therefore it follows a more atomistic idea of autonomy. This is unlike how autonomy in general has been developed by the courts over the years in the sense that it is now viewed as being more communal in nature¹⁸⁸ – and in line with Ubuntu.¹⁸⁹ This could be explained by the fact that the expression of opinions tends to be done by individuals. Yet, this does not mean that there is no room for group opinions. Because the Constitutional Court has linked the right to freedom of expression with other rights, such as the right to freedom of association and the right to assembly¹⁹⁰ – which are both group rights by their nature – the ability to fully exercise the right to freedom of expression can be strengthened by group

¹⁸¹ Ibid at para 145.

¹⁸² 2007 (5) SA 250 (CC).

¹⁸³ *NM v Smith* supra note 180 at para 145.

¹⁸⁴ Ibid at para 145.

¹⁸⁵ Thomas Scanlon ‘A theory of freedom of expression’ (1972) 1 *Philosophy and Public Affairs* 216.

¹⁸⁶ *NM v Smith* supra note 180 at para 145. This was also cited in *AB v Minister of Social Development As Amicus Curiae: Centre for Child Law* 2016 (2) SA 27 (GP) para 65.

¹⁸⁷ *NM v Smith* supra note 180 at para 146.

¹⁸⁸ See, *AB v Minister of Social Development* 2017 (3) SA 570 (CC) para 51; *Member of the Executive Council for Education: KwaZulu-Natal v Pillay* 2008 (1) SA 474 (CC) para 53; *Shoprite Checkers (Pty) Limited v Member of the Executive Council for Economic Development, Environmental Affairs and Tourism, Eastern Cape* 2015 (6) SA 125 (CC) para 47; *South African Police Service v Solidarity obo Barnard* 2014 (6) SA 123 (CC) para 174; *Port Elizabeth Municipality v Various Occupiers* 2005 (1) SA 217 (CC) para 37.

¹⁸⁹ *AB v Minister of Social Development* supra note 188 at para 51.

¹⁹⁰ Sections 18 and 17 of the Constitution respectively. This was cited in *South African National Defence Union v Minister of Defence* supra note 139 at para 8 and *Democratic Alliance v African National Congress* supra note 147 at para 125.

association.¹⁹¹ These rights safeguard individuals' ability to form and share opinions, as well as to 'establish associations and groups of like-minded people to foster and propagate their views'.¹⁹² These rights acknowledge the value of being able to form and express opinions, whether alone or with others, even if those opinions are controversial, for both the functioning of a democratic society and for individuals personally.¹⁹³

However, the converse may also be true, and may result in an adverse situation. The right to freedom of expression may be used to air views and opinions about a particular group – some of which may be negative. This may harm the group identity, as well as their 'dignity, social standing and assurance against exclusion, hostility, discrimination and violence',¹⁹⁴ and could even constitute hate speech.¹⁹⁵ In *Qwelane v South African Human Rights Commission (Qwelane)*,¹⁹⁶ it was held that:

'[H]ate speech marginalises and delegitimises individuals based on their membership of a group. This may diminish their social standing in the broader society, outside of the group they identify with...Not only does it wound the individuals who share this group identity, but it seeks to undo the very fabric of our society as envisioned by our Constitution'.¹⁹⁷

The right to freedom of expression plays a pivotal role in supporting and enhancing individual autonomy, which is integral to both personal development and democratic values. It is evident from South African jurisprudence that the right to freedom of expression is fundamental to upholding autonomy, as it allows individuals to form and share their own opinions. However, while the right to freedom of expression is crucial for individual and societal development, it also has potential downsides. It can be misused to express harmful or discriminatory views that negatively impact group identities and societal cohesion. Thus, while the right to freedom of expression is essential for fostering autonomy and democracy, it must be balanced with

¹⁹¹ *Pilane v Pilane* 2013 (4) BCLR 431 (CC) para 69.

¹⁹² *Democratic Alliance v African National Congress* supra note 147 at para 125; *South African National Defence Union v Minister of Defence* supra note 139 at para 8.

¹⁹³ *South African National Defence Union v Minister of Defence* supra note 139 at para 8.

¹⁹⁴ *Qwelane* supra note 178 at para 118.

¹⁹⁵ For a brief explanation of hate speech, see *Qwelane* supra note 178 at para 1.

¹⁹⁶ 2021 (6) SA 579 (CC).

¹⁹⁷ *Qwelane* supra note 178 at paras 1 & 129.

protections against hate speech and other forms of harmful expression to ensure it does not undermine the very principles it aims to uphold.

(d) *The promotion of democracy*

South Africa is a democratic society that is based on ‘human dignity, equality and freedom’.¹⁹⁸ Democracy extends beyond merely casting a vote in an election, and is inclusive of values like accountability, informed decision-making, participation in public life, and transparency.¹⁹⁹ The promotion of democracy requires freedom of expression.²⁰⁰ Democracy relies on the right to freedom of expression because it ensures that citizens can freely voice their opinions, participate in political discussions, hold leaders accountable, and make informed decisions.²⁰¹ This freedom allows for a diversity of viewpoints, promotes transparency in governance, and guards against authoritarian tendencies by empowering individuals to challenge and debate ideas openly.²⁰² Without freedom of expression, democracy would struggle to function effectively as it depends on the active participation of the people.²⁰³

The importance of the right to freedom of expression in South Africa’s democracy has been emphasised through the courts.²⁰⁴ Freedom of expression has been seen as being ‘of the utmost importance in the kind of open and democratic society the Constitution has set as our aspirational norm’.²⁰⁵ The Constitutional Court, in *South African National Defence Union v*

¹⁹⁸ Section 7(1) of the Constitution.

¹⁹⁹ Thaldar & Steytler op cit note 30 at 278.

²⁰⁰ Ibid at 278.

²⁰¹ Laura Neuman (ed) *Access to Information: A Key to Democracy* (2002) 5.

²⁰² Dominika Bychawska-Siniarska *Protecting the Right to Freedom of Expression under the European Convention on Human Rights: A Handbook for Legal Practitioners* (2017) 12; Centre for Law and Democracy International Media Support (IMS) *Briefing Note Series: Freedom of Expression* (2014) 2; Human Rights Guide ‘Freedom of expression’ 22 January 2024 available at <https://www.rights.in.ua/en/rights/freedom-of-expression>, accessed on 5 March 2024; Neuman op cit note 201 at 5.

²⁰³ Bychawska-Siniarska op cit note 202 at 12; Centre for Law and Democracy International Media Support (IMS) op cit note 202 at 2; Human Rights Guide op cit note 202; Neuman op cit note 201 at 5.

²⁰⁴ *South African National Defence Union v Minister of Defence* supra note 139; *Masuku v South African Human Rights Commission obo South African Jewish Board of Deputies* 2019 (2) SA 194 (SCA) para 17; *NM v Smith* supra note 180 at para 66; *Le Roux v Dey* 2011 (3) SA 274 (CC) para 47; *Print Media South Africa v Minister of Home Affairs* supra note 135 at para 93; *Islamic Unity Convention* supra note 128 at para 26; *Mail and Guardian Media Ltd v Chipu NO* supra note 150 at para 50; *De Reuck v Director of Public Prosecutions (Witwatersrand Local Division)* 2004 (1) SA 406 (CC) para 59; *Independent Newspapers (Pty) Ltd v Minister for Intelligence Services In re: Masetlha v President of the Republic of South Africa* 2008 (5) SA 31 (CC) note 34; *Dikoko v Mokhatla* 2006 (6) SA 235 (CC) para 138; *Nova Property Group Holdings Ltd v Cobbett* 2016 (4) SA 317 (SCA) para 43; *Citizen v McBride* supra note 145 at para 141; *Phillips v Director of Public Prosecutions* supra note 122 at para 23.

²⁰⁵ *S v Mamabolo* supra note 133 at para 37.

Minister of Defence,²⁰⁶ also expressed the importance of the right to freedom of expression as follows:

‘Freedom of expression lies at the heart of a democracy. It is valuable for many reasons, including its instrumental function as a guarantor of democracy, its implicit recognition and protection of the moral agency of individuals in our society and its facilitation of the search for truth by individuals and society generally. The Constitution recognises that individuals in our society need to be able to hear, form and express opinions and views freely on a wide range of matters’.²⁰⁷

The two purposes of the right to freedom of expression as expressed in *Case* above – namely, the search for truth and the exercise of autonomy – are repeated here. However, there is an additional purpose of the right to freedom of expression: The promotion of democracy. The right to freedom of expression has been viewed as ‘integral to democracy, to human development and to human life itself’.²⁰⁸ In *The Citizen 1978 (Pty) Ltd v McBride*,²⁰⁹ it was held that ‘[f]ree expression of opinion, including critical opinion, is essential to the proper functioning of our constitutional democracy’.²¹⁰ Further, the right to freedom of expression serves an ‘instrumental function as a guarantor of democracy’.²¹¹ *Reddell v Mineral Sands Resources (Pty) Ltd* stated that the right to freedom of expression is central to democracy, ‘not only because it is an “essential and constitutive feature” of our open democratic society, but also for its transformative potential’.²¹² One of the purposes of the right to freedom of expression is that it aims to encourage acceptance of diverse political perspectives and the ways that they are communicated.²¹³ In South Africa’s democratic society, individuals must tolerate

²⁰⁶ 1999 (4) SA 469 (CC).

²⁰⁷ *South African National Defence Union v Minister of Defence* supra note 139 at para 7. This was also cited in *Islamic Unity Convention* supra note 128 at para 24.

²⁰⁸ *Phillips v Director of Public Prosecutions* supra note 122 at para 23. In *Khumalo v Holomisa* supra note 147 at para 21 (which was also cited in *Citizen v McBride* supra note 145 at para 141), it was similarly held that ‘Freedom of expression is integral to a democratic society’. *Citizen v McBride* supra note 145 at para 141 stated that ‘Freedom of expression is an important instrument to a democratic government’.

²⁰⁹ 2011 (4) SA 191 (CC).

²¹⁰ *Citizen v McBride* supra note 145 at para 141.

²¹¹ *South African National Defence Union v Minister of Defence* supra note 139 at para 7.

²¹² *Reddell v Mineral Sands Resources (Pty) Ltd* supra note 156 at para 103.

²¹³ *Moyo v Minister of Justice and Constitutional Development; Sonti v Minister of Justice and Correctional Services (Moyo)* 2018 (2) SACR 313 (SCA) para 42.

differing viewpoints and recognise that these views may be expressed in ways that may be disagreeable or challenging.²¹⁴

As can be seen from the case law above, the right to freedom of expression is not only central to democracy, but it also guarantees democracy.²¹⁵ Therefore, I suggest that the promotion of democracy is another important purpose of the right to freedom of expression.

(e) The purpose of the right to freedom of expression

In the headings above, through an examination of South Africa case law, the primary purposes of the right to freedom of expression have been established – namely, the search for truth, the exercise of autonomy, and the promotion of democracy. Whilst each of these purposes have been dealt with separately, this heading considers all three of the purposes of the right to freedom of expression together. This serves to further clarify the purposes that underlie the right to freedom of expression, as well as reaffirm my findings above.

Although not specifically referring to the *purpose* of the right to freedom of expression, *South African Broadcasting Corporation Limited v National Director of Public Prosecutions (SABC v NDPP)*,²¹⁶ expressed why the right to freedom of expression is valuable and held that:

‘This Court has frequently emphasised that freedom of expression lies at the heart of democracy. It is valuable for many reasons, including its instrumental function as a guarantor of democracy, its implicit recognition and protection of the moral agency of individuals in our society and its facilitation of the search for truth by individuals and society generally. The Constitution recognises that individuals in our society need to be able to hear, form and express opinions and views freely on a wide range of matters’.²¹⁷

*Print Media South Africa v Minister of Home Affairs*²¹⁸ gave a list of reasons as to why the right to freedom of expression is worthy of protection. These are: (1) the search for truth; (2) being able to make democratic decisions; and (3) self-fulfillment.²¹⁹ In *Democratic Alliance v*

²¹⁴ *Moyo* supra note 213 at para 42.

²¹⁵ *Dikoko v Mokhatla* supra note 204 at para 138.

²¹⁶ 2007 (1) SA 523 (CC).

²¹⁷ *SABC v NDPP* supra note 137 at para 23.

²¹⁸ 2012 (6) SA 443 (CC).

²¹⁹ *Print Media South Africa v Minister of Home Affairs* supra note 135 at para 93.

African National Congress,²²⁰ the Constitutional Court (in a joint judgment) expanded on the purpose of the right to freedom of expression:

‘The Constitution recognises that people in our society must be able to hear, form and express opinions freely. For freedom of expression is the cornerstone of democracy. It is valuable both for its intrinsic importance and because it is instrumentally useful. It is useful in protecting democracy, by informing citizens, encouraging debate and enabling folly and misgovernance to be exposed. It also helps the search for truth by both individuals and society generally. If society represses views it considers unacceptable, they may never be exposed as wrong. Open debate enhances truth-finding and enables us to scrutinise political argument and deliberate social values. What is more, being able to speak freely recognises and protects “the moral agency of individuals in our society”. We are entitled to speak out not just to be good citizens, but to fulfil our capacity to be individually human’.²²¹

In *Van Breda v Media 24 Limited; National Director of Public Prosecutions v Media 24 Limited*,²²² the Supreme Court of Appeal quoted Lord Steyn in *R v Secretary of State for the Home Department, Ex parte Simms*²²³ in analysing the purposes of the freedom of expression. It reads as follows:

‘Freedom of expression is, of course, intrinsically important: it is valued for its own sake. But it is well recognised that it is also instrumentally important. It serves a number of broad objectives. First, it promotes the self-fulfilment of individuals in society. Secondly, in the famous words of Holmes J (echoing John Stuart Mill), “the best test of truth is the power of the thought to get itself accepted in the competition of the market”: *Abrams v United States* [1919] USSC 206; (1919) 250 US 616 at 630 per Holmes J (dissent). Thirdly, freedom of speech is the lifeblood of democracy. The free flow of information and ideas informs political debate. It is a safety valve: people are more ready to accept decisions that go against them if they can in principle seek to influence them. It acts as a brake on the abuse of power by public officials. It facilitates the exposure of errors in the governance and administration of justice of the country’.²²⁴

The objectives of freedom of expression that can be garnered from the above passage are: (1) the promotion of self-fulfilment; (2) truth; and (3) the furthering of democracy. These three primary aspects of the right to freedom of expression have featured in later case law. *Economic*

²²⁰ 2015 (2) SA 232 (CC).

²²¹ *Democratic Alliance v African National Congress* supra note 147 at paras 122–3.

²²² 2017 (2) SACR 491 (SCA).

²²³ [1999] 3 All ER 400.

²²⁴ *R v Secretary of State for the Home Department, Ex Parte Simms* [1999] 3 All ER 400 at 408 cited in *Van Breda v Media 24 Limited; National Director of Public Prosecutions v Media 24 Limited* 2017 (2) SACR 491 (SCA) para 9.

*Freedom Fighters v Minister of Justice and Correctional Services*²²⁵ mentioned that freedom of expression is ‘the lifeblood of a genuine constitutional democracy’.²²⁶ It facilitates both the exchange of ideas (which is a form of expression that promotes autonomy) and accountability (which links to truth).²²⁷

Most recently, in the case of *Qwelane*,²²⁸ the Constitutional Court referred to Emerson when determining the values underlying the right to freedom of expression.²²⁹ These values include: ‘(a) the pursuit of truth; (b) its value in facilitating the proper functioning of democracy; (c) the promotion of individual autonomy and self-fulfillment; and (d) the encouragement of tolerance’.²³⁰ The Constitutional Court, in *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service*,²³¹ cited *Qwelane*²³² and reaffirmed these four values underlying the right to freedom of expression.²³³ An additional value of the encouragement of tolerance seems to have been included in terms of the right to freedom of expression. The right to freedom of expression has been viewed as vital in a democracy as it ‘fosters the facilitation of truth, pluralism, and tolerance’.²³⁴ In *Moyo v Minister of Justice and Constitutional Development; Sonti v Minister of Justice and Correctional Services (Moyo)*,²³⁵ the Supreme Court of Appeal held that encouraging tolerance of conflicting political views and the way in which they are conveyed is one of the purposes of the right to freedom of expression.²³⁶ Is the encouragement of tolerance a fourth purpose relating to the right to freedom of expression?

Based on the case law above, from a South African perspective and interpretation of the right to freedom of expression, the encouragement of tolerance does not feature nearly as often as the other three values relating to the right to freedom of expression. Tolerance (in terms of the right to freedom of expression) is often mentioned in the context of democracy. For example, *Qwelane* held that a healthy democracy necessitates tolerance towards speech or

²²⁵ 2021 (2) SA 1 (CC).

²²⁶ *Economic Freedom Fighters v Minister of Justice and Correctional Services* supra note 126 at para 1.

²²⁷ Ibid at para 1.

²²⁸ 2021 (6) SA 579 (CC).

²²⁹ Thomas I Emerson *The System of Freedom of Expression* (1970) 6–7.

²³⁰ *Qwelane* supra note 178 at para 69.

²³¹ 2023 (5) SA 319 (CC).

²³² 2021 (6) SA 579 (CC).

²³³ *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service* 2023 (5) SA 319 (CC) para 71.

²³⁴ *South African Human Rights Commission obo South African Jewish Board of Deputies v Masuku* 2022 (4) SA 1 (CC) para 26.

²³⁵ 2018 (2) SACR 313 (SCA).

²³⁶ *Moyo* supra note 213 at para 42.

expression that might be shocking or offensive,²³⁷ and that principles of pluralism, tolerance, and open-mindedness demand that democracy creates a space where ideas can freely circulate without censorship, even if some of these ideas are offensive, shocking, or disturbing.²³⁸ In *Islamic Unity Convention v Independent Broadcasting Authority (Islamic Unity Convention)*,²³⁹ it was held that without inter alia tolerance, democracy cannot exist.²⁴⁰ Tolerance may be viewed as an aspect of the promotion of democracy in that it refers to the acceptance and respect for diverse beliefs, viewpoints, and lifestyles – including political opinions, religious beliefs, and cultural practices.²⁴¹ Tolerance fosters an environment where individuals can freely express themselves, engage in open dialogue, and participate in democratic processes without fear of discrimination or retaliation.²⁴² Therefore, tolerance is not only part of promoting democracy, but is fundamental to its functioning and sustainability.²⁴³

Additionally, in *South African National Defence Union v Minister of Defence*,²⁴⁴ tolerance by society of differing views is mentioned as a *corollary* of the right to freedom of expression and its related rights²⁴⁵ – it is not a purpose of the right to freedom of expression as such. Tolerance does not mean endorsing a specific viewpoint. Essentially, it means allowing public discussions of disagreements and resisting the urge to suppress unpopular opinions.²⁴⁶ I

²³⁷ *Qwelane* supra note 178 at para 79.

²³⁸ Ibid at para 74. This was also cited in *Premier of the Western Cape Province v Public Protector* 2022 (3) SA 121 (SCA) para 38.

²³⁹ 2002 (4) SA 294 (CC).

²⁴⁰ *Islamic Unity Convention* supra note 128 at para 26. This was also cited in *Qwelane* supra note 178 at para 73.

²⁴¹ Cambridge Dictionary ‘Tolerance’ available at <https://dictionary.cambridge.org/dictionary/english/tolerance>, accessed on 25 June 2024.

²⁴² Nuraan Davids & Yusef Waghid ‘How tolerance enhances democracy and the quest for human flourishing’ *The Conversation* 12 September 2017, available at <https://theconversation.com/how-tolerance-enhances-democracy-and-the-quest-for-human-flourishing-83538>, accessed on 17 June 2024.

²⁴³ Ibid.

²⁴⁴ 1999 (4) SA 469 (CC).

²⁴⁵ *South African National Defence Union v Minister of Defence* supra note 139 at para 8. This was also cited with approval in *Woodways CC v Vallie* 2010 (6) SA 136 (WCC) para 67; *Laugh It Off* supra note 137 at para 46; *Petro Props (Pty) Limited v Barlow* 2006 (5) SA 160 (W) para 53; *Qwelane* supra note 178 at para 73; *Premier of the Western Cape Province v Public Protector* supra note 238 at para 36.

²⁴⁶ *South African National Defence Union v Minister of Defence* supra note 139 at para 8.

suggest that the encouragement of tolerance can be seen as implicit value underlying the other three values.

These cases summarise and reinforce the three primary purposes of the right to freedom of expression that I identified above: (1) the search for truth; (2) the exercise of autonomy; and (3) the promotion of democracy.

(f) The right to freedom of expression and the right to freedom of scientific research

Since the importance of the right to freedom of expression, and the purposes that it serves, in South Africa have been established, it is still necessary to link the right to freedom of expression to the right to freedom of scientific research. Below, I analyse each of the three purposes of the right to freedom of expression and consider its application to the right to freedom of scientific research as an aspect of the right to freedom of expression.

(i) The search for truth

While the search for truth has been seen as a purpose underlying the right to freedom of expression, I suggest that the same purpose is applicable to the right to freedom of scientific research. The right to freedom of expression has been seen to aid the search for truth by both individuals and society.²⁴⁷ I suggest that the same can be said for the right to freedom of scientific research.

Those who undertake scientific research do so in order to come to conclusions and discover the truth about the subject of their project. As early as 1936, science has been described as ‘the search for truth’.²⁴⁸ This truth is obtained through using and testing various scientific methods.²⁴⁹ The knowledge that research seeks to obtain should be true – within human limits and the capabilities of science.²⁵⁰ In scientific research, truth entails refining evidence. The accuracy of scientific truth relies on several factors: The strength of the evidence, the rigor of the research methods, the competence and honesty of the researchers, and the careful oversight of editors and peer reviewers.²⁵¹ Scientific research entails developing a hypothesis, conducting a trial to test the hypothesis, and submitting the results for publication. Other researchers may undertake their own research in order to test the original hypothesis. If

²⁴⁷ *Democratic Alliance v African National Congress* supra note 147 at para 122.

²⁴⁸ WK Butts ‘The search for truth’ (1936) 7(4) *Bios* 214.

²⁴⁹ Merriam-Webster op cit note 2.

²⁵⁰ John Wesley Taylor ‘Research and the search for truth’ *Journal of Adventist Education* 2019, available at <https://www.journalofadventisteducation.org/2019.81.4.4>, accessed on 7 May 2024.

²⁵¹ Ibid; Rod Baber ‘What is scientific truth?’ (2017) 20(2) *Climacteric* 83.

they agree, they confirm that the original claim is valid,²⁵² but this does not mean that the result is true. Even if a theory is widely accepted now, it could later be proven incorrect or shown to be false. This acceptance simply means that, based on the evidence and understanding available at the time, most of the scientific community agrees that the theory is valid.²⁵³

Truth is also affected by individual perception and beliefs.²⁵⁴ Baber suggests that community agreement offers a solution to determining the truth.²⁵⁵ When a group of people collectively agree on a particular ‘truth’, this consensus, although not a definitive measure of truth, helps establish a knowledge community with common values.²⁵⁶

Scientific research is essential for advancing knowledge and understanding, allowing for a dynamic process where theories can be tested, refined, and, if necessary, revised in light of new evidence and insights. Freedom in research has been seen as ‘fundamental to the advancement of truth’.²⁵⁷ I suggest that through the conduct of research and the following of the scientific method, truths may be discovered by researchers and scientists (as individuals) and these truths are then published and implemented in practice for the benefit of society. The pursuit of truth is a fundamental purpose that underlies both the right to freedom of expression and the right to freedom of scientific research. Just as the right to freedom of expression allows individuals and society to explore and debate various viewpoints to uncover truths, the right to freedom of scientific research provides the framework for investigating hypotheses and refining evidence to approach scientific truths.

(ii) The exercise of autonomy

Autonomy is intertwined with the right to freedom of expression. Autonomy allows individuals to freely express their thoughts, beliefs, and ideas, which is essential for the healthy functioning of a democratic society.²⁵⁸ Freedom of expression, in turn, is a fundamental right that supports individuals’ ability to express new ideas.²⁵⁹ This extends to the realm of scientific research,

²⁵² Ibid at 83.

²⁵³ Ibid at 83.

²⁵⁴ Ibid at 83.

²⁵⁵ Ibid at 83.

²⁵⁶ Ibid at 83.

²⁵⁷ American Association of University Professors (AAUP) ‘1940 statement of principles on academic freedom and tenure’ AAUP available at <https://www.aaup.org/report/1940-statement-principles-academic-freedom-and-tenure>, accessed on 10 June 2024; Gerhard Fink ‘Freedom of science’ (2020) 49(7) *Kybernetes* 1944.

²⁵⁸ John Christman ‘Autonomy in moral and political philosophy’ *Stanford Encyclopedia of Philosophy* 29 June 2020, available at <https://plato.stanford.edu/entries/autonomy-moral/>, accessed on 27 February 2021.

²⁵⁹ WJ van Vollenhoven ‘The right to freedom of expression: The mother of our Democracy’ (2015) 18(6) *PER / PELJ* 2307.

and specifically the right to freedom of scientific research. Science thrives when researchers have the autonomy to explore, question, and disseminate findings without undue constraints.²⁶⁰

Fink contends that freedom of science is closely linked to ‘intellectual autonomy’, which is the freedom of thinking.²⁶¹ Resnik considers ‘the right to autonomy in science’, which he defines as ‘the right of individuals, groups, and organizations to make decisions related to scientific activities’.²⁶² According to Resnik, a right to autonomy in science may be justified in terms of a deontological approach or a utilitarian approach. In terms of the deontological approach, autonomy in science is defended through an emphasis on moral, political, or legal rights. Individuals have the right to participate in scientific activities based on their rights to freedom of thought and expression, for example. Once the individual scientist’s right to autonomy is established, this approach also supports the need for autonomy at the group or organisational level, as individuals can only exercise their rights through association, communication, and collaboration with others.²⁶³ In terms of the utilitarian approach, it starts by noting that science contributes significantly to society through its applications in technology, engineering, agriculture, medicine, communication, and other fields. To achieve these benefits, individual scientists, scientific groups, and organisations must be free to make their own decisions. Unlike the deontological approach, which begins with individual rights and moves to group rights, the utilitarian approach starts by justifying autonomy at the level of the scientific institution and then extends this justification to individual scientists.²⁶⁴

The right to freedom of scientific research can be seen to promote both individual and societal autonomy. The right to freedom of scientific research promotes individual autonomy through researchers. When researchers have the freedom to conduct their own research in a field of their interest, it allows them to more effectively develop their skills and attributes. This freedom also helps them achieve their personal ideals and goals regarding accomplishment.²⁶⁵ Thus, the right to freedom of scientific research advances individual autonomy.

The right to freedom of scientific research also promotes the autonomy of individual’s in society. Freedom of scientific research allows for the sharing of scientific advancement and its

²⁶⁰ Science Europe ‘A values framework for the organisation of research’ available at <https://scienceeurope.org/our-priorities/research-culture/research-values-framework/>, accessed on 17 October 2023.

²⁶¹ Fink op cit note 257 at 1941.

²⁶² David B Resnik ‘Scientific autonomy and public oversight’ (2008) 5(2) *Philos Sci* 4.

²⁶³ Ibid at 4.

²⁶⁴ Ibid at 4.

²⁶⁵ Thaldar & Steytler op cit note 30 at 275.

benefits.²⁶⁶ Science is viewed as being progressive in nature.²⁶⁷ Sarton stated that ‘progress has no definite and unquestionable meaning in other fields than the field of science’.²⁶⁸ Scientific research results in new knowledge, which may be utilised in many areas such as developing new technologies and solving practical issues.²⁶⁹ The results of scientific research hold numerous benefits for members of society, such as reducing mortality, curing disease, creating new technologies, and developing clean forms of energy.²⁷⁰ Scientific research has resulted in original innovations, novel applications of existing discoveries, new methods of doing things, and has thus provided choice. Many of the tools, technologies, and medicines that are used today, ranging from pens and rockets to aspirin and organ transplants, are results or by-products of scientific research.²⁷¹ Because of scientific research, individuals have choice in terms of treatment options for certain diseases or conditions that were not previously available, for example. When deciding which option to select, or whether to select an option at all, individuals are choosing to exercise their autonomy by freely making a decision and then acting on it. Given that progress in science allows society to exercise its autonomy, and given that scientific progress would not be possible without freedom of scientific research, the right to freedom of scientific research therefore promotes the constitutional value of autonomy generally.

Given this, I suggest that the type of autonomy that is promoted by the right to freedom of scientific research has both an individual and a communal aspect – in line with my findings in Chapter 3. The exercise of individual autonomy (as an aspect of the right to freedom of expression) is also applicable to, and promoted by, the right to freedom of scientific research through enabling researchers to undertake their own research and pursue their own interests. In addition, the right to freedom of scientific research enables the realisation of a type of group

²⁶⁶ UNESCO op cit note 17.

²⁶⁷ Ilkka Niiniluoto ‘Scientific progress’ *Stanford Encyclopedia of Philosophy* 22 January 2024, available at <https://plato.stanford.edu/entries/scientific-progress/#SciPro>, accessed on 19 March 2024.

²⁶⁸ Ibid; George Sarton *The Study of the History of Science* (1936).

²⁶⁹ Berkeley, University of California ‘Benefits of science’ available at <https://undsci.berkeley.edu/understanding-science-101/how-science-works/benefits-of-science/>, accessed on 27 March 2024.

²⁷⁰ Valentí Rull ‘The most important application of science’ (2014) 15(9) *EMBO Rep* 919.

²⁷¹ Ibid at 919.

autonomy through the dissemination and application of the results of scientific research in society.

(iii) *The promotion of democracy*

Modern societies are influenced by science and technology in countless ways.²⁷² Science is one of the key elements essential for the effective operation of modern democracies,²⁷³ and, in many instances, scientific progress has both accompanied and advanced the development of democratic societies.²⁷⁴ Linked to this, academic research plays a crucial role in democratic societies, driving both technological advancements and social progress. Likewise, research flourishes most effectively within open and democratic societies that uphold constitutional guarantees of freedom of research.²⁷⁵ Freedom of research refers to the right, often constitutionally guaranteed, for researchers to independently choose their research topics and methods. This safeguards against external pressures, such as political or economic influences, which could otherwise shape research agendas and outcomes.²⁷⁶

In a democracy, citizen empowerment, transparency, accountability, and engagement are important. Given that it is the duty of a democratic government to promote these aspects of a democracy, the type of expression that features in a democracy is generally political expression. But it is not only political expression that is essential for democracy. The accurate, evidence-based knowledge generated by science is an additional form of expression that supports democracy.²⁷⁷ Wilholt recognises that ‘scientific knowledge has become an important input for the democratic process’.²⁷⁸ This is because citizens, when making political decisions, depend on science to clarify uncertainties and shape their understanding of the world. Therefore, in order to uphold democracy, those who create scientific knowledge should be independent from political powers.²⁷⁹ Additionally, in a liberal democracy, the open and unrestricted sharing of ideas, even unconventional ones, is crucial. Engaging with diverse viewpoints and perspectives, backed by research, fosters a dynamic environment where well-informed and

²⁷² Matthias Jung ‘Science as a democratic life-function and the challenge of scientism’ (2020) XII(2) *European Journal of Pragmatism and American Philosophy* 2.

²⁷³ Ibid at 14.

²⁷⁴ Ibid at 2.

²⁷⁵ Sebastian Wäscher & Anna Deplazes-Zemp ‘Freedom of research in a democratic society’ (2020) 21 *EMBO Rep* 1.

²⁷⁶ Ibid at 2.

²⁷⁷ Thaldar & Steytler op cit note 30 at 279.

²⁷⁸ Torsten Wilholt ‘Scientific freedom: Its grounds and their limitations’ (2010) 41 *Studies in History and Philosophy of Science* 177.

²⁷⁹ Ibid at 177.

nuanced societal views can develop. This exchange promotes critical thinking and helps society evolve by considering a wide range of perspectives and evidence.²⁸⁰

Science and technology significantly influence modern societies and are integral to the functioning of contemporary democracies. Scientific progress has not only advanced democratic institutions by promoting transparency, accountability, and citizen engagement but also plays a critical role in informing and empowering the public with accurate, evidence-based knowledge. This underscores the importance of the right to freedom of scientific research. To ensure that scientific research can continue to provide reliable information and support informed decision-making, it must remain free from political interference. Protecting the right to freedom of scientific research is therefore essential for upholding democratic values and ensuring that science can contribute effectively to the health and progress of democratic societies.

From the above, I suggest that the three purposes of the right to freedom of expression found in case law – namely, the search for truth, the exercise of autonomy, and the promotion of democracy – are also purposes of the right to freedom of scientific research as an aspect of the right to freedom of expression.

VI FREEDOM OF SCIENTIFIC RESEARCH AND OPEN CONSENT

The important question that must now be considered is whether open consent is aligned with the right to freedom of scientific research. As there is no jurisprudence on the right to freedom of scientific research, I analysed the broader right to freedom of expression. The right to freedom of expression comprises of three main purposes, according to the case law. These are: (1) the search for truth; (2) the exercise of autonomy; and (3) the promotion of democracy. Above, I established that these three purposes are also applicable to the right to freedom of scientific research. Therefore, the right to freedom of scientific research is an aspect of the right to freedom of expression.

But the question that must now be asked is: How does all of this link to open consent? First, I consider open science which was explored above. Both open science and open consent are committed to transparency and autonomy in research. Open science aims to make research processes, data, and findings accessible to all, fostering collaboration and reproducibility.²⁸¹ In

²⁸⁰ Wäscher & Deplazes-Zemp op cit note 275 at 2.

²⁸¹ ScienceDirect ‘Open science’ available at <https://www.sciencedirect.com/topics/social-sciences/open-science>, accessed on 15 February 2024.

South Africa, the draft Open Science Policy holds potential in the realisation of open science in the country, where it can democratise access to scientific knowledge and drive innovation across diverse communities.²⁸² The PGP's open consent model requires research participants to provide informed consent to participate in the PGP (and to undergo an assessment in order to test their understanding), but part of this also requires consent to the open sharing of their genomic and health data.²⁸³ This approach ensures that research participants are fully aware of how their data will be used and shared, promoting ethical standards and trust in research. It has also been found that increased transparency and open disclosure of the risks associated with publicly sharing genetic and health data may encourage more individuals to take part in human research.²⁸⁴ In South Africa, adopting a similar open consent framework within open science practices could enhance ethical engagement with research participants, ensuring that their contributions are respected and their rights are safeguarded while facilitating broad scientific inquiry and advancement.

As the link between open consent and open science in South Africa has been established, I now move on to consider the right to freedom of scientific research. Using each of the purposes of the right to freedom of expression, which can be extrapolated to the right to freedom of scientific research, I consider whether and how open consent aligns with the right to freedom of scientific research in South Africa.

(a) *The search for truth*

The search for truth is one of the purposes of the right to freedom of expression based on South African case law. The search for truth is also an applicable purpose to the right to freedom of scientific research because it underpins the development of knowledge and innovation. Through research, the search for truth aids in building a foundation of knowledge, leading to advancements in fields such as technology and medicine.²⁸⁵ Freedom allows researchers to investigate questions and test hypotheses without censorship or political influence, ensuring

²⁸² DSI op cit note 22.

²⁸³ Madeleine P Ball, Jason R Bobe, Michael F Chou et al 'Harvard Personal Genome Project: Lessons from participatory public research' (2014) 6(10) *Genome Med* 1; Oscar A Zarate, Julia Green Brody, Phil Brown et al 'Balancing benefits and risks of immortal data: Participants' views of open consent in the Personal Genome Project' (2016) 46(1) *Hastings Center Rep* 3; The Harvard Personal Genome Project 'The PGP is not a traditional research study' available at <https://pgp.med.harvard.edu/about>, accessed 6 June 2022; Silent Spring Institute 'Participants in Personal Genome Project weigh the risks and benefits of sharing genetic and health data' 3 February 2016 available at <https://silentspring.org/news/participants-personal-genome-project-weigh-risks-and-benefits-sharing-genetic-and-health-data>, accessed on 29 January 2024.

²⁸⁴ Silent Spring Institute op cit note 283.

²⁸⁵ German Research Foundation *Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security-Relevant Research* (2014) 9.

objective and unbiased findings that benefit society.²⁸⁶ Without such freedom, the quality and reliability of scientific knowledge would be compromised, hindering societal advancement.²⁸⁷

Given that the search for truth is one of the purposes underlying the right to freedom of scientific research, in order for open consent to align with the constitutional right to freedom of scientific research, it must promote the search for truth.

I suggest that open consent aligns with the search for truth. In order to test hypotheses and conduct rigorous studies into better understanding health and disease, genomics research requires vast amounts of data.²⁸⁸ This allows inferences to be made between a genetic variation and a specific disease – ensuring credibility, particularly because drawing conclusions from limited datasets could lead to inaccuracies.²⁸⁹ And without large datasets, researchers' findings may not be accurate or representative. However, researchers may face obstacles when it comes to obtaining data. Data generated from genomics research are often shared with other researchers.²⁹⁰ This may be done using an open or unrestricted access data sharing method,²⁹¹ or access may be controlled in which case approval from a Data Access Committee is required.²⁹² This may be laborious and limiting as the Data Access Committee may only grant access to certain aspects of the data and related information. Moreover, repositories and databases are encountering growing challenges in maintaining data accuracy and efficiently organising and curating data.²⁹³ Genomic data often consists of numerous large and small files, presenting complexities in organisation and accessibility for researchers.²⁹⁴ In order to abide by institution and funder policies and to protect the privacy of research participants,²⁹⁵ certain

²⁸⁶ National Academies of Sciences, Engineering, and Medicine *Fostering Integrity in Research* (2017) 31.

²⁸⁷ UNESCO op cit note 17.

²⁸⁸ It is predicted that genomics research will produce two to 40 exabytes of data in the next decade. Jerome Atutornu, Richard Milne, Alesia Costa et al 'Towards equitable and trustworthy genomics research' (2022) 76 *The Lancet* 2; Warren C Lathe, Jennifer M Williams, Mary E Mangan et al 'Genomic data resources: Challenges and promises' (2008) 1(3) *Nature Education* 2; National Human Genome Research Institute 'Genomic data science' *NIH* 5 April 2022, available at <https://www.genome.gov/about-genomics/fact-sheets/Genomic-Data-Science>, accessed on 8 May 2023; Nicola Mulder, Clement A Adebamowo, Sally N Adebamowo et al 'Genomic research data generation, analysis and sharing – Challenges in the African setting' (2017) 16(49) *Data Science Journal* 9.

²⁸⁹ Atutornu et al op cit note 288 at 2.

²⁹⁰ National Human Genome Research Institute op cit note 288.

²⁹¹ Open or unrestricted access is the most inclusive type of data sharing where information is freely available to the public for any research-related use. National Human Genome Research Institute op cit note 288.

²⁹² Controlled access involves a process where researchers must detail their research intentions. A dedicated Data Access Committee then reviews these intentions to ensure they align with participant consent. Access to the data is granted only upon approval from this the Data Access Committee. National Human Genome Research Institute op cit note 288; Mulder et al op cit note 288 at 5.

²⁹³ Lathe et al op cit note 288 at 2.

²⁹⁴ Mulder et al op cit note 288 at 3.

²⁹⁵ National Cancer Institute 'Data submission policies' *NIH* available at <https://gdc.cancer.gov/submit-data/data-submission-policies>, accessed on 7 January 2024; University of Washington 'Genomic data sharing' available at

information may be redacted before being shared – which may pose disadvantageous for genomics research.

In addition to practical and logistical challenges, being transparent in research is challenging as science does not consistently value openness and may even discourage it at times.²⁹⁶ Researchers keep their data private to maintain exclusive control over the interpretations that can be made from it, they may withhold data that contradicts their hypotheses desired or conclusions, or they may even neglect to disclose crucial data or other information essential to their published findings, potentially to conceal any falsification.²⁹⁷ This all hinders the search for truth in research generally, and in genomics research specifically. However, open consent may offer a potential solution. The use of publicly available data enables researchers to address new questions and explore secondary hypotheses.²⁹⁸ It supports the development and evaluation of new methods, the creation of innovative products and services, and facilitates interdisciplinary research.²⁹⁹ Meta-analysis becomes possible by combining data from various sources, allowing for new discoveries that individual datasets might not reveal.³⁰⁰

In terms of the PGP's open consent model, the genome, health, and trait data of research participants in openly accessible online, and available for anyone to download³⁰¹ – this extends to the general public, and is not only limited to researchers. All data and information that the PGP obtains from research participants, with their consent, is uploaded and made openly accessible.³⁰² Researchers are therefore able to access all the data obtained and provided by the

<https://www.washington.edu/research/hsd/guidance/ancillary/gds/>, accessed 7 January 2024; Luca Bonomi, Yingxiang Huang & Lucila Ohno-Machado 'Privacy challenges and research opportunities for genomic data sharing' (2020) 52(7) *Nat Genet* 2.

²⁹⁶ Openness is not synonymous with honesty, but it relies heavily on honesty. It involves being transparent and disclosing all relevant information when presenting decisions or conclusions. This transparency is crucial for others involved in the research community to comprehend how conclusions were reached. Openness also entails sharing the data used to generate results, enabling others to replicate findings, verify accuracy, and further develop scientific knowledge. However, there are significant hurdles to sharing data, stemming from both academic and commercial motivations. Genomic data holds potential commercial value, such as for creating new vaccines or therapies. Balancing the benefits of open access to data, which can accelerate scientific progress, against concerns over intellectual property ownership and the associated financial gains, often presents barriers to widespread sharing. National Academies of Sciences, Engineering, and Medicine op cit note 286 at 33; Mulder et al op cit note 288 at 5.

²⁹⁷ National Academies of Sciences, Engineering, and Medicine op cit note 286 at 33.

²⁹⁸ Mulder et al op cit note 288 at 5.

²⁹⁹ Ibid at 5.

³⁰⁰ Ibid at 5.

³⁰¹ Personal Genome Project: Global Network 'The Personal Genome Project' available at <https://www.personalgenomes.org/>, accessed on 30 April 2022.

³⁰² Ball et al op cit note 283 at 1; Zarate et al op cit note 283 at 3; The Harvard Personal Genome Project op cit note 283; Silent Spring Institute op cit note 283.

PGP without any hinderances. As such, the data from the PGP that researchers use is as complete and comprehensive as it can be. This aids in the search for truth because researchers using the PGP's data do so with awareness of the fact that nothing may have been redacted or hidden. Any researchers who may subsequently use the data of the initial researchers that was obtained from the PGP will not only have access to the original data (as it is openly available on the PGP website and can therefore check its validity), but will be building on from a foundation that was thorough. Because the data is more reliable, this makes the search for truth for accurate and meaningful.

In turn, truth enhances transparency and public trust – both of which are elements of the PGP. The PGP is defined by its commitment to transparency. It emphasises active involvement from research participants and ensures that datasets, which participants have consented to share, are openly accessible.³⁰³ This heightened transparency could aid in maintaining relationships with research participants,³⁰⁴ and increased transparency may even enhance research by building trust over time.³⁰⁵

In having the freedom to advance knowledge, researchers also have a duty to be honest.³⁰⁶ Science relies on the integrity of researchers. It assumes that researchers uphold honesty as a core principle in their work, adhering to agreed-upon methods to establish the validity of their ideas, whether empirical or theoretical.³⁰⁷ Honesty serves as the bedrock upon which scientific values such as openness, accountability, and fairness rest. Without honesty, achieving these values in scientific practice would be unattainable.³⁰⁸ Honesty is a cornerstone of trust, and without honesty there can be no trust. Therefore, by ensuring honesty, researchers enhance trust. If research participants, the public, and other researchers know that the research project has been conducted ethically and based on a genuine search for the truth using comprehensive and accurate data, then trust in the research is more likely to increase. Open consent enhances public trust in research by demonstrating a commitment to ethical standards and respect for individuals. This trust is crucial for the successful advancement of science and for encouraging public participation in research, aligning with the principles of freedom of scientific research by ensuring that such freedom is exercised responsibly and ethically. The PGP aims to be

³⁰³ Jeantine E Lunshof, Ruth Chadwick, Daniel B Vorhaus et al 'From genetic privacy to open consent' (2008) *Nat Genet* 5.

³⁰⁴ Ball et al op cit note 283 at 6.

³⁰⁵ Zarate et al op cit note 283 at 12.

³⁰⁶ National Academies of Sciences, Engineering, and Medicine op cit note 286 at 31.

³⁰⁷ Ibid at 31.

³⁰⁸ Ibid at 31.

honest and open with its research participants and with the public. The free availability of research participant data is unlike many other models that exist for genomics research. This transparency enhances trust, but also allows the truth to be verified – leading to more credible findings.

- (b) Given the meaning that the search for truth has been afforded in the South African context and in terms of scientific research generally, I suggest that open consent aligns with the search for truth. By ensuring that research participants' data is freely available and comprehensively shared, this fosters a more robust search for truth. Adopting an open consent model for genomics research in South African can enhance transparency, address practical challenges, and uphold the integrity of scientific inquiry. Open consent not only facilitates more accurate and meaningful discoveries by providing complete datasets, but also builds trust between researchers and the public. This trust is crucial for encouraging participation and ensuring that research is conducted ethically. As such, embracing open consent in genomics research aligns with the constitutional right to freedom of scientific research by promoting rigorous, transparent, and honest scientific practices. This approach ensures that the search for truth remains central to research efforts, ultimately benefiting both scientific progress and societal well-being.*The exercise of autonomy*

The exercise of autonomy is a fundamental purpose of the right to freedom of scientific research because it empowers researchers to pursue knowledge independently and with integrity. Autonomy in scientific research allows scholars to select research topics based on intellectual curiosity and societal relevance, rather than external pressures such as political or commercial interests.³⁰⁹ This freedom enables scientists to explore unconventional ideas, challenge established theories, and innovate in their respective fields. Moreover, autonomy fosters a culture of academic freedom where researchers can experiment with diverse methodologies and approaches, leading to new discoveries and advancements.³¹⁰

As I suggested above that the type of autonomy that is promoted by the right to freedom of scientific research has both an individual and a communal aspect, so too do I suggest that this is the case with open consent. Individual autonomy is applicable to researchers and individual research participants. However, there is a communal autonomy from a broader

³⁰⁹ Science Europe op cit note 260; Resnik op cit note 262 at 4.

³¹⁰ Thaldar & Steytler op cit note 30 at 275.

perspective when one considers the cumulative effect that all PGP research participants are having on genomics research.

In terms of open consent and the PGP, the exercise of autonomy is applicable to both researchers and research participants. In terms of researchers, scientists typically have more freedom and autonomy compared to other professions, often choosing both the questions that they investigate and the methods that they employ to find answers.³¹¹ The right to freedom of scientific research allows researchers to explore and advance knowledge without undue restrictions.³¹²

In terms of research participants, open consent is built on the idea that for consent to be valid and decisions to be autonomous, individuals must have access to full and accurate information.³¹³ The PGP recognises that promises of complete anonymity are often unrealistic and can lead to invalid consent.³¹⁴ As concerns about data identifiability and security grow, providing honest information about the limits of privacy protections is becoming crucial for informed consent, particularly when creating essential public datasets with full consent.³¹⁵ In terms of the PGP, while efforts are made to protect privacy and confidentiality, these cannot be fully guaranteed to research participants.³¹⁶ The approach of the PGP upholds veracity, which is essential – though insufficient – for ensuring meaningful autonomy. Only by providing accurate and honest information can the standards required for truly informed consent be met.³¹⁷ Open consent also aligns with the promotion of autonomy by requiring clear, comprehensible information about the research and allowing research participants to make informed decisions about their involvement. Research participants have a choice regarding whether to enrol in the PGP. At any stage during the enrolment process or even once they are a participant, they still have the opportunity to withdraw from the PGP.³¹⁸ Research participants also have the autonomy to decide what data they would like to have available on the PGP website.³¹⁹

³¹¹ National Academies of Sciences, Engineering, and Medicine op cit note 286 at 28.

³¹² Thaldar & Steytler op cit note 30 at 275.

³¹³ Ball et al op cit note 283 at 2.

³¹⁴ Ibid at 2.

³¹⁵ Ibid at 2.

³¹⁶ Jeantine E Lunshof, Jason Bobe, John Aach et al 'Personal genomes in progress: From the Human Genome Project to the Personal Genome Project' (2010) 12(1) *Dialogues Clin Neurosci* 56.

³¹⁷ Ibid at 56.

³¹⁸ Ball et al op cit note 283 at 2 & 3; Lunshof et al op cit note 316 at 55.

³¹⁹ Zarate et al op cit note 283 at 4.

In South Africa, autonomy are crucial for the ethical conduct of genomics research, aligning with the fundamental right to freedom of scientific research. Autonomy, both for researchers and participants, is central to the right to freedom of scientific research, allowing researchers the freedom to explore diverse scientific questions and methodologies without external constraints. This autonomy promotes intellectual curiosity and innovation, essential for advancing knowledge and addressing societal needs. For research participants, open consent ensures that autonomy is respected by providing them with comprehensive and truthful information about the research. This transparency is vital because it enables participants to make fully informed decisions about their involvement. Although complete anonymity cannot be guaranteed, the open consent model upholds the principle of veracity, which is essential for meaningful autonomy. By allowing participants to understand the limitations of privacy protections and make informed choices about their data, open consent fosters a more ethical and inclusive research environment. This approach not only respects individual autonomy, but also contributes to the collective advancement of genomics research by ensuring that the data shared is comprehensive and reliable.

(c) The promotion of democracy

The promotion of democracy is a purpose that underlies both the right to freedom of expression and the right to freedom of scientific research. Freedom in science ensures that research outcomes are based on rigorous evidence and are transparently communicated, which enhances public trust in both scientific institutions and democratic processes.³²⁰ Moreover, scientific freedom encourages citizen participation and engagement, where individuals can contribute directly to scientific endeavours and influence research agendas that address societal needs.³²¹ By supporting innovation, advancing knowledge, and addressing critical issues with evidence-based solutions, scientific research plays a crucial role in promoting the values of democracy. It must now be considered whether and how the promotion of democracy links to open consent.

Principles that are important in a democracy – such as citizen empowerment, transparency, and engagement – are all applicable to open consent. The PGP empowers individuals by allowing them to choose to partake in genomics research that may lead to importance medical and scientific advances that benefit society. The PGP’s approach to open consent upholds transparency and ensures that research participants are aware of how their data

³²⁰ Maya J Goldenberg ‘Public trust in science’ (2022) 48(9) *Interdisciplinary Science Reviews* 1.

³²¹ Wäscher & Deplazes-Zemp op cit note 275 at 1.

will be used, shared, and published.³²² This informed participation supports the integrity of scientific research by fostering trust and ensuring that research participants are willing contributors, fully aware of the implications of their involvement in the PGP. Additionally, open consent promotes democracy through protecting the constitutional right to freedom of scientific research and allowing researchers to have the liberty to access data freely and openly, and conduct genomics research that may potentially benefit the population.

In recent decades, democratic principles have become more influential in research policy. Citizen science initiatives exemplify this shift by involving non-scientists directly in the research process. This inclusion of laypeople extends beyond simply undertaking research tasks; it signifies a broader engagement where ordinary individuals contribute to shaping and influencing scientific endeavours.³²³ The PGP is considered a citizen science project, although not the first example of such,³²⁴ and the PGP-UK refers to itself as a ‘hybrid between a research and a citizen science project’.³²⁵ Interestingly, Angrist asserts that citizen science has evolved into community-based participatory research, which emphasises collaboration involving communities impacted by the issues being studied.³²⁶ Community-based participatory research is marked by inter alia the exchange of knowledge between researchers and community members and shared decision-making processes.³²⁷ It is clear that citizen science is an expression of democracy in research. Citizen science has transformed into community-based participatory research. Given that community engagement is one of the elements that I suggested in Chapter 3 be included in a South African version of open consent from the perspective of autonomy, I suggest that community-based participatory research is therefore a promoter of democracy – in line with the purpose of the right to freedom of scientific research.

(d) Conclusion

Compared to the norm in genomics research projects where, for the sake of research participant privacy and researcher incentives, genomic data lies behind a Data Access Committee, the PGP and its open consent model makes the accessibility of data for genomics research significantly easier. As research participants are aware of the fact that there are no attempts to protect their

³²² Ball et al op cit note 283 at 4–5; Zarate et al op cit note 283 at 4.

³²³ Wäscher & Deplazes-Zemp op cit note 275 at 1.

³²⁴ Misha Angrist ‘Eyes wide open: The Personal Genome Project, citizen science and veracity in informed consent’ (2009) 6(6) *Per Med* 4.

³²⁵ PGP-UK Consortium ‘Personal Genome Project UK (PGP-UK): A research and citizen science hybrid project in support of personalized medicine’ (2018) 11 *BMC Med Genomics* 2.

³²⁶ Angrist op cit note 324 at 4.

³²⁷ Ibid at 4.

privacy and that their information and data will be openly accessible online (and their understanding is tested through an assessment prior to participation in the PGP), there are fewer obstacles to overcome in sharing data for genomics research. Furthermore, because the PGP uploads all the data that it receives from research participants to their website and makes it freely available to researchers, issues associated with the reliability and completeness of data are decreased.

The right to freedom of scientific research is closely linked to the concept of open consent as defined by the PGP. Open consent emphasises the need for transparency and ongoing communication between researchers and research participants, ensuring that individuals fully understand and agree to the scope, risks, and potential uses of their data.³²⁸ Furthermore, the fact that the open consent model developed by the PGP advocates for the open uploading and sharing of individual's genomic and trait data means that there are fewer barriers to access and use by researchers. This is a positive step towards realising the right to freedom of scientific research through open consent in genomics research in South Africa.

VII RECOMMENDATIONS AND CONCLUSION

This Chapter has examined the constitutional right to freedom of scientific research, and its links with both open science and open consent. This Chapter began by defining science, research, and the right to freedom of scientific research. It then explored open science as a promoter of the right to freedom of scientific research. Following this, this Chapter examined the right to freedom of expression – which is the umbrella right under which the right to freedom of scientific research falls. This entailed looking at the history of the right to freedom of expression, the link between the right to freedom of expression and other rights, and the meaning of the right to freedom of expression in South African case law. The right to freedom of expression was found to have three primary purposes: (1) the search for truth; (2) the exercise of autonomy; and (3) the promotion of democracy. The encouragement of tolerance, although mentioned in case law, is not a purpose of the right to freedom of expression – it is rather a consequence. Thereafter, the link between the right to freedom of expression and the right to freedom of scientific research was established, and I found that the right to freedom of scientific research is a dimension of the right to freedom of expression. Finally, this Chapter applied the

³²⁸ Ball et al op cit note 283 at 3 & 6.

findings of the analysis of the right to freedom of scientific research and applied it to open consent for genomics research in South Africa.

Given that open science is an important movement, and is essential in the furtherance of genomics research, it is necessary that this be considered. The draft Open Science Policy aims to include open science in South Africa's national strategy. This will be a significant step in giving open science the due recognition that it deserves in the country, and will assist in advancing the research landscape. However, despite the fact that open science is facilitated by the right to freedom of scientific research, and the right to freedom of scientific research is a promoter of open science, it has not featured in relevant South African policies and guidance documents. The draft Open Science Policy which, once finalised, could prove vital in the realisation of open science in South Africa, fails to give due regard to the right to freedom of scientific research. It is clear that open science may be promoted through reliance on the right to freedom of scientific research. As such, I suggest that the DSI, in developing the final version of the draft Open Science Policy, place greater emphasis on the right to freedom of scientific research.

Regarding the question of whether open consent aligns with South Africa's interpretation and view of the right to freedom of scientific research in terms of case law, this is not possible to answer directly given that there is no South African jurisprudence on the right to freedom of scientific research. Instead, the right to freedom of expression was explored and it was examined whether the purposes underlying the right to freedom of expression could be translated to the right to freedom of scientific research. I suggest that the answer is affirmative.

The next consideration is whether open consent aligns with the right to freedom of scientific research. An open consent model, where research participants agree to openly share their data for research and where researchers do not have many obstacles to conducting research using this data, can be seen to promote the right to freedom of scientific research in South Africa. Any potential hinderances that are typically present in genomics research – such as issues surrounding de-identification or anonymisation, future uses of samples and data, and re-consenting participants³²⁹ – are generally not present with an open consent model as the processes and procedures are transparent: Research participants go into the research knowing

³²⁹ Stacey Pereira, Richard A Gibbs & Amy L McGuire 'Open access data sharing in genomic research' (2014) 5 *Genes* 740; Jane Kaye 'The tension between data sharing and the protection of privacy in genomics research' (2012) 13 *Annu Rev Genomics Hum Genet* 10–1; C Staunton, R Adams, M Botes et al 'Safeguarding the future of genomic research in South Africa: Broad consent and the Protection of Personal Information Act No. 4 of 2013' (2019) 109(7) *S Afr Med J* 469.

that their privacy and confidentiality cannot be guaranteed and that their data will be openly available for anyone to download and use for any range of purposes.³³⁰ In this way, open consent removes barriers to research and thereby promotes the right to freedom of scientific research.

This Chapter has demonstrated how the constitutional right to freedom of scientific research underpins and promotes open science and, by extension, open consent models in genomics research. However, the freedoms inherent in open consent – particularly the transparency and broad sharing of data – raise critical ethical and legal questions, especially regarding the privacy of research participants. As genomic data is inherently personal and often identifiable, balancing the right to scientific freedom with the protection of individual privacy becomes a pressing challenge. The following Chapter will explore this tension in depth by examining the constitutional right to privacy within the South African context and assessing how privacy concerns intersect with open consent in genomics research. This analysis is essential to ensure that the advancement of science respects and safeguards the dignity and rights of research participants.

³³⁰ Lunshof et al op cit note 316 at 56.

CHAPTER 5

PRIVACY

I INTRODUCTION

Genomics research holds great potential, especially in terms of applications of future health technologies and precision medicine.¹ However, the privacy of participants in genomics research has come to the fore given the inherently identifiable nature of genomic data,² as well as the largely online environment in which genomic data is uploaded and shared.³ Unlike other types of information, genomic data not only reveals individual health risks and predispositions, but also has the potential to affect family members and future generations.⁴ The growing ability to analyse and interpret large-scale genomic datasets heightens the risk of breaches and misuse, making it essential to address privacy issues.⁵ Genomics research, therefore, entails a balancing act between sharing data in order to improve scientific progress, and protecting the privacy of research participants.⁶

II CHAPTER OVERVIEW

In this Chapter, I analyse the right to privacy and its relevance to open consent in terms of genomics research in South Africa – specifically through an evaluation of privacy from a constitutional perspective with a focus on South African jurisprudence. Research participant privacy has been questioned in genomics research where sensitive genomic information about an individual is used and shared globally. One way in which the privacy of research participants can be addressed is through consent. Although the adequacy of many modes of consent have

¹ National Human Genome Research Institute ‘A brief guide to genomics’ *NIH* 15 August 2020, available at <https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics>, accessed on 2 May 2022.

² Leslie E Wolf, Erin Fuse Brown, Ryan Kerr et al ‘The web of legal protections for participants in genomic research’ (2019) 29(1) *Health Matrix Clevel* 5; C Staunton, R Adams, M Botes et al ‘Safeguarding the future of genomic research in South Africa: Broad consent and the Protection of Personal Information Act No. 4 of 2013’ (2019) 109(7) *S Afr Med J* 469.

³ Mahsa Shabani & Pascal Borry ‘Challenges of web-based personal genomic data sharing’ (2015) 11 *Life Sciences, Society and Policy* 1–2.

⁴ Gemma A Bilkey, Belinda L Burns, Emily P Coles et al ‘Genomic testing for human health and disease across the life cycle: Applications and ethical, legal, and social challenges’ (2019) 7 *Front Public Health* 7; Muhammad Naveed, Erman Ayday, Ellen W Clayton et al ‘Privacy in the genomic era’ (2015) 48(1) *ACM Comput Surv* 3.

⁵ Luca Bonomi, Yingxiang Huang & Lucila Ohno-Machado ‘Privacy challenges and research opportunities for genomic data sharing’ (2020) 52 *Nature Genetics* 646.

⁶ National Human Genome Research Institute ‘Privacy in genomics’ *NIH* 24 February 2020, available at <https://www.genome.gov/about-genomics/policy-issues/Privacy>, accessed on 3 March 2020.

been questioned, open consent acknowledges that complete privacy is not always possible and therefore promotes the idea that research participants should only share their data.

This Chapter begins by clarifying certain relevant concepts, such as the nature of genomic information and its importance in genomics research, de-identification and anonymisation, as well as the familial element of genomic data. This Chapter then considers the differences between privacy and confidentiality. This is done in an effort to provide a greater understanding of the concept. Thereafter, this Chapter explores various philosophical conceptions of privacy in order to place privacy in context. Following this, privacy in South Africa's legal system is examined – with a specific focus on privacy jurisprudence in South African case law in order to determine the meaning of privacy and how it has been interpreted by the courts. This Chapter also addresses the links between privacy and other constitutional rights and values, such as autonomy and human dignity, as well as examining confidentiality. Finally, this Chapter examines the link between autonomy and privacy and applies the concept of privacy in South Africa to open consent in order to determine whether open consent may be reconciled with privacy and how it should be applied in genomics research in South Africa.

III THE NATURE OF GENOMIC DATA

Genomic data is an expansive term denoting sequenced DNA in the form of raw data resulting from sequencing an individual's genome, or individual DNA variations.⁷ It is recognised as sensitive personal information concerning an individual and their relatives.⁸ Genomic data has the ability to reveal the identity of the individual and offer insights into their traits or health.⁹ Genomic data is hugely valuable for research, but in order to fully leverage this information, it needs to be connected with additional phenotype data.¹⁰ The usefulness of datasets are enhanced when genotype and phenotype data are used in combination.¹¹ Incorporating

⁷ Thomas Finnegan & Alison Hall 'Identification and genomic data' (2017) *PHG Foundation* 11.

⁸ Dianne Nicol, Meredith Hagger, Nola Ries et al 'Time to get serious about privacy policies: The special case of genetic privacy' (2014) 42 *Fed L Rev* 149; Lauren Friend, Jessica O'Neill, Adrienne Rivlin et al 'Direct-to-consumer genetic testing: Opportunities and risks in a rapidly evolving market' (2018) *KPMG International* 2.

⁹ Rachel Horton & Anneke Lucassen 'Ethical considerations in research with genomic data' (2023) 29(1) *The New Bioethics* 38.

¹⁰ The genotype is the specific DNA sequence of an individual. On the other hand, the phenotype is the physical expression of the genotype – how an individual looks or behaves. The phenotype emerges from the interplay between the genotype and environmental factors. Ibid at 39; Garvan Institute of Medical Research 'Genomics explainer: Genotype and phenotype' available at <https://www.garvan.org.au/news-resources/science-explained/genotype-phenotype/>, accessed on 17 February 2024; Peter Taylor & Richard Lewontin 'The genotype/phenotype distinction' *Stanford Encyclopedia of Philosophy* 6 June 2017, available at <https://plato.stanford.edu/entries/genotype-phenotype/>, accessed on 17 February 2024.

¹¹ Horton & Lucassen op cit note 9 at 39.

phenotypic and genomic data can reveal new insights, such as the interaction between genes and the environment or drugs, which assists in deepening the understanding of health and disease.¹²

Genomic data offers a wealth of information for researchers,¹³ but it remains with an individual for life and, once shared, cannot be made confidential again.¹⁴ Unlike other types of data, genomic data is stable throughout an individual's life, meaning that data will remain significant for the individual and their relatives for many years.¹⁵ Given this, it is crucial to maintain the privacy and security of genomic data.¹⁶

As provided for in Chapter 1, genomic data holds great potential but also many risks – especially in terms of privacy. This is because genomic data contains detailed and personal information about the genetic makeup of an individual.¹⁷ It may reveal sensitive information about an individual's health, potential disease risks, and inherited traits.¹⁸ Because this information is so specific, it can be used to identify individuals and their family members, sometimes without their consent.¹⁹ Additionally, if genomic data is shared or accessed improperly, it can lead to unauthorised uses or breaches of privacy, potentially resulting in discrimination or other negative consequences.²⁰ To combat this, many research projects rely on the de-identification or anonymisation of genomic data in an attempt to safeguard individual privacy while still preserving the scientific value of the data.²¹ The assumption is that because certain identifiers have been removed, research participants (and their genetic relatives) can no

¹² Helen Daniels, Kerina Helen Jones, Sharon Heys et al 'Exploring the use of genomic and routinely collected data: Narrative literature review and interview study' (2021) 23(9) *J Med Internet Res* 2.

¹³ Valerie Gutmann Koch & Kelly Todd 'Research revolution or status quo: The new common rule and research arising from direct-to-consumer genetic testing' (2018) 56(1) *Houston Law Review* 90.

¹⁴ Jennifer Cacchio 'What you don't know can hurt you: The legal risk of peering into the gene pool with direct-to-consumer genetic testing' (2018) 87(1) *UMKC L Rev* 226; Finnegan & Hall op cit note 7 at 11; Canan Kelten Talu et al 'Pathology and biobanking' (2020) 36(2) *Turkish Journal of Pathology* 2.

¹⁵ Horton & Lucassen op cit note 9 at 38.

¹⁶ Friend et al op cit note 8 at 2.

¹⁷ Bonomi, Huang & Ohno-Machado op cit note 5 at 2; Johanna Rahnasto 'Genetic data are not always personal – Disaggregating the identifiability and sensitivity of genetic data' (2023) 10(2) *J Law Biosci* 2.

¹⁸ Rahnasto op cit note 17 at 2; Bonomi, Huang & Ohno-Machado op cit note 5 at 2.

¹⁹ Amicia Phillips, Pascal Borry, Ine Van Hoyweghen et al 'Disclosure of genetic information to family members: A systematic review of normative documents' (2021) 23 *Genet Med* 2038; Leslie P Francis 'Genomic knowledge sharing: A review of the ethical and legal issues' (2014) 3 *Applied & Translational Genomics* 122; Saadia Arshad, Junaid Arshad, Muhammad Mubashir Khan et al 'Analysis of security and privacy challenges for DNA-genomics applications and databases' (2021) 119 *Journal of Biomedical Informatics* 1.

²⁰ Rahnasto op cit note 17 at 3 & 9; Bonomi, Huang & Ohno-Machado op cit note 5 at 2; Arshad et al op cit note 19 at 4.

²¹ For example, the National Institutes of Health (NIH) mandates that any research funded by them that produces extensive genomic data must ensure that the data is de-identified. Francis op cit note 19 at 122; Ellen Wright Clayton, Barbara J Evans, James W Hazel et al 'The law of genetic privacy: Applications, implications, and limitations' (2019) *Journal of Law and the Biosciences* 6.

longer be identified, thus their privacy is protected. However, it is becoming increasingly clear that there are fundamental limitations to how much protection can be achieved through the de-identification and anonymisation of samples and data in genomics research.²² There have been many examples where supposedly de-identified data has been re-identified by combining it with various other databases.²³ This not only poses risks to the privacy of research participants, but also has a negative impact on the willingness of individuals to participate in genomics research.²⁴

(a) *De-identification, anonymisation, and pseudonymisation*

De-identification, anonymisation, and pseudonymisation are crucial terms that often feature when discussing the privacy and confidentiality of genomic data and genomics research. Any one or more of these terms have also been defined and used in various data protection laws worldwide – such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the US, the General Data Protection Regulation 2016/679 (GDPR) in the EU, the Data Protection Act 24 of 2019 in Kenya, the Data Protection Act of 2024 in Malawi, the Data Protection Act of 2023 in Nigeria, Law N° 058/2021 of 13/10/2021 relating to the Protection of Personal Data and Privacy in Rwanda, the Personal Data Protection Act 11 of 2022 in Tanzania, and POPIA in South Africa.²⁵ However, despite their importance, these terms have been defined and interpreted differently across jurisdictions and academic fields, and are also often used interchangeably. At the outset and in the paragraphs that follow, I first provide broad definitions for de-identification, anonymisation, and pseudonymisation, and briefly clarify

²² Heidi C Howard et al ‘Blurring lines: The research activities of direct-to-consumer genetic testing companies raise questions about consumers as research subjects’ (2010) 11(8) *EMBO Rep* 580–1.

²³ Stacey Pereira, Richard A Gibbs & Amy L McGuire ‘Open access data sharing in genomic research’ (2014) 5 *Genes* 740; Jane Kaye ‘The tension between data sharing and the protection of privacy in genomics research’ (2012) 13 *Annu Rev Genomics Hum Genet* 10–1; Bradley Malin, David Karp & Richard H Scheuermann ‘Technical and policy approaches to balancing patient privacy and data sharing in clinical and translational research’ (2010) 58(1) *J Invest Med* 4; Elizabeth R Pike ‘Securing sequences: Ensuring adequate protections for genetic samples in the age of big data’ (2015) 37 *Cardozo L Rev* 2016–7; Cacchio op cit note 14 at 231; RB Altman ‘Direct-to-consumer genetic testing: Failure is not an option’ (2009) 86(1) *Clin Pharmacol Ther* 16; David B Resnik ‘Direct-to-consumer genomics, social networking, and confidentiality’ (2009) 9(6-7) *Am J Bioeth* 46; Melissa Gymrek, Amy L McGuire, David Golan et al ‘Identifying personal genomes by surname inference’ (2013) 339(6117) *Science* 321–4; Yaniv Erlich, James B Williams, David Glazer et al ‘Redefining genomic privacy: Trust and empowerment’ (2014) 12(11) *PLoS Biol* 1; Zachary Shapiro ‘Big data, genetics, and re-identification’ *Harvard Law* 24 September 2015, available at <https://blog.petrieflom.law.harvard.edu/2015/09/24/big-data-genetics-and-re-identification/>, accessed on 1 June 2022; Mats G Hansson, Hanns Lochmüller, Olaf Riess et al ‘The risk of re-identification versus the need to identify individuals in rare disease research’ (2016) 24 *Eur J Hum Genet* 1553.

²⁴ Bonomi, Huang & Ohno-Machado op cit note 5 at 646.

²⁵ See also, Aliko Edgcumbe, Marietjie Botes, Dusty-Lee Donnelly et al ‘“Potato potahto”? Disentangling de-identification, anonymisation and pseudonymisation for health research in Africa’ (2024) Forthcoming in *JLB*.

their differences. I then focus on where and how these terms have been used in the South African context.

(i) *De-identification and anonymisation*

Many academics in the literature have attempted to define de-identification and anonymisation. Based on this, both de-identification and anonymisation involve the removal of personal identifiers (such as name and contact information). However, de-identification can be reversed, making it possible to trace the data back to its source.²⁶ In contrast, anonymisation involves permanently removing personal identifiers from the data, thus making it nearly impossible to re-identify the original source of the data.²⁷

Even though de-identification is often used to justify both the consensual and non-consensual sharing of genomic data,²⁸ achieving complete de-identification is impossible. Records, databases, and other methods can be used together to potentially re-identify individuals.²⁹ This can be done through statistical methods with information about an individual's phenotypic characteristics, such as age, gender, and disease status. This not only holds implications for the individual concerned, but their close relatives too.³⁰ Because of the nature of genomic data and the possibility of re-identification,³¹ privacy cannot be guaranteed.

Another issue is that even if de-identification was successful in terms of truly anonymising genetic data, identifiability must be balanced against its usefulness. The removal of too much data results in decreased scientific value and may hamper research.³²

It is also important to consider the local context, and the meanings given to de-identification and anonymisation in South African law. These terms frequently acquire specific

²⁶ Kaye op cit note 23 at 10; Lee Swales 'The Protection of Personal Information Act and data de-identification' (2021) 117(7/8) *S Afr J Sci* 2; Pike op cit note 23 at 2018.

²⁷ Kaye op cit note 23 at 10; Educause 'Guidelines for data de-identification or anonymization' July 2015 available at <https://www.educause.edu/focus-areas-and-initiatives/policy-and-security/cybersecurity-program/resources/information-security-guide/toolkits/guidelines-for-data-deidentification-or-anonymization>, accessed on 21 May 2021. See also, Swales op cit note 26 at 2.

²⁸ Pike op cit note 23 at 2016.

²⁹ Pike op cit note 23 at 2016–7; Cacchio op cit note 14 at 231; Academy of Science of South Africa *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (2018) 57; Altman op cit note 23 at 16; Resnik op cit note 23 at 46; Gymrek et al op cit note 23 at 321–4; Erlich et al op cit note 23 at 1.

³⁰ The insufficiency of de-identification of genomic data was further demonstrated by Gymrek et al in 2013. Using only the date of birth and state of residence, the researchers identified the source simply by juxtaposing sections of an individual's genetic sequence with those shared in publicly accessible databases – allowing anyone possessing internet research skills to repeat this process. Gymrek et al op cit note 23 at 321–4; Pike op cit note 23 at 2017; Resnik op cit note 23 at 46.

³¹ Kaye op cit note 23 at 10; Swales op cit note 26 at 2; Pike op cit note 23 at 2018.

³² Pike op cit note 23 at 2018.

legal and technical meanings that are unique across jurisdictions.³³ South African data protection legislation does not include ‘anonymisation’, but POPIA uses the term ‘de-identification’,³⁴ and it also defines ‘de-identify’ as:

“‘de-identify”, in relation to personal information of a data subject, means to delete any information that—

- (a) identifies the data subject;
- (b) can be used or manipulated by a reasonably foreseeable method to identify the data subject;
- or
- (c) can be linked by a reasonably foreseeable method to other information that identifies the data subject’.³⁵

The definition of ‘de-identify’ in POPIA refers to the reasonable *foreseeability* that a method could be used to identify individuals.³⁶ Additionally, POPIA requires that personal information must be de-identified ‘to the extent that it cannot be re-identified again’.³⁷

(ii) *Pseudonymisation*

Like anonymisation, pseudonymisation is not a term used in South African law and it does not feature in POPIA, but it remains relevant. The proposed *POPIA Code of Conduct for Research* included the term ‘pseudonymisation’, defining it as meaning that ‘Personal Information is Processed in such a way that the Personal Information can no longer be attributed to a specific Research Participant without the use of additional information, provided that such additional information is kept separately, confidential and secure from unauthorised access’.³⁸ The proposed *POPIA Code of Conduct for Research* stipulates that additional information must be kept ‘confidential and secure from unauthorised access’.³⁹

Terms relating to data protection – specifically de-identification, anonymisation, and pseudonymisation – require clarification in order to create greater legal certainty.⁴⁰ When defining and using these terms, it is important that the correct terminology for each country is used as they are distinct legal concepts in different jurisdictions. This highlights the need for

³³ Edgcumbe et al op cit note 25.

³⁴ Section 6(1)(b) of POPIA.

³⁵ Section 1 of POPIA.

³⁶ Edgcumbe et al op cit note 25.

³⁷ Section 6(1)(b) of POPIA; *ibid*.

³⁸ Academy of Science of South Africa (ASSAf) *POPIA [proposed] Code of Conduct for Research* (2023) GG 48589 of 12 May 2023 59.

³⁹ *Ibid* at 59; Edgcumbe et al op cit note 25.

⁴⁰ Edgcumbe et al op cit note 25.

researchers to be precise when using these terms and avoid the assumption that they are interchangeable.⁴¹

(b) The familial element of genomic data

Genomic data not only contains information about an individual, but it also relates to their family members.⁴² It may include delicate details about personal relationships or potential future health risks.⁴³ Therefore, privacy risks inherent in the sharing of genomic data also contain a familial element. This familial nature of genomic information may be seen to have both positive and negative aspects. The first (and more positive) aspect is that when an individual submits their DNA, the resulting genomic information may provide insights for the individual, as well as genetic relatives, regarding certain health conditions or ethnicity.⁴⁴ On the other hand, this genomic information may reveal adoption or paternity relationships that family members may not have been aware of.⁴⁵ Further, it may expose individuals and their relatives to privacy risks – such as the revealing of certain sensitive health conditions, which may have an impact on employment or insurance.⁴⁶

In highlighting the hereditary nature of genomic data and the fact that genomic data sharing has both a personal and familial element,⁴⁷ it has been noted that:

‘Respect for persons supports giving persons the opportunity to share their whole genome sequence information for scientific advancement, subject to strong baseline privacy protections. At the same time, individuals have a responsibility to safeguard their privacy as well as that of others, by giving thoughtful consideration to how sharing their whole genome sequencing data in a public forum might expose them to unwanted incursions upon their privacy and that of their immediate relatives’.⁴⁸

When an individual provides their genomic data for research, they are also providing genomic data from their biological relatives – typically without them knowing rather than going against their wishes.⁴⁹ Generally, family members are not required to give consent when an individual

⁴¹ Ibid.

⁴² Cacchio op cit note 14 at 226.

⁴³ British Society for Genetic Medicine *The Retention of Genetic Family Records: Guidance for Clinical Practice* (2023) 5.

⁴⁴ Shabani & Borry op cit note 3 at 8.

⁴⁵ British Society for Genetic Medicine op cit note 43 at 9.

⁴⁶ Shabani & Borry op cit note 3 at 4; Friend et al op cit note 8 at 6.

⁴⁷ Shabani & Borry op cit note 3 at 8.

⁴⁸ Presidential Commission for the Study of Bioethical Issues *Privacy and Progress in Whole Genome Sequencing* (2012) 46–7 cited in Shabani & Borry op cit note 3 at 10–1.

⁴⁹ Horton & Lucassen op cit note 9 at 40.

submits their DNA sample.⁵⁰ Although the connection between an individual's genomic data and that of their family members should not prevent genomics research, it highlights the need for strong and reliable systems to ensure that the data is handled and protected ethically.⁵¹ Given that the sharing and use of genomic data heightens the risk of privacy infringements, a common solution in genomics research is to encourage individuals to discuss the research and its implications with their family members.⁵²

There appears to have been a shift in the approach towards the privacy of genomic information. Whilst the traditional view focused on the fact that because genomic information is sensitive and may have implications for individuals, as well as their genetic relatives, privacy protections should be taken seriously⁵³ – and there was concern regarding the age of social media and direct-to-consumer genetic testing, where genomic information was easily accessible and shareable.⁵⁴ However, an alternative view is to consider that individuals who submit their DNA – whether it be for genetic testing or genomics research – are also providing their families with certain insights on their own health, which is a positive and relatives should have access to relevant information.⁵⁵ Although some express concern about the possibility of upsetting family dynamics,⁵⁶ it has been emphasised that genomic information should be confidential to families rather than individuals.⁵⁷ Given that previous chapters have established the importance of Ubuntu in South Africa, which highlights the importance of the community as well as the individual, I suggest that this familial approach to genomic information is suited to the South African context.

Genomic data provides profound insights into an individual's traits and health, and its integration with phenotypic data enhances research into the interactions between genes, environment, and health. However, the privacy of genomic data is a complex issue that involves balancing the benefits of data sharing with the risks of privacy violations, particularly due to the familial nature of genomic information. While de-identification and anonymisation offer

⁵⁰ Friend et al op cit note 8 at 6.

⁵¹ Horton & Lucassen op cit note 9 at 40.

⁵² Shabani & Borry op cit note 3 at 8; Horton & Lucassen op cit note 9 at 40.

⁵³ Bonomi, Huang & Ohno-Machado op cit note 5 at 2; Tobias Haeusermann, Marta Fadda, Alessandro Blasimme et al 'Genes wide open: Data sharing and the social gradient of genomic privacy' (2018) 9(4) *AJOB Empirical Bioethics* 208.

⁵⁴ Bermseok Oh 'Direct-to-consumer genetic testing: Advantages and pitfalls' (2019) 17(3) *Genomics Inform* 1; Amy Gooden & Donrich W Thaldar 'Direct-to-consumer genetic testing in South Africa: Stumbling over the first legal hurdle?' (2022) 25 *PER/PELJ* 2.

⁵⁵ Rachel H Horton & Anneke M Lucassen 'Recent developments in genetic/genomic medicine' (2019) 133(5) *Clinical Science* 704.

⁵⁶ Ibid at 704.

⁵⁷ Ibid at 704.

some level of privacy, they are not foolproof and may also impact data usefulness. In the context of South Africa, where communal values are emphasised, a familial approach to genomic data privacy – recognising the interconnectedness of individuals and their families – might be more culturally appropriate. Nevertheless, regardless of the approach, it is crucial to implement strong privacy protections and encourage thoughtful consideration of the implications of genomic data sharing for both individuals and their relatives.

IV PRIVACY AND CONFIDENTIALITY

Privacy and confidentiality are two important terms which must be distinguished from one another. The protection of privacy and confidentiality is enumerated in the bioethical principle of non-maleficence, to do no harm.⁵⁸ Privacy and confidentiality are also foundational principles in the realm of personal data protection, ensuring that individuals' sensitive information remains secure and is handled with the utmost discretion.⁵⁹

Although the exact meanings given to privacy and confidentiality may differ slightly depending on the context in which they are used, my focus in this thesis (and for the purposes of this Chapter) is on privacy and confidentiality in terms of genomic data and genomics research. Therefore, the meanings afforded to privacy and confidentiality in the sub-headings below are relevant to, and viewed in light of, genomics specifically.

(a) Privacy

Privacy is a universal concept that has been difficult to define, and it varies depending on the prevailing social norms, economic conditions, and cultural context.⁶⁰ What is considered private can change based on the time period, the society, and the individual.⁶¹ The modern notion of privacy, developed by Warren and Brandeis, was defined as 'the right to be let alone'.⁶² Since then, various others have attempted to define privacy. According to Solove, privacy is: (1) the right to be left alone; (2) restricted access to the self; (3) secrecy; (4) having control over personal information; (5) personhood; and (6) intimacy.⁶³ Westin defines privacy as 'the claim of an individual to determine what information about himself or herself should be

⁵⁸ Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 5 ed (2001) 128.

⁵⁹ Latifa Adarmouch, Marwan Felaefel, Robert Wachbroit et al 'Perspectives regarding privacy in clinical research among research professionals from the Arab region: An exploratory qualitative study' (2020) 21 *BMC Med Ethics* 2.

⁶⁰ Adrienn Lukács 'What is privacy? The history and definition of privacy' (2016) 258.

⁶¹ Ibid at 256.

⁶² Samuel D Warren & Louis D Brandeis 'The right to privacy' (1890) 4(5) *Harvard L Rev* 193.

⁶³ Daniel J Solove 'Conceptualizing privacy' (2002) 90(4) *Cal L Rev* 1099; Lukács op cit note 60 at 258–9.

known to others'.⁶⁴ Bloustein contends that privacy is closely linked to individuality, personhood, and human dignity.⁶⁵

Privacy shields individuals from unauthorised access to their personal selves.⁶⁶ Privacy refers to an individual's right of control over the collection, use, and disclosure of their personal information. It relates to 'persons and to their interest in controlling the access of others to themselves'.⁶⁷ Privacy means restricting access to a person or their information. The right to privacy encompasses the ethical and legal principles that uphold the importance of controlling who can access an individual or information about them.⁶⁸

Privacy is not a standalone concept, but it also exists in various dimensions.⁶⁹ The first is *informational* privacy, which concerns the restrictions on access to personal information.⁷⁰ It encompasses the right of an individual to choose when, how, and to what extent their information is shared with others.⁷¹ As technology advances and the risks inherent therein grow, there is a greater need for strong data protection. As such, informational privacy extends beyond what individuals can personally control; it also involves preventing the spread of private information about individuals. Informational privacy is compromised when an individual's personal information is collected without their consent.⁷²

The second is *social* privacy, which entails an individual's capability to guide social contacts, and includes freedom from exchanges with others as well as any coercion on their chosen path.⁷³ Privacy is maintained to the degree that an individual can manage their own behaviour by controlling their interactions with others.⁷⁴ Social privacy is considered to be both

⁶⁴ Alan F Westin 'Social and political dimensions of privacy' (2003) 59(2) *Journal of Social Issues* 431; Lukács op cit note 60 at 258–9.

⁶⁵ Edward J Bloustein 'Privacy as an aspect of human dignity: An answer to Dean Prosser' in Edward J Bloustein (ed) *Individual and Group Privacy* (2017) 974; Lukács op cit note 60 at 258–9.

⁶⁶ Francis op cit note 19 at 122.

⁶⁷ Joan E Sieber 'Privacy and confidentiality: As related to human research in social and behavioral science' (2001) *Online Ethics Center at the National Academy of Engineering*.

⁶⁸ Wright Clayton et al op cit note 21 at 4–5.

⁶⁹ H Leino-Kilpia, M Välimäki, T Dassen et al 'Privacy: A review of the literature' (2001) 38 *International Journal of Nursing Studies* 664; Marcel Ayres & José Carlos Ribeiro 'The informational dimension in the regulation of the privacy context in social interactions mediated by cellular mobile devices' (2018) 41(1) *São Paulo* 81.

⁷⁰ Jeantine E Lunshof, Ruth Chadwick, Daniel B Vorhaus et al 'From genetic privacy to open consent' (2008) *Nature Reviews Genetics* 3; Wright Clayton et al op cit note 21 at 4–5.

⁷¹ Leino-Kilpia et al op cit note 69 at 666.

⁷² Ibid at 666.

⁷³ Ibid at 665.

⁷⁴ Ibid at 665.

an individual and a collective condition. It is influenced by cultural factors, which affect how individuals attempt to protect their privacy.⁷⁵

The third is *psychological* privacy, which concerns an individual's ability to control cognitive functions, create values, and decide when and with whom they share thoughts or information.⁷⁶ Psychological privacy is linked to how individuals internally reflect on their feelings about the information they choose to share.⁷⁷ Psychological privacy is crucial because it helps to maintain a safe mental space where individuals can uphold their personal and cultural values during interactions with others.⁷⁸ Psychological privacy can either support or hinder an individual's personal development.⁷⁹

The fourth is *physical* privacy, which refers to how physically available an individual is to others.⁸⁰ It relates to access to individuals and personal spaces.⁸¹ This describes ideas of personal space and territoriality. Personal space is an invisible area around an individual that acts as a buffer, keeping individuals apart and offering a sense of protection.⁸² Territoriality, on the other hand, refers to a physical space such as a home or office, and sometimes extends to areas of expertise or social standing.⁸³ Territoriality allows individuals to have a private space of their own, and can be seen to promote autonomy, privacy, security, and self-identity.⁸⁴

(i) *Genetic privacy*

Privacy also presents unique challenges to genomic data. Since genomic information about one individual can reveal information about their relatives, there is a privacy concern that someone might obtain information about individuals without directly accessing them or even informing them.⁸⁵ This has given rise to the concept of 'genetic privacy'. Genetic privacy involves the interests of individuals, families, and communities regarding genetic information.⁸⁶ These interests underpin various claims related to rights and responsibilities, such as ownership,

⁷⁵ Ibid at 665.

⁷⁶ Ibid at 665.

⁷⁷ Ayres & Ribeiro op cit note 69 at 84.

⁷⁸ Natalia Serenko 'Informational, physical, and psychological privacy as determinants of patient behaviour in health care' in Vaughan Michell, Deborah J Rosenorn-Lanng, Stephen R Gulliver et al (eds) *Handbook of Research on Patient Safety and Quality Care through Health Informatics* (2013) 8.

⁷⁹ Leino-Kilpia et al op cit note 69 at 665.

⁸⁰ Ibid at 665.

⁸¹ Wright Clayton et al op cit note 21 at 4–5.

⁸² Leino-Kilpia et al op cit note 69 at 665.

⁸³ Ibid at 665.

⁸⁴ Ibid at 665.

⁸⁵ Francis op cit note 19 at 122; Wright Clayton et al op cit note 21 at 5.

⁸⁶ Bartha Maria Knoppers & Michael JS Beauvais 'Three decades of genetic privacy: A metaphoric journey' (2021) 30(20) *Human Molecular Genetics* 157.

control, exclusion, non-interference, and protection.⁸⁷ Genetic privacy affects a diverse group of stakeholders, including probands, their families, sequencing labs, researchers, clinicians, health administrators, insurance companies, and public health agencies.⁸⁸

Genetics is intricately linked to information, ranging from the vast dataset of the human genome to genetic test results.⁸⁹ As such, genetic privacy is an instance of privacy (and is important to informational privacy),⁹⁰ and refers to the right of an individual – which may also extend to their family and community – to be protected from having their genetic information disclosed without their consent.⁹¹ Genetic privacy allows individuals to control who can access their genetic information, giving individuals authority over their genetic data and any information derived from it.⁹²

(b) Confidentiality

Confidentiality is a concept that exists within the domain of privacy,⁹³ and typically features in the medical setting. In the traditional doctor-patient relationship, confidentiality is of paramount importance, and is one of the duties contained in the Hippocratic Oath.⁹⁴ Confidentiality denotes the obligation to ensure that information remains classified as far as possible.⁹⁵ It safeguards personal information from being used or shared without consent.⁹⁶ Whilst privacy relates to individuals, confidentiality involves data.⁹⁷ Confidentiality refers to ‘agreements with persons about what may be done with their data’.⁹⁸ Confidentiality refers to the sharing of information within a trusted relationship with the understanding – whether

⁸⁷ Ibid at 157.

⁸⁸ Ibid at 157.

⁸⁹ Wright Clayton et al op cit note 21 at 5.

⁹⁰ Lunshof et al op cit note 70 at 2 & 3; Wright Clayton et al op cit note 21 at 5.

⁹¹ Lunshof et al op cit note 70 at 2.

⁹² Ana Santurtuna, Carlos Lema & María T Zarrabeitia ‘Fundamental rights regarding forensic databases: Review and analysis of Kuwait’s law 78/2015’ (2017) 43(2) *Rev Esp Med Legal* 81.

⁹³ Wright Clayton et al op cit note 21 at 5; Lunshof et al op cit note 70 at 3.

⁹⁴ General Assembly of World Medical Association *Declaration of Geneva* (1948).

⁹⁵ Sharon Young ‘Privacy versus confidentiality’ *Office of the Saskatchewan Information and Privacy Commissioner* 8 December 2017, available at <https://oipc.sk.ca/privacy-versus-confidentiality/#:~:text=In%20terms%20of%20information%2C%20privacy,used%2C%20and%20For%20disclosed.&text=Confidentiality%20is%20the%20duty%20to,only%20to%20the%20extent%20possible.>, accessed on 20 April 2020; Association for the Accreditation of Human Research Protections ‘Privacy vs. confidentiality – What’s the difference?’ (2009) *University of Kentucky* 1.

⁹⁶ Francis op cit note 19 at 122.

⁹⁷ Association for the Accreditation of Human Research Protections op cit note 95 at 1.

⁹⁸ Joan E Sieber *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards* (1992) 52.

explicit or implied – that it will not be revealed to others without consent.⁹⁹ It involves trust in both personal and professional interactions.¹⁰⁰

In terms of research, confidentiality applies in terms of maintaining the privacy of genetic information and ensuring that it is not shared without permission.¹⁰¹ It involves the researcher's commitment as to how they will handle, manage, and share the research participant's identifiable private information based on their agreement.¹⁰² Confidentiality involves putting in place the necessary measures to prevent any information that could identify a research participant from being disclosed, whether intentionally or accidentally.¹⁰³ It focuses on ensuring that research data is not carelessly or unintentionally shared in a way that could reveal a research participant's identity or make them susceptible to harm.¹⁰⁴ In practice, confidentiality usually means making sure that only the researcher knows the identities of the research participants.¹⁰⁵ However, in research confidentiality is often upheld at a more generalised level because various research stakeholders have access to the data.¹⁰⁶ Confidentiality may be violated through encouraging the sharing of personal genomic data online.¹⁰⁷

Although confidentiality is an important concept that may be relevant – and will be mentioned where necessary – the focus of this Chapter is on privacy in terms of genomics research and open consent. Privacy is the primary focus of this Chapter because it is the overarching concept within which confidentiality falls. Additionally, privacy is a central issue in genomics research and a constitutional right in South Africa.

V SELECTED CONCEPTUAL APPROACHES TOWARDS PRIVACY

The concept of privacy has been subject to various meanings and is challenging to define – it has tended to be characterised in relation to, and occasionally confused with, concepts like autonomy, secrecy, freedom, and solitude.¹⁰⁸ Privacy has been approached from numerous

⁹⁹ Wright Clayton et al op cit note 21 at 5.

¹⁰⁰ Lunshof et al op cit note 70 at 3.

¹⁰¹ Wright Clayton et al op cit note 21 at 5.

¹⁰² Association for the Accreditation of Human Research Protections op cit note 95 at 1.

¹⁰³ Department of Health *Ethics in Health Research: Principles, Processes and Structures* 2 ed (2015) 15.

¹⁰⁴ Ibid at 20.

¹⁰⁵ Karen Kaiser 'Protecting confidentiality' in Jaber F Gubrium, James A Holstein, Amir B Marvasti et al (eds) *The SAGE Handbook of Interview Research: The Complexity of the Craft* 2 ed (2012) 457.

¹⁰⁶ ASSAf op cit note 29 at 55.

¹⁰⁷ Gemma R Brett et al 'An exploration of genetic health professionals' experience with direct-to-consumer genetic testing in their clinical practice' (2012) 20 *European Journal of Human Genetics* 825.

¹⁰⁸ Herman T Tavani 'Philosophical theories of privacy: Implications for an adequate online privacy policy' (2007) 38(1) *Metaphilosophy* 3.

perspectives in both philosophical and interdisciplinary scholarship. While an overview of these diverse conceptualisations of privacy is crucial to provide context, this heading focuses in more depth on approaches that are directly relevant to the challenges posed by open consent in genomics research, specifically in the South African context. In particular, the emphasis on individual rights, as per the Constitution, is important. Also, familial and group privacy, as well as the relational aspects of privacy, aligns closely with the communal values of Ubuntu and the unique ethical considerations of sharing genomic data in a culturally diverse society. Other approaches, such as differential privacy, inferential privacy, and predictive privacy – while valuable in broader data privacy discussions – are less directly applicable to the specific issues examined here and are therefore only briefly addressed. The primary conceptual approaches towards privacy that are explored below are: (1) differential privacy, inferential privacy, and predictive privacy; (2) individual privacy and personal privacy; (3) restricted access/limited control theory of privacy; (4) privacy as a social contract; (5) relational privacy; (4) categorical privacy; and (5) group privacy. It should be noted that the four dimensions of privacy detailed above – namely, informational privacy, social privacy, psychological privacy, and physical privacy – may fall within the various conceptual approaches below, but will not be discussed here as it has been done above.

(a) Differential privacy, inferential privacy, and predictive privacy

Differential privacy, inferential privacy, and predictive privacy are mathematical standards of privacy, and are not directly relevant to this thesis, but will be mentioned briefly. Differential privacy ensures that the removal or addition of a single individual's data does not significantly affect the outcome of data analysis, thus protecting individuals' privacy in large datasets.¹⁰⁹ Differential privacy is a method used to protect the privacy of individuals in a dataset, even when the data is made publicly accessible.¹¹⁰

Inferential privacy focuses on the inferences that can be drawn about a group of individuals based on a shared characteristic or feature, such as being a smoker, that applies to all members of the group.¹¹¹ Loi and Christen define inferential privacy as '[t]he inferential privacy of an entity (individual or group) X, is a measure of the logically valid inferences, about the *sensitive features* of X, that *cannot* be made about X, based on the available data

¹⁰⁹ Harvard University 'Differential privacy' 2024 available at <https://privacytools.seas.harvard.edu/differential-privacy>, accessed on 6 October 2024.

¹¹⁰ Rishabh Subramanian 'Have the cake and eat it too: Differential privacy enables privacy and precise analytics' (2023) 10 *Journal of Big Data* 2.

¹¹¹ Michele Loi & Markus Christen 'Two concepts of group privacy' (2020) 33 *Philosophy & Technology* 208.

about X'.¹¹² There is concern that an individual's privacy may be compromised through inferences drawn from data about other individuals.¹¹³

Predictive privacy aims to safeguard individuals and groups from unjust treatment and violations of their autonomy, dignity, and well-being that arise from the use of information predicted through statistical correlations with the behaviour of others.¹¹⁴ It is considered a breach of an individual's or group's predictive privacy if sensitive information about them is statistically estimated without their consent or awareness, based on data from others.¹¹⁵ This is particularly problematic if these predictions result in unequal treatment or decisions that impact an individual's economic, social, physical, and psychological well-being, or freedom.¹¹⁶ Predictive privacy is violated when a prediction about individuals or a profiling of groups is made using data collected from many other users of digital services, rather than when an individual's private information is stolen or exposed.¹¹⁷

Though beyond the scope of this thesis, differential privacy, inferential privacy, and predictive privacy may be relevant in the discussion of how genomic data is anonymised or de-identified in research.

(b) Individual privacy and personal privacy

The terms individual privacy and personal privacy are often used interchangeably, but they both feature in discussions relating to technology, computer science, and big data.¹¹⁸ The widespread availability of modern technologies and tools – such as search engines, hacking software, social networks, and data mining and machine learning tools – presents significant challenges to individual privacy.¹¹⁹ Individual privacy is the right of individuals to keep their personal information private and to manage how their data is collected and shared.¹²⁰ Personal

¹¹² Sensitive features are characteristics that the majority of individuals in a particular society at a specific time prefer to keep private, as well as features that an individual does not want to be disclosed about themselves. Ibid at 218.

¹¹³ Rainer Mühlhoff 'Predictive privacy: Towards an applied ethics of data analytics' (2021) 23 *Ethics and Information Technology* 679.

¹¹⁴ Ibid at 676.

¹¹⁵ Ibid at 676.

¹¹⁶ Ibid at 676.

¹¹⁷ Ibid at 678.

¹¹⁸ ScienceDirect 'Personal privacy' available at <https://www.sciencedirect.com/topics/computer-science/personal-privacy>, accessed on 7 September 2024; Shui Yu 'Big privacy: Challenges and opportunities of privacy study in the age of big data' (2016) 4 *IEEE Access* 2751; Mackenzie Adams 'Big data and individual privacy in the age of the internet of things' (2017) 7(4) *Technology Innovation Management Review* 12.

¹¹⁹ Yu op cit note 118 at 2751.

¹²⁰ ScienceDirect 'Individual privacy' available at <https://www.sciencedirect.com/topics/computer-science/individual-privacy>, accessed on 7 September 2024.

privacy involves an individual actively protecting themselves from being physically or psychologically observed by others. It includes aspects like solitude, reserve anonymity, and intimacy. Personal privacy safeguards individuals' right to be left alone, allowing them to make decisions and express themselves authentically while supporting values such as personal freedom, dignity, and loving relationships.¹²¹ Both individual privacy and personal privacy are at risk when data is collected, as a data breach can reveal an individual's private information. Additionally, privacy is threatened when individuals and companies use this collected data, claiming consent for personalised experiences.¹²²

(c) Restricted access/limited control theory of privacy

The restricted access/limited control theory of privacy (RALC) was developed by Tavani and Moor.¹²³ RALC operates on the premise that a comprehensive theory of privacy must distinguish between the concept of privacy itself and both its justification and management. RALC framework consists of three main components: defining privacy, justifying privacy, and managing privacy.¹²⁴ When analysing the concept of privacy, RALC differentiates between the condition of privacy – what is needed to have privacy in a descriptive sense – and the right to privacy. This distinction helps clarify the difference between a loss of privacy and a violation or invasion of privacy.¹²⁵

According to RALC, an individual experiences privacy 'in a situation with regard to others' when they are protected from intrusion, interference, and access to their information by others. The term 'situation' is intentionally vague, allowing it to cover various circumstances typically seen as private, such as activities in a specific location, personal relationships, or the handling of information on a computer.¹²⁶ RALC further distinguishes between naturally private situations and normatively private situations. In naturally private situations, individuals are protected from observation and intrusion through natural means, like physical barriers while hiking or camping. Here, privacy can be lost but not violated, as there are no established norms or rights to protection.¹²⁷ In contrast, normatively private situations include places like an individual's home, confidential relationships (such as religious confessions), activities like

¹²¹ ScienceDirect op cit note 118.

¹²² Adams op cit note 118 at 13.

¹²³ Herman T Tavani & James H Moor 'Privacy protection, control of information, and privacy-enhancing technologies' (2001) 31(1) *Computers and Society* 6–11.

¹²⁴ Tavani op cit note 108 at 10.

¹²⁵ Ibid at 10.

¹²⁶ Ibid at 10.

¹²⁷ Ibid at 10.

voting, and sensitive information like medical records. In these situations, privacy can be both lost and violated, as there are laws and norms that exist to safeguard them.¹²⁸

The RALC theory connects privacy to the idea of protecting individuals by limiting access to them or their information, which might make it seem like just another version of the limitation theory.¹²⁹ RALC is not just a variation of restricted access theory as it recognises the role of control in both justifying and managing privacy. RALC defines privacy as protection from intrusion and information gathering rather than solely as control over an individual's information.¹³⁰

Moor and Tavani's analysis of the control theory revealed challenges in defining privacy solely based on control.¹³¹ For instance, it is possible to have privacy without complete control, and vice versa. Nonetheless, the concept of 'limited control' is integral to the RALC framework.¹³² To illustrate how control functions within RALC, consider medical information: It is private because specific norms restrict access, not because the individual fully controls who sees that information. Healthcare professionals may legitimately access parts of it. The justification for protecting medical records includes individuals' desires to avoid embarrassment and maintain some control over their lives, such as who they associate with and what jobs they take.¹³³

Privacy policies that restrict access help provide individuals with limited control. Management of privacy does not require absolute control; instead, it involves having some degree of control over three key elements: (1) choice; (2) consent; and (3) correction. Individuals should be able to choose situations that determine the level of access others have, consent to share certain information, and correct their personal data if necessary.¹³⁴ RALC distinguishes the concept of privacy from its justification and management, consisting of three main components. Privacy is defined as protection from intrusion in specific situations, backed by explicit norms or laws. While privacy centres on protection and restricted access, the notion of control is also crucial in the RALC framework, informing both the justification for and management of privacy.¹³⁵

¹²⁸ Ibid at 10.

¹²⁹ Ibid at 11.

¹³⁰ Ibid at 11.

¹³¹ Tavani & Moor op cit note 123 at '6–11.

¹³² Tavani op cit note 108 at 11.

¹³³ Ibid at 11.

¹³⁴ Ibid at 12.

¹³⁵ Ibid at 12.

(d) *Privacy as a social contract*

Privacy norms can be seen as agreements that are beneficial and sustainable for everyone within a community, shaped by the specific context.¹³⁶ These are the unwritten rules that individuals and groups follow in different situations, communities, and relationships. In other words, individuals share their information with the understanding of the privacy guidelines that apply to each specific context.¹³⁷

Privacy as a social contract recognises that the right to privacy is not absolute, and is subject to the compromises individuals and society must make in order to co-exist within a community. Privacy as a social contract is an understanding within a community about how personal information is exchanged and used in ways that benefit both individuals and society as a whole.¹³⁸

In terms of genomics research, privacy as a social contract underpins discussions on the balance between individual privacy and the benefits that genomics research may hold for society as a whole – which is particularly relevant given South Africa’s focus on community and Ubuntu.

(e) *Relational privacy*

Like autonomy (discussed in Chapter 3), privacy has also been critiqued for focusing on the individual and not taking the collective into account.¹³⁹ Relational autonomy – which emphasises a contextual view of autonomy – forms the foundation of relational privacy. This concept encompasses all ideas of privacy that take a contextualised or networked approach.¹⁴⁰

Both informational privacy and data protection have tended to be seen as individual rights. Although the social aspects of these concepts are recognised, the individual data subject ultimately remains the holder of these rights.¹⁴¹ Consequently, collective interests are often viewed as a collection of individual concerns, and collective or public issues are usually addressed through remedies focused on individual rights and their enforcement.¹⁴² However, the connections between individual in networks are crucial to shaping identities, leading many

¹³⁶ Kirsten Martin ‘Understanding privacy online: Development of a social contract approach to privacy’ (2016) 137 *J Bus Ethics* 553.

¹³⁷ *Ibid* at 553.

¹³⁸ *Ibid* at 553.

¹³⁹ Urbano Reviglio & Rogers Alunge “‘I am datafied because we are datafied’: An Ubuntu perspective on (relational) privacy’ (2020) 33 *Philos Technol* 598.

¹⁴⁰ *Ibid* at 598.

¹⁴¹ *Ibid* at 599.

¹⁴² *Ibid* at 599.

theorists to shift from a strict ‘public’ versus ‘private’ view to a more relational understanding of privacy.¹⁴³ Relational autonomy promotes a networked view of privacy, suggesting that the context and related informational norms are co-created by participants and can change over time. Therefore, it acknowledges that individuals may have different interpretations of contexts, that these contexts can become unstable, or that others may exert control over them in ways that are not within an individual’s control, such as through surveillance, information leaks, or data mining.¹⁴⁴ Relational privacy can be seen in the development of earlier concepts, such as categorical privacy and group privacy.¹⁴⁵

(f) Categorical privacy

Most views on individual privacy assume that personal data relates to identifiable individuals and that, even after processing, it continues to include details about those individuals. This leads to two significant issues: (1) it complicates the identification of problematic aspects when using data to create group profiles or generalisations; and (2) it makes it hard to grasp the real-world impact of these issues.¹⁴⁶ Group profiles and generalisations can sometimes conflict with the principles of individual privacy and data protection laws. For example, when individuals can be easily identified through a combination of information, these generalisations can be seen as privacy violations.¹⁴⁷ In contrast, non-distributive profiles link information to a group rather than to specific individuals, making it harder to trace back to anyone personally. The definitions of these groups often remain obscure to those outside the group, leading to perceptions that the criteria used are arbitrary.¹⁴⁸ Importantly, these generalisations focus on individuals as group members rather than as unique individuals. Thus, traditional privacy protections may not apply. Although collective privacy may be considered as a solution to the privacy of the group as a whole, this concept is problematic because it is often tied to collective rights, which assume groups function like individuals with the ability to advocate for their rights. However, the groups defined by these profiles often lack any organisational structure or loyalty among members, meaning they cannot act collectively.¹⁴⁹

¹⁴³ Ibid at 599.

¹⁴⁴ Ibid at 599.

¹⁴⁵ Ibid at 599.

¹⁴⁶ Anton Vedder ‘KDD: The challenge to individualism’ (1999) 1 *Ethics and Information Technology* 278.

¹⁴⁷ Ibid at 278.

¹⁴⁸ Ibid at 278.

¹⁴⁹ Ibid at 278.

In order to address the abovementioned shortcomings of individual privacy concepts, Vedder proposed the idea of categorical privacy.¹⁵⁰ Categorical privacy refers to privacy concerns that arise from being linked to a specific category, which can unintentionally result in discrimination, even if individuals themselves are not identifiable.¹⁵¹ Categorical privacy was introduced in order to address the limitations of traditional privacy concepts that focus solely on individuals. It aims to better protect the privacy of individuals within a group, considering the collective profile of that group rather than just individual privacy.¹⁵² Categorical privacy is akin to individual privacy, but pertains specifically to data with two conditions: (1) the data relates to information that originates from individuals but, after being aggregated and processed, loses personal identifiers and is instead associated with group identifiers; and (2) when disclosed, this information can have negative consequences for group members similar to those for individuals.¹⁵³ Categorical privacy is closely linked to individual privacy, as both oppose violations of personal autonomy and individuality. However, unlike collective privacy, categorical privacy emphasises the protection of individuals rather than the group to which the individual belongs.¹⁵⁴

Unlike individual privacy, categorical privacy highlights how generalised traits can affect individuals similarly to how specific attributes do. Violations of categorical privacy require different approaches than those for individual privacy. For instance, applying principles like consent and correction is challenging, as the reference group often lacks the ability to make collective decisions. Moreover, allowing individuals to opt out could harm both the group and the individual, as it could undermine the reliability of profiles that impact all members.¹⁵⁵ The best way to protect individuals from the negative effects of generalisations and profiles based on personal data may involve a case-by-case analysis of how this data is actually used.¹⁵⁶

(g) Group privacy

Group privacy has been defined as a ‘right that is held by a group as a group rather than by its members severally. It is the group, not its members, that is correctly identified as the right-

¹⁵⁰ Ibid at 279.

¹⁵¹ United Nations Children's Fund (UNICEF) *UNICEF Procedure on Ethical Standards in Research, Evaluation, Data Collection and Analysis* (2021) 18.

¹⁵² Lunshof et al op cit note 70 at 2–3; Mühlhof op cit note 113 at 680.

¹⁵³ Vedder op cit note 146 at 279.

¹⁵⁴ Ibid at 279.

¹⁵⁵ Ibid at 279.

¹⁵⁶ Ibid at 279.

holder'.¹⁵⁷ Group privacy is similar to the concept of categorical privacy, proposed by Vedder.¹⁵⁸ Privacy has tended to be viewed mainly in terms of individual rights, with the data subject as rights holders exercising their informational privacy. The group has typically been understood in terms of privacy only as a collection of individuals, each with their own privacy interests.¹⁵⁹ Groups are dynamic and can vary greatly in size, composition, and nature – making it challenging to establish a clear theory of group privacy. Because the individual is the only fixed entity, it is often argued that group privacy is simply the total of each member's individual privacy.¹⁶⁰ However, Floridi considers this perspective counterintuitive and contends that groups can possess rights to certain privileges collectively, independent of whether each individual member has those same rights.¹⁶¹ This is similar to the internationally recognised right to self-determination, which applies to a population as a whole, rather than to individuals within that population.¹⁶²

VI PRIVACY IN SOUTH AFRICA'S LEGAL SYSTEM

South Africa's legal system contains laws and regulations designed to protect privacy and personal information.¹⁶³ The Constitution recognises and protects the right to privacy, as does the common law. However, the right to privacy is not absolute and may be restricted if it is reasonable and justifiable.¹⁶⁴ In the sub-headings that follow, I examine where privacy and confidentiality feature in South African law, and where privacy and confidentiality have appeared in South African case law. This is done in an attempt to understand the meaning and application of these concepts from a South African perspective. It should be noted that because this thesis entails a constitutional analysis (and not a legal analysis), I will not be examining the specific provisions of relevant South African legislation in detail, but rather laying a foundation for the analysis of open consent below.

¹⁵⁷ Luciano Floridi 'Open data, data protection, and group privacy' (2014) 27 *Philos Technol* 1.

¹⁵⁸ Vedder op cit note 146 at 275–81; Mühlhof op cit note 113 at 680.

¹⁵⁹ Reviglio & Alunge op cit note 139 at 601.

¹⁶⁰ Ibid at 601.

¹⁶¹ Luciano Floridi 'Group privacy – A defense and an interpretation' in Linnet Taylor, Luciano Floridi & Bart van der Sloot (eds) *Group Privacy: New Challenges of Data Technologies* (2017) 83–100.

¹⁶² Reviglio & Alunge op cit note 139 at 601.

¹⁶³ Preeta Bhagattjee 'South Africa – Data protection overview' *Data Guidance* July 2024, available at <https://www.dataguidance.com/notes/south-africa-data-protection-overview>, accessed on 28 August 2024.

¹⁶⁴ DLA Piper 'Data protection laws of the world: South Africa' 17 January 2024 available at <https://www.dlapiperdataprotection.com/index.html?t=law&c=ZA#:~:text=The%20right%20to%20privacy%20is,and%20justifiable%20to%20do%20so.,> accessed on 29 August 2024.

(a) *Privacy in South African law*

Neethling et al define privacy as ‘an individual condition of life characterised by seclusion from the public’,¹⁶⁵ incorporating ‘all those personal facts which the person concerned has himself determined to be excluded from the knowledge of outsiders and in respect of which he has the will that they be kept private’.¹⁶⁶ Privacy is a legal right that patients and research participants have, and safeguarding personal information is a legal duty. In South Africa, the legal framework requires balancing the protection of personal information with the right of access to information and the right to freedom of expression.¹⁶⁷ Importantly, the right to privacy is protected in section 14 of the Constitution, which provides that:

‘Everyone has the right to privacy, which includes the right not to have –

- (e) their person or home searched;
- (f) their property searched;
- (g) their possessions seized; or
- (h) the privacy of their communications infringed’.¹⁶⁸

Section 14 of the Constitution provides for both a general right to privacy as well as protection against certain violations, such as searches and seizures and infringements of communications – though this list is not exhaustive.¹⁶⁹

In addition to the Constitution, various South African legislation is relevant to privacy. Of importance is POPIA, which regulates both the privacy of, and access to, data.¹⁷⁰ POPIA recognises that the right to privacy includes protection against the unlawful collection, storage, dissemination and use of personal information.¹⁷¹ In fulfilling its duties, POPIA aims to uphold the constitutional right to privacy by ensuring that the processing of personal information balances the right to privacy against the right of access to information.¹⁷² POPIA provides that personal information must be processed lawfully and in a way that protects the data subject’s

¹⁶⁵ J Neethling, JM Potgieter & PJ Visser *Neethling’s Law of Personality* 2 ed (2005) 32; Sandra Govender *The Protection of Genetic Privacy in South Africa: Towards a Legislative Response Based on a Cross-Jurisdictional Review of Legal Developments* (unpublished PhD thesis, University of the Witwatersrand, 2012) 95.

¹⁶⁶ Neethling, Potgieter & Visser op cit note 165 at 32; Govender op cit note 165 at 95.

¹⁶⁷ ASSAf op cit note 29 at 55.

¹⁶⁸ Section 14 of the Constitution.

¹⁶⁹ Beverley Alice Townsend *Privacy and Data Protection in eHealth in Africa – An Assessment of the Regulatory Frameworks that Govern Privacy and Data Protection in the Effective Implementation of Electronic Health Care in Africa: Is there a need for Reform and Greater Regional Collaboration in Regulatory Policymaking?* (unpublished PhD thesis, University of Cape Town, 2017) 113. See also, South African Law Reform Commission *Privacy and Data Protection Discussion Paper 109 Project 124* (2005) 4.

¹⁷⁰ ASSAf op cit note 29 at 56–7.

¹⁷¹ Preamble of POPIA.

¹⁷² Section 2 of POPIA.

privacy.¹⁷³ POPIA has heightened the need for robust computer security, secure storage for records, and strict controls on access to raw data, including informed consent forms.¹⁷⁴ In the context of POPIA, ‘de-identification’ involves removing all personal information that could identify a data subject.¹⁷⁵ For research, data is considered de-identified when it is not possible for researchers to use or link the data to identify the individual by a ‘reasonably foreseeable method’.¹⁷⁶ POPIA does not apply to de-identified personal information that cannot be re-identified.¹⁷⁷ Since genomic data is inherently identifiable and can potentially be traced back to an individual, it is likely that it still falls under POPIA, unless an individual deliberately makes the information public.¹⁷⁸ While POPIA is designed to protect privacy, it does not cover data that has been de-identified. However, because genomic data remains identifiable to some degree, POPIA still applies to genomics research.

Although dealing with confidentiality,¹⁷⁹ the NHA does not refer to privacy. However, the Human Research Participant Regulations – which form part of the NHA’s subsidiary legislation – recognise that health research must respect the privacy of research participants.¹⁸⁰ Moreover, when conducting health research, research participants must be informed of inter alia how their privacy and confidentiality will be protected.¹⁸¹

It is not just legislation, but there are numerous other documents and guidelines which, although not necessarily binding, serve to shed some light on privacy in the South African context. First, the DoH Ethics Guidelines – which are legally binding on health researchers – provide that one of the key norms is respect for privacy, something which all research participants are entitled to.¹⁸² Privacy is about determining who is allowed access to an individual’s personal information and records.¹⁸³ It involves an individual’s interest in managing who can access their personal information.¹⁸⁴ The DoH Ethics Guidelines define ‘privacy risks’ as ‘potential harms to participants from collection, use and disclosure of personal information for research purposes’.¹⁸⁵ Proposals to conduct health research must detail

¹⁷³ Section 9 of POPIA.

¹⁷⁴ Department of Health op cit note 103 at 15.

¹⁷⁵ Sections 1 and 6(1)(b) of POPIA.

¹⁷⁶ As per the definition of ‘de-identify’ in section 1 of POPIA.

¹⁷⁷ Section 6(1)(b) of POPIA.

¹⁷⁸ Section 27(1)(e) of POPIA.

¹⁷⁹ Section 14 of the NHA.

¹⁸⁰ Regulation 2(h) of the Human Research Participant Regulations.

¹⁸¹ Regulation 5(g) of the Human Research Participant Regulations.

¹⁸² Department of Health op cit note 103 at 15.

¹⁸³ Ibid at 15.

¹⁸⁴ Ibid at 20.

¹⁸⁵ Ibid at 54.

how constitutionally protected rights, such as privacy, will be safeguarded during the research process.¹⁸⁶ This includes explaining how data will be secured, the period of storage, and who will handle its storage and/or eventual disposal.¹⁸⁷ Informed consent documents should clearly outline how inter alia privacy will be safeguarded.¹⁸⁸ Research Ethics Committees (RECs) should focus on reducing risks to privacy and autonomy that may arise from re-identification.¹⁸⁹

Furthermore, the recently published NHREC Ethics Guidelines make reference to privacy in several different contexts.¹⁹⁰ The NHREC Ethics Guidelines recognise the ‘constitutionally protected right to privacy’ as an aspect of autonomy.¹⁹¹ It upholds the principle of respect for persons, which recognises inter alia privacy and confidentiality as central concerns in research involving human participants.¹⁹² The NHREC Ethics Guidelines define ‘privacy risks’ as ‘potential harms to participants from collection, use and disclosure of personal information for research purposes’.¹⁹³ Given that a type of research covered in the NHREC Ethics Guidelines in genomics research, and given that it has been established that genomics research poses privacy risks not only to individual, but their families and community too, there is a lack of focus on this in the NHREC Ethics Guidelines, which largely only mentions participants (though there are brief considerations for families and identifiable populations, which broadly entails that researchers should be aware of the risks that genomics research may hold for families and identifiable populations and should take steps to manage this information, reduce potential risks, and inform research participants about such information).¹⁹⁴

In terms of data science research (including big data), one of the questions that the NHREC Ethics Guidelines encourage RECs to ask is: ‘What measures are in place to uphold

¹⁸⁶ Ibid at 15.

¹⁸⁷ Ibid at 20.

¹⁸⁸ Ibid at 36.

¹⁸⁹ Ibid at 31.

¹⁹⁰ National Department of Health *South African Ethics in Health Research Guidelines: Principles, Processes and Structures* 3 ed (2024).

¹⁹¹ In terms of research, a research participant maintains the right to control who can access their personal information. This means that their information remains private unless they provide consent for others to access it, or if the law mandates its disclosure. Ibid at 19.

¹⁹² Ibid at 8.

¹⁹³ Ibid at 108.

¹⁹⁴ When evaluating the ethical implications of proposed genetic research, HRECs must consider various factors, including privacy and how the research findings might impact families, communities, and other social groups. Given the sensitive nature of the information that genetic research can uncover, which may have significant implications for participants and their relatives, HRECs should contemplate creating a plan to manage this information. Ibid at 74 & 77.

individual privacy and confidentiality?'.¹⁹⁵ This purely focuses on the individual and there is no mention of the family or community (although there is a subsequent question that asks whether there is a possibility for data to be re-linked to groups of individuals).¹⁹⁶ Additionally, under the heading relating to the sharing of human biological material (HBM) and data, the NHREC Ethics Guidelines provide that the sharing of HBM and data can lead to ethical challenges, primarily concerning the protection of *individual* privacy and confidentiality. There is no mention of the possible risks to the privacy of others.¹⁹⁷ This omission is concerning given that research using large amounts of data – some of which may be genetic – can have implications for family members. Additionally, this position fails to take the local context into consideration, where the focus is not purely on the individual but also on the community.

ASSAf was established through the Academy of Science of South Africa Act 67 of 2001 and the Science and Technology Laws Amendment Act 9 of 2020, and serves to provide evidence-based scientific guidance on public interest matters to the government and other stakeholders. ASSAf frequently publishes its findings and recommendations.¹⁹⁸ One such document, which relates to genetics and genomics in South Africa is the ASSAf Report, and it makes mention of both privacy and confidentiality. It takes the stance that in research generally, and in terms of genomics research specifically, individuals' personal and health information is private.¹⁹⁹ Collecting a genetic sample, conducting genetic testing, and accessing, disclosing, or publishing the results without an individual's consent would violate their right to privacy.²⁰⁰ The ASSAf Report makes reference to POPIA and its protection of genomic data (as a type of biometric information) as special personal information.²⁰¹ POPIA generally prohibits the processing of special personal information, but there are specific exceptions, such as when the data subject consents or when processing is necessary for historical, statistical, or research purposes.²⁰²

¹⁹⁵ Ibid at 61.

¹⁹⁶ Ibid at 61.

¹⁹⁷ Ibid at 72.

¹⁹⁸ Academy of Science of South Africa (ASSAf) *Constitutional and Legal Documentation* (2021) 3.

¹⁹⁹ ASSAf op cit note 29 at 46.

²⁰⁰ Ibid at 56.

²⁰¹ Ibid at 55.

²⁰² Ibid at 56–7.

The SAMRC seeks to respect, amongst others, the privacy of research participants²⁰³ – ensuring that their rights to privacy and confidentiality are respected by researchers. Any use of participants’ personal information, whether current or planned, must comply with POPIA.²⁰⁴

In general, the HPCSA recognises that healthcare practitioners hold private information about patients,²⁰⁵ and thus they must safeguard their privacy and respect their autonomy.²⁰⁶ In terms of research, health researchers are required to respect and protect research participants’ privacy and dignity.²⁰⁷ Personal information must be processed in a way that respects the privacy of the individual to whom it belongs.²⁰⁸ Researchers must ensure that when collecting, storing, using, or disposing of personal information about research participants or a community, they do so in a manner that upholds privacy and confidentiality and adheres to any agreements made with research participants or the community.²⁰⁹

Apart from privacy, confidentiality also features in South Africa. Different laws provide protection for personal health information, ensuring that its confidentiality is upheld by individuals in both public and private healthcare settings.²¹⁰ The NHA addresses the confidentiality of health information maintained by hospitals and other healthcare facilities.²¹¹ Section 14(1) of the NHA states that ‘[a]ll information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential’,²¹² unless the user consents to the disclosure in writing, a court order or law requires disclosure, or non-disclosure poses a serious threat to public health.²¹³ Although section 14 of the NHA emphasises the confidentiality of an individual’s health information,²¹⁴ there are certain circumstances in which this information may be disclosed. These are when: (1) an individual provides written consent for the disclosure of such information;²¹⁵ (2) a court order or law

²⁰³ South African Medical Research Council (SAMRC) *Research Ethics Policy* (2022) 2.

²⁰⁴ South African Medical Research Council (SAMRC) *Guidelines on the Responsible Conduct of Research* (2022) 7.

²⁰⁵ Health Professions Council of South Africa (HPCSA) *Guidelines for Good Practice in the Healthcare Professions – Confidentiality: Protecting and Providing Information* (Booklet 5) 1.

²⁰⁶ *Ibid* at 5.

²⁰⁷ Health Professions Council of South Africa (HPCSA) *Guidelines for Good Practice in the Healthcare Professions – General Ethical Guidelines for Health Researchers* (Booklet 13) 4.

²⁰⁸ *Ibid* at 12.

²⁰⁹ *Ibid* at 3.

²¹⁰ Townsend *op cit* note 169 at 166.

²¹¹ ASSAf *op cit* note 29 at 55.

²¹² Section 14(1) of the NHA.

²¹³ Section 14(2) of the NHA; ASSAf *op cit* note 29 at 55.

²¹⁴ Section 14(1) of the NHA states that ‘[a]ll information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential’.

²¹⁵ Section 14(2)(a) of the NHA.

necessitates disclosure;²¹⁶ or (3) the disclosure of such information is in the interests of public health.²¹⁷

Privacy is a fundamental legal right for patients and research participants, mandated by South Africa's Constitution and supported by various legislative frameworks. The various documents examined reinforce the necessity of safeguarding privacy, especially in sensitive areas, like genomics research. They collectively mandate that researchers implement rigorous measures to protect research participants' personal information, including secure data handling and clear informed consent processes. Adherence to these laws and guidelines is crucial for ensuring ethical standards in research.

(b) Privacy in South African case law

Privacy is not only referred to in South African laws, guidelines, and documents – this concept has also featured in South African jurisprudence. However, the meaning of privacy has not always been clear. *Bernstein v Bester NO (Bernstein)*²¹⁸ confirmed that privacy is uncertain in terms of its exact nature, content, and scope. In *Bernstein*,²¹⁹ the concept of privacy was described as 'an amorphous and elusive one, which has been the subject of much scholarly debate'.²²⁰ However, privacy is considered to be one of the most significant human rights concerns in modern society.²²¹ It has been linked to the concept of identity, and has been seen as 'the voluntary and temporary withdrawal of a person from the general society through physical and psychological means, either in a state of solitude or small group intimacy or, when among larger groups, in a condition of anonymity or reserve'.²²² The right to privacy 'embraces the right to be free from intrusions and interference by the state and others in one's personal life'.²²³ In *National Coalition for Gay and Lesbian Equality v Minister of Justice*,²²⁴ the Constitutional Court held that:

²¹⁶ Section 14(2)(b) of the NHA.

²¹⁷ Section 14(2)(c) of the NHA.

²¹⁸ 1996 (2) SA 751 (CC).

²¹⁹ 1996 (2) SA 751 (CC).

²²⁰ *Bernstein v Bester NO (Bernstein)* 1996 (2) SA 751 (CC) para 65.

²²¹ Townsend op cit note 169 at 113.

²²² Alan F Westin *Privacy and Freedom* (1967) 7 cited in *Gaertner v Minister of Finance (Gaertner)* 2014 (1) SA 442 (CC) para 47.

²²³ *Gaertner* supra note 222 at para 47; *AmaBhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services; Minister of Police v AmaBhungane Centre for Investigative Journalism NPC* 2021 (3) SA 246 (CC) para 2.

²²⁴ 1999 (1) SA 6 (CC).

‘Privacy recognises that we all have a right to a sphere of private intimacy and autonomy which allows us to establish and nurture human relationships without interference from the outside community’.²²⁵

Privacy does not only relate to the individual themselves, but also personal information about them. In this regard, *National Media Ltd v Jooste*²²⁶ acknowledged that privacy involves all personal information that an individual has chosen to keep from outsiders and wishes to remain private.²²⁷ In *Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd. In re: Hyundai Motor Distributors (Pty) Ltd v Smit NO (Hyundai)*,²²⁸ the Constitutional Court held that ‘[w]herever a person has the ability to decide what he or she wishes to disclose to the public and the expectation that such a decision will be respected is reasonable, the right to privacy will come into play’.²²⁹ An individual has the right to determine when and under what conditions private information may be shared. Furthermore, such disclosure or consent to disclosure may be restricted, either conditionally or unconditionally, regardless of the motive behind it.²³⁰ Data protection laws, such as POPIA, play an important role in safeguarding the right to privacy.²³¹ Data protection laws establish standards for how personal information should be handled, ensuring that it is processed and managed in a fair and legal manner.²³²

(i) *Privacy as a continuum*

Like other rights, privacy is not absolute,²³³ and has been viewed as existing on a continuum. In this context, the right to privacy provides varying levels of protection based on how closely an interest relates to an individual’s personal space, as opposed to the communal sphere.²³⁴ As early as 1996 – and under the interim Constitution – the Constitutional Court, in the case of

²²⁵ *National Coalition for Gay and Lesbian Equality v Minister of Justice (National Coalition)* 1999 (1) SA 6 (CC) para 32. This was also cited in *Teddy Bear Clinic for Abused Children v Minister of Justice and Constitutional Development (Teddy Bear Clinic)* 2014 (2) SA 168 (CC) para 59.

²²⁶ 1996 (3) SA 262 (SCA).

²²⁷ *National Media Ltd v Jooste* 1996 (3) SA 262 (SCA) para 13 (translated from Afrikaans).

²²⁸ 2001 (1) SA 545 (CC).

²²⁹ *Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd. In re: Hyundai Motor Distributors (Pty) Ltd v Smit NO (Hyundai)* 2001 (1) SA 545 (CC) para 16.

²³⁰ Townsend op cit note 169 at 115.

²³¹ Beverley A Townsend & Donrich W Thaldar ‘Navigating uncharted waters: Biobanks and informational privacy in South Africa’ (2019) 35(4) *South African Journal on Human Rights* 333.

²³² Ibid at 333.

²³³ *Gaertner* supra note 222 at para 49. This was also cited in *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* 2021 (2) SA 220 (GJ) para 32.

²³⁴ DW Jordaan *Medical Biotechnology Law in South Africa: A Human Rights Analysis of Selected Topics* (unpublished PhD thesis, University of Cape Town, 2012) 93–6.

Bernstein,²³⁵ laid out its approach to the right to privacy. The Constitutional Court determined that an individual's privacy encompasses those areas where there is a 'legitimate expectation of privacy'.²³⁶ The test in *Bernstein* that is used to determine the nature and extent of the right to privacy has been referred to as the 'reasonable expectation test',²³⁷ and consists of two parts. First, there must be a subjective expectation of privacy²³⁸ and, second, that expectation must be objectively considered reasonable by society.²³⁹ Therefore, the first part is subjective, while the second part is objective.

A valuable way to evaluate reasonableness is through the 'continuum of privacy interests'.²⁴⁰ In terms of this, the right to privacy exists across a continuum, whereby '[p]rivacy is acknowledged in the truly personal realm, but as a person moves into communal relations and activities such as business and social interaction, the scope of personal space shrinks accordingly'.²⁴¹ Referring to *Bernstein*,²⁴² Ackermann J, in *S v Jordan*,²⁴³ stated that the right to privacy should be seen as a continuum of privacy rights. This spectrum begins with an entirely protected inner self, progresses to a relatively secure space such as the home and personal life, and ends with a public sphere where privacy is only minimally involved, if at all.²⁴⁴ This was also repeated in *Hyundai*,²⁴⁵ where it was held that privacy is a right that

²³⁵ 1996 (2) SA 751 (CC).

²³⁶ Ackermann J illustrated the concept as a series of concentric circles, with the innermost circles representing the most protected areas of privacy and the outer circles bring more susceptible to the rights of others and the public interest. *Magajane v Chairperson, North West Gambling Board (Magajane)* 2006 (5) SA 250 (CC) para 42.

²³⁷ *Bernstein* supra note 220 at para 75; *Centre for Social Accountability v Secretary of Parliament* 2011 (5) SA 279 (ECG) para 74; *Haze Club (Pty) Ltd v Minister of Police* [2023] 1 All SA 280 (WCC) para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening)*; *National Director of Public Prosecutions v Rubin*; *National Director of Public Prosecutions v Acton* 2018 (6) SA 393 (CC).

²³⁸ In *Centre for Social Accountability v Secretary of Parliament* supra note 237 at para 72, it was suggested that the objector must first demonstrate that, from a subjective perspective, the matter falls within the inner sanctum of the individual's private and personal life. *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening)*; *National Director of Public Prosecutions v Rubin*; *National Director of Public Prosecutions v Acton* supra note 237.

²³⁹ In *Centre for Social Accountability v Secretary of Parliament* supra note 237 at para 73, it was suggested that 'society' refers to the ethical, legal, and moral expectations of society. *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening)*; *National Director of Public Prosecutions v Rubin*; *National Director of Public Prosecutions v Acton* supra note 237; *Centre for Social Accountability v Secretary of Parliament* supra note 237 at para 72.

²⁴⁰ *Mistry v Interim National Medical and Dental Council of South Africa* 1998 (4) SA 1127 (CC) para 27.

²⁴¹ *Bernstein* supra note 220 at para 67.

²⁴² 1996 (2) SA 751 (CC).

²⁴³ *Sex Workers Education and Advocacy Task Force as Amici Curiae* 2002 (6) SA 642 (CC).

²⁴⁴ *S v Jordan (Sex Workers Education and Advocacy Task Force as Amici Curiae)* 2002 (6) SA 642 (CC) para 76.

²⁴⁵ *Hyundai* supra note 229 at para 18. This was also cited in *AmaBhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services*; *Minister of Police v AmaBhungane Centre for Investigative Journalism NPC* supra note 223 at para 24.

becomes stronger as it pertains to an individual's 'intimate personal sphere' and weaker as it extends further from that core.²⁴⁶

The expectation of privacy is deemed reasonable when it relates to the 'inner sanctum' or the 'truly personal realm',²⁴⁷ such as an individual's home environment or family life.²⁴⁸ The 'inner sanctum' that is safeguarded by the right to privacy, as identified in *Bernstein*,²⁴⁹ includes an individual's 'family life, sexual preference and home environment, which is shielded from erosion by conflicting rights of the community'.²⁵⁰ In *De Lange v Presiding Bishop of the Methodist Church of Southern Africa for the time being*,²⁵¹ the Constitutional Court held that '[t]he closer courts get to personal and intimate spheres, the more they enter into the inner sanctum and thus interfere with our privacy and autonomy'.²⁵² However, the reasonableness of the expectation of privacy gradually decreases in the context of 'communal relations and activities'.²⁵³ As an individual engages more in communal relationships and activities like business and social interactions, their personal space diminishes.²⁵⁴ Put differently, 'the more a person inter-relates with the world, the more the right to privacy becomes attenuated'.²⁵⁵ This reduced personal space does not imply that individuals lose their right to privacy when engaging in social or business interactions.²⁵⁶ Instead, it means that this

²⁴⁶ *Hyundai* supra note 229 at para 18. This was also cited in *AmaBhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services; Minister of Police v AmaBhungane Centre for Investigative Journalism NPC* supra note 223 at para 24. See also, *Mistry v Interim Medical and Dental Council of South Africa* 1998 (4) SA 1127 (CC) para 27; *Magajane* supra note 236 at para 46.

²⁴⁷ *Bernstein* supra note 220 at para 67.

²⁴⁸ *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening); National Director of Public Prosecutions v Rubin; National Director of Public Prosecutions v Acton* supra note 237.

²⁴⁹ 1996 (2) SA 751 (CC).

²⁵⁰ *Bernstein* supra note 220 at para 67. This was also cited in *Teddy Bear Clinic* supra note 225 at para 59.

²⁵¹ 2016 (2) SA 1 (CC).

²⁵² *De Lange v Presiding Bishop of the Methodist Church of Southern Africa for the time being* 2016 (2) SA 1 (CC) para 80. This was also cited in *Wilkinson v Crawford* NO 2021 (4) SA 323 (CC) para 118.

²⁵³ *Bernstein* supra note 220 at para 67. This was also cited in *Centre for Child Law v Media 24 Limited* 2020 (4) SA 319 (CC) para 45.

²⁵⁴ *Gaertner* supra note 222 at para 49. This was also cited in *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* supra note 233 at para 32. See also, *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening); National Director of Public Prosecutions v Rubin; National Director of Public Prosecutions v Acton* supra note 237.

²⁵⁵ *Hyundai* supra note 229 at para 15. This was also cited in *Centre for Child Law v Media 24 Limited* supra note 253 at para 45.

²⁵⁶ *Gaertner* supra note 222 at para 49. This was also cited in *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* supra note 233 at para 32. See also, *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening); National Director of Public Prosecutions v Rubin; National Director of Public Prosecutions v Acton* supra note 237.

right to privacy is weakened, but not entirely removed. The degree of this weakening varies based on how far an individual has moved away from the inner sanctum of the home.²⁵⁷

What is clear from the above is that the right to privacy operates along a continuum, reflecting varying levels of protection based on the context of personal and communal spaces. The right to privacy does not remain in one form offering a certain degree of protection. The right to privacy is affected by the interactions that individuals have with others. Therefore, it can be said that the right to privacy contains a social component, and the degree of protection lessens based on the degree of interaction that an individual has with others. The right to privacy does not exist in a bubble and is shaped according to how individuals choose to live and interact. This indicates a nuanced understanding of privacy, where rights are preserved but can be moderated by context. Ultimately, this continuum of privacy rights necessitates a careful balancing act, where the legal system must weigh personal privacy against communal rights and societal expectations, ensuring that individuals retain a meaningful degree of privacy even as they participate in broader social interactions.

(ii) *Informational privacy*

Given its relevance to this thesis in general, and to privacy in particular, it would be prudent to consider informational privacy and its interpretation in South African case law. Informational privacy is the right of an individual to manage how their personal information is shared with others, including deciding when and in what way it is disclosed.²⁵⁸ *National Media Ltd v Jooste*²⁵⁹ underscored this right:

‘A right to privacy encompasses the competence to determine the destiny of private facts...The individual concerned is entitled to dictate the ambit of disclosure e.g. to a circle of friends, a professional adviser or the public...He may prescribe the purpose and method the disclosure...Similarly, I am of the view that a person is entitled to decide when and under what conditions private facts may be made public. A contrary view will place undue constraints upon the individual’s so-called “absolute rights of personality”’.²⁶⁰

²⁵⁷ Gaertner supra note 222 at para 49. This was also cited in *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* supra note 233 at para 32. See also, *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening)*; *National Director of Public Prosecutions v Rubin*; *National Director of Public Prosecutions v Acton* supra note 237.

²⁵⁸ ScienceDirect ‘Information privacy’ available at <https://www.sciencedirect.com/topics/social-sciences/information-privacy>, accessed on 7 October 2024.

²⁵⁹ 1996 (3) SA 262 (SCA).

²⁶⁰ *National Media Ltd v Jooste* supra note 227 at para 15.

In the recent case of *De Jager v Netcare Limited*,²⁶¹ though informational privacy was not discussed in the judgment itself, the amicus curiae heads of argument prove insightful. It provided that '[i]nformational privacy is a cornerstone of personal liberty and agency'.²⁶² It is crucial for allowing individuals to shape their own futures, define their identities, and safeguard the integrity of their private lives. Without control over their personal information, individuals risk losing autonomy and become vulnerable to external forces. Therefore, informational privacy is not a mere privilege, but a fundamental aspect of self-determination, empowering individuals to define themselves and navigate their interactions with others.²⁶³ Respecting informational privacy upholds the dignity of the individual, recognising that each individual is more than just a collection of data. This respect is essential in protecting individuals from the potential harms that can result from the improper use of personal information, such as identity theft, discrimination, or emotional distress.²⁶⁴

The interpretation of informational privacy in South African jurisprudence, primarily illustrated in *National Media Ltd v Jooste* and *De Jager v Netcare Limited* amicus curiae heads of argument, underscores the fundamental importance of protecting an individual's right to control their personal information. The recognition and protection of informational privacy are essential for safeguarding autonomy and dignity. The ability to control the flow of one's genomic data is not just a matter of privacy, but a critical aspect of self-determination, especially in a society where personal information can be easily misused. Consequently, upholding informational privacy is not only a legal necessity but also a moral imperative, central to protecting individual freedoms in a data-driven society.

(iii) *Privacy and autonomy*

An analysis of privacy jurisprudence in South Africa would be incomplete without exploring autonomy in this context. This is also because autonomy features prominently in this thesis (discussed in Chapter 3). Privacy has been referred to as the 'right to be left alone'.²⁶⁵ The Constitutional Court has recognised that the right to privacy includes an individual's freedom to live their life as they choose without interference from others.²⁶⁶ This freedom from

²⁶¹ (42041/16) [2024] ZAGPPHC 503.

²⁶² *De Jager v Netcare Limited* (42041/16) [2024] ZAGPPHC 503 Amicus Curiae Heads of Argument para 9.

²⁶³ *Ibid* at para 9.

²⁶⁴ *Ibid* at para 10.

²⁶⁵ *British American Tobacco South Africa (Pty) Ltd v Minister of Co-operative Governance and Traditional Affairs* 2021 (7) BCLR 735 (WCC) para 143.

²⁶⁶ *AB v Minister of Social Development (As Amicus Curiae: Centre for Child Law)* 2016 (2) SA 27 (GP) para 94.

interference shares links with the meaning of autonomy.²⁶⁷ This is because the definition of autonomy is inclusive of freedom from external interference.²⁶⁸ Additionally, Sachs J, in *Ferreira v Levin NO; Vryenhoek v Powell NO*,²⁶⁹ held that the state should not only avoid *interfering* with the personal choices of individuals, but should also set up the right conditions so individuals can make these choices effectively, thereby enhancing autonomy.²⁷⁰

The link between autonomy and privacy has also been expressly stated by the courts.²⁷¹ It is recognised that individuals have a right to a personal space and autonomy that should be safeguarded from intrusion.²⁷² Privacy includes the ‘autonomy to make decisions in relation to intensely significant aspects of one’s personal life’.²⁷³ *NM v Smith* established a direct link between autonomy and privacy.²⁷⁴ Madala J, for the majority, noted that privacy includes an individual’s right to live their life as they choose,²⁷⁵ and that ‘the nature and the scope of the right envisage a concept of the right to be left alone’.²⁷⁶ In *National Coalition for Gay and Lesbian Equality v Minister of Justice*,²⁷⁷ Ackermann J held that:

‘Privacy recognises that we all have a right to a sphere of private intimacy and autonomy which allows us to establish and nurture human relationships without interference from the outside community’.²⁷⁸

The ideas expressed by the courts presuppose that autonomy and privacy are inextricably linked – generally in terms of allowing individuals the personal space in which to make decisions and

²⁶⁷ Mappes and DeGrazia define an autonomous person as someone who can make ‘rational and unconstrained decisions and being able to act accordingly’. Tom L Beauchamp & James F Childress *Principles of Biomedical Ethics* 4 ed (1994) cited in Dain van der Reyden ‘The right to respect for autonomy’ (2008) 38(1) *South African Journal of Occupational Therapy* 27; Thomas A Mappes & David Degrazia (eds) *Biomedical Ethics* 4 ed (1996) cited in Dain van der Reyden ‘The right to respect for autonomy’ (2008) 38(1) *South African Journal of Occupational Therapy* 27; Dain van der Reyden ‘The right to respect for autonomy’ (2008) 38(1) *South African Journal of Occupational Therapy* 27.

²⁶⁸ Beauchamp & Childress op cit note 267 at 27; Mappes & Degrazia op cit note 267 at 27; van der Reyden op cit note 267 at 27.

²⁶⁹ 1996 (1) SA 984 (CC).

²⁷⁰ *Ferreira v Levin NO; Vryenhoek v Powell NO* 1996 (1) SA 984 (CC) para 251. O’Regan J, in *Bernstein* supra note 220 at para 151, was also in agreement with this statement.

²⁷¹ *British American Tobacco South Africa (Pty) Ltd v Minister of Co-operative Governance and Traditional Affairs* supra note 265 at para 143. See also, *Prince v Minister of Justice and Constitutional Development*; *Rubin v National Director of Public Prosecutions*; *Acton v National Director of Public Prosecutions* 2017 (4) SA 299 (WCC) para 24.

²⁷² *Tshabalala-Msimang v Makhanya* 2008 (6) SA 102 (W) para 2.

²⁷³ *S v Jordan* supra note 244 at para 76.

²⁷⁴ *NM v Smith* 2007 (5) SA 250 (CC).

²⁷⁵ *Ibid* at para 33.

²⁷⁶ *Ibid* at para 32.

²⁷⁷ 1999 (1) SA 6 (CC).

²⁷⁸ *National Coalition* supra note 225 at para 32. This was also cited in *S v Jordan* supra note 244 at para 76.

act as they wish without the influence of others. This suggests that autonomy is relevant to privacy in the context of an individual's personal space and intimate sphere.

However, the courts have also recognised that autonomy goes further than merely preventing external control within an individual's personal life. In *National Coalition for Gay and Lesbian Equality v Minister of Justice*,²⁷⁹ it was held that autonomy 'must mean far more than the right to occupy an envelope of space in which a socially detached individual can act freely from interference by the state'.²⁸⁰ The Constitution acknowledges the inherent value of every individual, but it does not view them as isolated or detached beings. Instead, the Constitution recognises that individuals 'live in their bodies, their communities, their cultures, their places and their times'.²⁸¹ *NM v Smith*²⁸² held that privacy is valued at least partly because:

'[T]he constitutional conception of being a human being asserts and seeks to foster the possibility of human beings choosing how to live their lives within the overall framework of a broader community. The protection of this autonomy, which flows from our recognition of individual human worth, presupposes personal space within which to live this life'.²⁸³

The relationship between autonomy (as self-realisation) and privacy can be seen in Sachs J's concurring opinion in *National Coalition for Gay and Lesbian Equality v Minister of Justice*,²⁸⁴ where he stated that just as 'liberty must be viewed not merely "negatively or selfishly as a mere absence of restraint, but *positively* and socially as an adjustment of restraints to the end of freedom of opportunity"', privacy should also be seen as implying that the state has a responsibility to create an environment that fosters personal self-realisation.²⁸⁵ As self-realisation is defined as 'fulfillment by oneself of the possibilities of one's character or personality',²⁸⁶ which suggests that an individual is free to make choices to reach this self-realisation (autonomy). Therefore, in the context of privacy, there is some duty on the state to allow personal self-realisation. Linked to self-realisation is the idea of identity. In this regard, *Bernstein*²⁸⁷ held that privacy is closely tied to identity, and the right to privacy has been seen

²⁷⁹ 1999 (1) SA 6 (CC).

²⁸⁰ *National Coalition* supra note 225 at para 117 (concurring opinion of Sachs J).

²⁸¹ *Ibid* at para 117 (concurring opinion of Sachs J).

²⁸² 2007 (5) SA 250 (CC).

²⁸³ *NM v Smith* supra note 274 at para 131.

²⁸⁴ 1999 (1) SA 6 (CC).

²⁸⁵ *National Coalition* supra note 225 at para 116.

²⁸⁶ Merriam-Webster 'Self-realization' available at <https://www.merriam-webster.com/dictionary/self-realization>, accessed on 14 September 2024.

²⁸⁷ 1996 (2) SA 751 (CC).

to be rooted not in what is essential for maintaining an autonomous identity, and not in the idea of an unrestricted self.²⁸⁸

The link between privacy and autonomy can also be seen in relation to personal information, specifically – in the cases of *NM v Smith*²⁸⁹ and *Tshabalala-Msimang v Makhanya*²⁹⁰ – confidential medical information and records of individuals, which contains ‘sensitive and personal information about the user’.²⁹¹ In *NM v Smith*,²⁹² Madala J adopted a genetic exceptionalist view by differentiating between health information, which includes sensitive personal information about individuals, and ‘other forms of documentation’.²⁹³ The reasoning given for this was because health information reveals decisions linked to inter alia personal autonomy,²⁹⁴ making autonomy relevant to health information. This private information is valuable to safeguard because it relates directly to autonomy and dignity.²⁹⁵ In supporting privacy, dignity, and autonomy, an individual should decide whether to release personal information.²⁹⁶ In *NM v Smith*,²⁹⁷ the Constitutional Court held that:

‘Individuals value the privacy of confidential medical information because of the vast number of people who could have access to the information and the potential harmful effects that may result from disclosure. The lack of respect for private medical information and its subsequent disclosure may result in fear of jeopardising an individual’s right to make certain fundamental choices that he/she has a right to make’.²⁹⁸

Given this, providing individuals with control over their own medical information enhances autonomy. Autonomy allows individuals to ‘make certain fundamental choices that he/she has a right to make’,²⁹⁹ and therefore, the unwarranted disclosure of personal information affects autonomy. Privacy is linked to autonomy as stronger privacy protection encourages autonomy.

The interconnection between privacy and autonomy is a foundational aspect of South African jurisprudence. The courts have consistently affirmed that privacy is not merely about shielding individuals from external interference; it is fundamentally tied to the ability of

²⁸⁸ *Bernstein* supra note 220 at para 65.

²⁸⁹ 2007 (5) SA 250 (CC).

²⁹⁰ 2008 (6) SA 102 (W).

²⁹¹ *Tshabalala-Msimang v Makhanya* supra note 272 at para 27.

²⁹² 2007 (5) SA 250 (CC).

²⁹³ *NM v Smith* supra note 274 at para 40.

²⁹⁴ *Ibid* at para 40; *Tshabalala-Msimang v Makhanya* supra note 272 at para 27.

²⁹⁵ *Tshabalala-Msimang v Makhanya* supra note 272 at para 27.

²⁹⁶ *NM v Smith* supra note 274 at para 132.

²⁹⁷ 2007 (5) SA 250 (CC).

²⁹⁸ *NM v Smith* supra note 274 at para 41.

²⁹⁹ *Ibid* at para 41.

individuals to make autonomous choices within their personal lives. Autonomy, as emphasised by the Constitutional Court, encompasses the freedom to navigate one's existence in connection with community and culture, not in isolation. By safeguarding privacy, the legal framework not only protects individual dignity, but also fosters an environment in which autonomy can thrive. Thus, enhancing privacy protection is essential for promoting autonomy, allowing individuals to make informed decisions that shape their lives in meaningful ways.

(iv) *Privacy and human dignity*

Human dignity has been recognised as a 'foundational constitutional value' that is worthy of protection.³⁰⁰ In terms of the Constitution, human dignity encompasses both an individual's personal sense of self-worth as well as how the public views the value or worth of an individual.³⁰¹ The link between privacy and human dignity may be established in two ways. The first is through South African jurisprudence that establishes the relationship between privacy and human dignity. However, another way in which the link between privacy and dignity may be viewed is that: Because it has been established above that privacy shares links with autonomy, and given that autonomy is part of dignity (discussed in detail in Chapter 3), I suggest that this also ties privacy and dignity together.

Case law has made the link between privacy and human dignity clear. The Constitutional Court has consistently highlighted the interconnectedness and supportive relationship between human dignity and other enumerated rights, including privacy.³⁰² Through the Constitution, the right to privacy serves to further human dignity.³⁰³ In *NM v Smith*,³⁰⁴ O'Regan J held that the rights to privacy, liberty, and dignity are 'inter-dependent and mutually reinforcing'.³⁰⁵ The Constitutional Court has recognised and highlighted that our interpretation of the right to privacy is rooted in the value placed on human dignity in the Constitution.³⁰⁶ A link exists between an individual's right to privacy and their right to dignity.³⁰⁷ In *Khumalo v Holomisa*,³⁰⁸ the Constitutional Court held that:

³⁰⁰ *Khumalo v Holomisa* 2002 (5) SA 401 (CC) para 26.

³⁰¹ *Ibid* at para 27.

³⁰² Jordaan *op cit* note 234 at 20.

³⁰³ *Centre for Child Law v Media 24 Limited* *supra* note 253 at para 44.

³⁰⁴ 2007 (5) SA 250 (CC).

³⁰⁵ *NM v Smith* *supra* note 274 at para 131.

³⁰⁶ *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* *supra* note 233 at para 41.

³⁰⁷ *Prince v Minister of Justice and Constitutional Development; Rubin v National Director of Public Prosecutions; Acton v National Director of Public Prosecutions* *supra* note 271 at para 23.

³⁰⁸ 2002 (5) SA 401 (CC).

‘It should also be noted that there is a close link between human dignity and privacy in our constitutional order. The right to privacy, entrenched in section 14 of the Constitution, recognises that human beings have a right to a sphere of intimacy and autonomy that should be protected from invasion. This right serves to foster human dignity’.³⁰⁹

As the Constitutional Court pointed out in *Teddy Bear Clinic for Abused Children v Minister of Justice and Constitutional Development (Teddy Bear Clinic)*,³¹⁰ privacy supports human dignity by establishing and safeguarding an individual’s right to a ‘sphere of private intimacy and autonomy’.³¹¹ This means that the essence of privacy includes the right to make personal decisions and to have one’s autonomy protected, which is fundamental to an individual’s identity and allows them to make decisions in these areas without excessive state interference.³¹² The right to privacy is essential in upholding the constitutional commitment of protecting human dignity.³¹³

(v) *Privacy and the right to freedom of expression*

The ‘very essence of an open and participatory society where debate is encouraged and flourishes is dependent on the free flow and exchange of information and ideas’.³¹⁴ A recent judgment of the Constitutional Court in the case of *Botha v Smuts*³¹⁵ may have great significance in terms of the right to privacy and its links to the right to freedom of expression, specifically in contexts where individuals have voluntarily made personal information public. Based on *Bernstein*,³¹⁶ *Botha v Smuts*³¹⁷ held that privacy rights are not forfeited when an individual moves into communal relations, but they do ‘shrink’.³¹⁸ In the cases of *Prince*³¹⁹ and

³⁰⁹ *Khumalo v Holomisa* supra note 300 at para 27. This was also cited in *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* supra note 233 at para 41 and *Tshabalala-Msimang v Makhanya* supra note 272 at para 2.

³¹⁰ 2014 (2) SA 168 (CC).

³¹¹ *Teddy Bear Clinic* supra note 225 at para 64. This was also cited in *Prince v Minister of Justice and Constitutional Development*; *Rubin v National Director of Public Prosecutions*; *Acton v National Director of Public Prosecutions* supra note 271 at para 23.

³¹² *Prince v Minister of Justice and Constitutional Development*; *Rubin v National Director of Public Prosecutions*; *Acton v National Director of Public Prosecutions* supra note 271 at para 23.

³¹³ Townsend op cit note 169 at 113.

³¹⁴ *Botha v Smuts* 2024 (12) BCLR 1477 (CC) para 75.

³¹⁵ 2024 (12) BCLR 1477 (CC).

³¹⁶ 1996 (2) SA 751 (CC).

³¹⁷ 2024 (12) BCLR 1477 (CC).

³¹⁸ *Botha v Smuts* supra note 314 at para 94; *Bernstein* supra note 220 at para 67.

³¹⁹ *Minister of Justice and Constitutional Development v Prince (Clarke Intervening)*; *National Director of Public Prosecutions v Rubin*; *National Director of Public Prosecutions v Acton* supra note 237 at para 47.

Bernstein,³²⁰ the Constitutional Court concluded that privacy rights diminish once information is made public, discarded, or shared with consent.³²¹

The test from *Bernstein* entails answering two questions: (1) whether the individual had a subjective expectation of privacy; and (2) if so, whether society would consider the individual's subjective expectation of privacy to be reasonable. If both of these questions are answered in the affirmative, then there has been a breach of privacy – in which case, the court performs a balancing exercise to determine how the right to privacy weighs against other rights or interests that may also deserve recognition.³²²

Relying on the test formulated in *Bernstein*,³²³ the majority of the Constitutional Court, in *Botha v Smuts*,³²⁴ found that voluntarily choosing to disclose information to the public means that the subjective expectation of privacy is significantly reduced.³²⁵ The digital era allows individuals to 'move into communal relations'³²⁶ using online platforms. Although this is advantageous, it also has its drawbacks – particularly, it is challenging to keep information both private and public. The inner sanctum still exists, even if the line between inner and outer sanctums has become blurred.³²⁷ Moreover, the Constitutional Court held that while posting a business address (which was also a home address) online led to a diminished subjective expectation of privacy, it did not mean that *all* expectations of privacy in respect of that address were relinquished – only those aspects which related to the business.³²⁸ It further provided that '[i]n using online platforms, we are not required to surrender our autonomy nor the intimate aspects of our lives. It is how they are managed that ultimately matters'.³²⁹

Importantly, the case of *Botha v Smuts* required balancing the right to privacy with the right to freedom of expression. This requires the Court to assess whether, in the context of the specific case, the public interest demands prioritising freedom of expression over privacy.³³⁰ In this instance, the privacy that an individual has over their home address (and the fact that it was not critical to free expression) overrides the publicising of this address by others.³³¹ Given

³²⁰ 1996 (2) SA 751 (CC).

³²¹ *Botha v Smuts* supra note 314 at para 94.

³²² *Ibid* at paras 98–9; *Bernstein* supra note 220.

³²³ 1996 (2) SA 751 (CC).

³²⁴ 2024 (12) BCLR 1477 (CC).

³²⁵ *Botha v Smuts* supra note 314 at para 110.

³²⁶ *Bernstein* supra note 220 at para 67.

³²⁷ *Botha v Smuts* supra note 314 at para 118.

³²⁸ *Ibid* at paras 133 & 136.

³²⁹ *Ibid* at para 143.

³³⁰ *Ibid* at para 148.

³³¹ *Ibid* at para 151.

that ‘freedom of expression does not enjoy superior status in our law’,³³² when private information is highly personal and holds little public interest, courts have determined that the right to privacy carries more weight in the balance against the right to freedom of expression.³³³ In concluding, the majority for the Constitutional Court in *Botha v Smuts* held that:

‘What has emerged from this case is that public disclosure of information does not necessarily mean that a data subject loses all expectation of privacy over that information. The compatibility in the purpose for which information was originally posted and thereafter used will remain a relevant factor in determining the bounds of the expectation of privacy’.³³⁴

This case highlights certain complex issues that the law must address in the age of online platforms, easily accessible information, and the increasing trend of publicising personal information.³³⁵ The law must remain adaptable to account for different privacy expectations, consider context, individual choices, and the public interest.³³⁶

(vi) *A communal version of privacy?*

Privacy is closely tied to the idea of identity. It has been argued that rights, such as privacy, are not about an entirely free or unburdened self, but rather about what is needed to maintain one’s own independent identity.³³⁷ As such, communal connections should not be replaced with abstract relationships.³³⁸ In *Bernstein*,³³⁹ Ackermann J refers to Forst,³⁴⁰ who advocates for a recognition of identity on multiple levels: In addition to the concrete and abstract aspects, this includes one’s membership in a society and to the community of humanity.³⁴¹ Interpreting the right to privacy in this way means that the process of establishing context cannot be limited to a single area, particularly not to a purely individualistic perspective.³⁴²

Individual autonomy and the rights linked to it – such as the right to freedom of expression and the right to privacy – play a crucial role in human development. However, it is essential that, in addition to respecting individual autonomy, legitimate community interests

³³² *S v Mamabolo* 2001 (3) SA 409 (CC) para 41. This was cited in *Botha v Smuts* supra note 314 at para 151.

³³³ *Botha v Smuts* supra note 314 at para 151.

³³⁴ *Ibid* at para 176.

³³⁵ *Ibid* at para 175.

³³⁶ *Ibid* at para 175.

³³⁷ *Bernstein* supra note 220 at para 65.

³³⁸ *Ibid* at para 66.

³³⁹ 1996 (2) SA 751 (CC).

³⁴⁰ Rainer Forst ‘How (not) to speak about identity: The concept of the person in a theory of justice’ (1992) 18(1) *Philosophy & Social Criticism* 293–312.

³⁴¹ *Bernstein* supra note 220 at para 66.

³⁴² *Bernstein* supra note 220 at para 67.

and the rights of others are considered in helping to define the limits of that autonomy.³⁴³ As mentioned above, in *Bernstein*,³⁴⁴ it was held that:

‘The truism that no right is to be considered absolute, implies that from the outset of interpretation each right is always already limited by every other right accruing to another citizen. In the context of privacy this would mean that it is only the inner sanctum of a person, such as his/her family life, sexual preference and home environment, which is shielded from erosion by conflicting rights of the community. This implies that community rights and the rights of fellow members place a corresponding obligation on a citizen, thereby shaping the abstract notion of individualism towards identifying a concrete member of civil society. Privacy is acknowledged in the truly personal realm, but as a person moves into communal relations and activities such as business and social interaction, the scope of personal space shrinks accordingly’.³⁴⁵

Privacy is not absolute, and the more that an individual engages with others, the more their personal space is diminished.³⁴⁶ In diverse societies, communal interests are likely to clash with individual interests. Similarly, privacy and individual self-determination often come into conflict with the collective public interest and the principles of openness and transparency.³⁴⁷ There is therefore a need to balance individual privacy against the interests of the community.

Privacy is essential for maintaining one’s independent identity, but it cannot exist in a vacuum; it must be balanced against communal interests and the rights of others. As highlighted in *Bernstein*,³⁴⁸ no right is absolute, and the right to privacy is particularly constrained by the presence of communal rights and obligations. This suggests that while individuals have the right to protect their personal spaces, these rights must be weighed against the needs and rights of the community. Therefore, a nuanced interpretation of privacy that recognises both individual privacy and communal interests is necessary.

(vii) Confidentiality

It is worth briefly mentioning that confidentiality commonly appears in South African case law dealing with medical information and health records. Health records must be safeguarded to prevent unauthorised access. The privacy of the individual is paramount as they have control over their personal information – they may decide whether to keep their information

³⁴³ *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service* 2023 (5) SA 319 (CC) para 124.

³⁴⁴ 1996 (2) SA 751 (CC).

³⁴⁵ *Bernstein* supra note 220 at para 67. This was also cited in *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service* supra note 343 at para 124.

³⁴⁶ *Gaertner* supra note 222 at para 49.

³⁴⁷ *Arena Holdings (Pty) Ltd t/a Financial Mail v South African Revenue Service* supra note 343 at para 129.

³⁴⁸ 1996 (2) SA 751 (CC).

confidential or share it with others.³⁴⁹ The case of *Tshabalala-Msimang v Makhanya*³⁵⁰ provides a rationale for treating an individual's health information as confidential:

'[C]onfidential medical information invariably contains sensitive and personal information about the user. This personal and intimate information concerning the individual's health, reflects sensitive decisions and the choices that relate to issues pertaining to bodily and psychological integrity as well as personal autonomy. Section 14(1) of the National Health Act imposes a duty of confidence in respect of information that is contained in a user's health record. This is simply because the information contained in the health records is information that is private'.³⁵¹

In *NM v Smith*,³⁵² it was held that '[i]ndividuals value the privacy of confidential medical information because of the vast number of people who could have access to the information and the potential harmful effects that may result from disclosure'.³⁵³ Disregarding private medical information and disclosing it can create fear, undermining an individual's ability to make important personal choices.³⁵⁴ Thus, according to *NM v Smith*,³⁵⁵ there is 'a strong privacy interest in maintaining confidentiality'.³⁵⁶

(viii) Conclusion

There is no doubt that privacy protection is well established and understood in South African jurisprudence.³⁵⁷ Based on the above exploration of privacy in South African case law, three key aspects emerge. First, privacy operates along a continuum. This means that the degree of privacy protection varies depending on the context of personal interactions. While individuals have robust privacy rights in their most intimate spaces, these rights become more attenuated in communal settings. Second, the links between privacy and other rights and values suggests that safeguarding privacy is essential for promoting autonomy and human dignity. Third, in diverse societies, the challenge lies in navigating conflicts between individual privacy and communal rights. While privacy is essential for maintaining independent identity, it must also be weighed against the rights and interests of the community. Privacy in South African law is a dynamic and multifaceted concept that intertwines deeply with autonomy and dignity. It

³⁴⁹ *Tshabalala-Msimang v Makhanya* supra note 272 at para 27. See also, *Thabela v Nedgroup Medical Aid Scheme/Medscheme* 2020 (1) SA 318 (GJ) paras 14–5.

³⁵⁰ 2008 (6) SA 102 (W).

³⁵¹ *Tshabalala-Msimang v Makhanya* supra note 272 at para 27.

³⁵² 2007 (5) SA 250 (CC).

³⁵³ *NM v Smith* supra note 274 at para 41. This was also cited in *WB v RB* 2024 (4) SA 316 (KZD) para 24.

³⁵⁴ *NM v Smith* supra note 274 at para 41. This was also cited in *WB v RB* supra note 353 at para 24.

³⁵⁵ 2007 (5) SA 250 (CC).

³⁵⁶ *NM v Smith* supra note 274 at para 41. This was also cited in *WB v RB* supra note 353 at para 24.

³⁵⁷ Townsend op cit note 169 at 119.

requires a careful balancing act that acknowledges the importance of individual rights while respecting communal interests, ultimately fostering an environment where both personal and societal values can exist harmoniously.

VII THE LINK BETWEEN AUTONOMY AND PRIVACY

Privacy has been seen to share links with autonomy (discussed in Chapter 3). Whilst autonomy is a constitutional value, privacy is a right protected in section 14 of the Constitution. Privacy provides that individuals ‘have a right to a sphere of intimacy and autonomy that should be protected from invasion’.³⁵⁸ Privacy allows individuals their ‘inner sanctum’³⁵⁹ that is free from interference by others.³⁶⁰ In this way, individuals are able to exercise their autonomy, without interference, relating to a private aspect of their life. Common to the various definitions of privacy is the idea of controlling personal information and having freedom to act autonomously.³⁶¹

Traditionally, privacy has been viewed as safeguarding individual autonomy.³⁶² However, as autonomy has come to be recognised as being more socially embedded, so too has privacy been seen as a social interest.³⁶³ In this regard, privacy does not entail a separation from social life, but instead protects social engagements that enable autonomy.³⁶⁴

It has been established above that privacy occurs in several dimensions, including informational privacy, social privacy, psychological privacy, and physical privacy.³⁶⁵ Given the nature and use of genomic data, *informational* privacy is the relevant dimension in the current context. At the heart of the protection of informational privacy is *autonomous choice*: Individuals themselves ought to decide when, and under what conditions, information about themselves may be disclosed, as well as the ambit of disclosure.³⁶⁶ This means that while the safeguarding of research participants’ genomic data may be the ethical default position, research participants ought to be free to waive such protection and make their genomic data

³⁵⁸ *Khumalo v Holomisa* supra note 300 at para 27.

³⁵⁹ *Bernstein* supra note 220.

³⁶⁰ *NM v Smith* supra note 274.

³⁶¹ Hanno N Olinger, Johannes J Britz & Martin S Olivier ‘Western privacy and/or Ubuntu? Some critical comments on the influences in the forthcoming data privacy bill in South Africa’ (2007) 39(1) *International Information & Library Review* 33.

³⁶² Dorota Mokrosinska ‘Privacy and autonomy: On some misconceptions concerning the political dimensions of privacy’ (2018) 37 *Law and Philos* 118.

³⁶³ *Ibid* at 119.

³⁶⁴ *Ibid* at 122.

³⁶⁵ Leino-Kilpia et al op cit note 69 at 664; Ayres & Ribeiro op cit note 69 at 81.

³⁶⁶ *National Media Ltd v Jooste* supra note 227 at para 15.

open access. Accordingly, as a matter of principle, the notion that research participants' genomic data *must always* be safeguarded from being made public and identified is mistaken. Also, in practice it cannot merely be assumed that research participants would always *want* to exercise their right to privacy in respect of their genomic data – this is not only overly paternalistic towards research participants, but also fails to account for Ubuntu-inspired persons who are willing to forego individual privacy for the benefit of their community.

Where research participants are requested, as part of the informed consent process of a research project, to forego their privacy rights and make their genomic data open access, they are vulnerable to privacy infringements and are at increased risk of the possible adverse consequences associated with identified genomic data – especially if they lack adequate knowledge of the potential consequences.³⁶⁷ However, a possible solution lies in open consent.

VIII APPLYING OPEN CONSENT TO GENOMICS RESEARCH IN SOUTH AFRICA IN TERMS OF PRIVACY

Based on the above analysis, the key question is whether open consent fits within the South African legal framework and its constitutional rights and values, particularly regarding its alignment with privacy. Privacy is significant in terms of several aspects of a research project (and the PGP's open consent model), namely: (1) informed consent and the provision of information; (2) uploading information openly online; and (3) the community and privacy. These are discussed in turn under the sub-headings below. They are considered in terms of the open consent model and South Africa's view on privacy.

(a) Informed consent and the provision of information

One way in which the privacy of research participants can be addressed is through consent. Valid consent in research must be informed, understood, voluntary, and given by a competent individual.³⁶⁸ In genomics research involving populations in LMICs, several challenges arise in designing and implementing consent processes (discussed in more detail in Chapter 3).³⁶⁹ One major challenge is providing information to research participants in a way that is clear and understandable. Explaining complex concepts like 'genomics' can be difficult. While some

³⁶⁷ Hsiao-Ying Huang & Masooda Bashir 'Direct-to-consumer genetic testing: Contextual privacy predicament' (2015) *ASIST* 2.

³⁶⁸ Jantina de Vries, Susan J Bull, Ogobara Doumbo et al 'Ethical issues in human genomics research in developing countries' (2011) 12 *BMC Med Ethics* 3.

³⁶⁹ *Ibid* at 3.

aspects of genomics research can be conveyed in familiar terms, ensuring that research participants fully understand and can give valid consent remains a significant hurdle.³⁷⁰ Additionally, there has been considerable focus on the necessity of protecting the privacy of participants in genomic studies. But even when personal identifiers are removed from genomic datasets, the risk of identifying participants may be reduced, but there is still a potential for revealing sensitive information about populations, communities, or families.³⁷¹

As can be seen from the case law above, the reasonableness of the expectation of privacy diminishes in terms of ‘communal relations and activities’.³⁷² Therefore, the more communal the activities of the individual, the smaller the expectation of privacy. However, what must also be considered is whether there is a reasonable expectation of privacy.³⁷³ Given that open consent makes it clear that no guarantees of privacy are made, that individuals undergo an objective assessment to test their understanding of inter alia the risks to privacy, and that information is openly shared and available online, a reasonable expectation of privacy in this situation is very unlikely. Given this, in order for research participants to agree to a research project that utilises an open consent model and fully understand what it entails, the provision of accurate and adequate information is vital.

If open consent entails no guarantees of privacy, this then means that those who choose to participate in the PGP forgo their right to privacy. This would be the case in South Africa where individuals’ right to privacy diminishes the further away that they move from the inner sanctum. Given that sharing of genomic data and personal information online is a largely intrusive act that exposes individuals to all sorts of potential privacy violations, those who choose to partake in genomics research using an open consent model would therefore relinquish their right to privacy in South Africa. Given these risks, it is imperative that the implications to the privacy of research participants be made clear. The open consent model utilised by the PGP does this in the informed consent document and study material, and it is then tested using the objective assessment.³⁷⁴ The informed consent document and study material are readily available and thorough, covering various aspects of genomics research.³⁷⁵ Potential participants are then required to review the information and may ask questions.³⁷⁶ Thereafter, potential

³⁷⁰ Ibid at 3.

³⁷¹ Ibid at 3.

³⁷² *Centre for Child Law v Media 24 Limited* supra note 253 at para 45.

³⁷³ Ibid at para 48.

³⁷⁴ The Harvard Personal Genome Project ‘How it works’ available at <https://pgp.med.harvard.edu/how-it-works>, accessed 4 June 2022.

³⁷⁵ Ibid.

³⁷⁶ Ibid.

participants must pass an assessment with a score of 100% in order to qualify as a research participant in the PGP.³⁷⁷

However, in South Africa, researchers cannot simply provide research participants with information, but there must be steps taken to ensure that research participants *understand* this information.³⁷⁸ The PGP's open consent model requires research participants to understand the implications of sharing their genomic data publicly. In South Africa, there are varying levels of understanding and health literacy, which means that ensuring that all research participants are fully informed poses a challenge.³⁷⁹ Additionally, South Africa consists of multiple cultures and languages. The PGP's consent form and study material offer a limited individualistic view in one language, namely English. Therefore, adopting open consent for genomics research in South Africa would require amending the current open consent model. All documentation and assessments would need to be available in multiple languages and consider the various different cultures and communities that exist.

Notwithstanding the need for revised documentation if open consent were to be implemented in genomics research in South Africa, as mentioned above, it is questionable whether the provision of documentation alone to research participants is sufficient. It has been shown that in LMICs, specifically in the context of informed consent documents, more is needed. Poorly designed documents, confusion over local language and terminology, and low literacy levels all contribute to a lack of understanding.³⁸⁰ Many countries in sub-Saharan Africa consist of multilingual communities, which creates two challenges for informed consent: (1) ensuring that the language used aligns with local communities' terminology; and (2) accurately translating these terms into local languages for better understanding.³⁸¹ There have been issues with miscommunication and misunderstandings, particularly when researchers and research participants speak different languages, when documents need to be translated, and when research participants are unfamiliar with scientific research or the concept

³⁷⁷ Ibid.

³⁷⁸ Ciara Staunton 'Informed consent for HIV cure research in South Africa: Issues to consider' (2015) 16 *BMC Med Ethics* 3.

³⁷⁹ Kirsten Rowe & Keymanthri Moodley 'Patients as consumers of health care in South Africa: The ethical and legal implications' (2013) 14(15) *BMC Medical Ethics* 1-9 cited in Sidney F Engelbrecht 'Can autonomy be limited – An ethical and legal perspective in a South African context?' (2014) 32(1) *JFOS* 36; Francis Akpa-Inyang & Sylvester C Chima 'South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: A cross-cultural qualitative study' (2021) 22 *BMC Med Ethics* 12.

³⁸⁰ Nkosi Busisiwe, Janet Seeley, Ann Strode et al 'Beyond translations, perspectives for researchers to consider to enhance comprehension during consent processes for health research in sub-Saharan Africa: A scoping review' (2023) 24 *BMC Med Ethics* 2.

³⁸¹ Ibid at 11–2.

of informed consent.³⁸² Although assessment tools have been used to improve comprehension of informed consent forms, it has also been found that the language used may be more crucial in bettering comprehension.³⁸³ Another major issue is that in rural communities, individuals place significant value on oral communication. Verbal consent is often preferred, typically in the presence of a literate witness who can read the consent documents.³⁸⁴ The importance of flexibility and negotiating norms to fit diverse socio-cultural settings has therefore been emphasised in the literature.³⁸⁵

An important point to consider is that many studies conducted in sub-Saharan Africa have focused on how research participants respond during the informed consent process, while few have examined the researchers' communication skills and how they delivered the consent process. This suggests an imbalance, where the emphasis is placed on research participants' failures, without considering the important role that researchers' communication and delivery skills play in the process.³⁸⁶ Therefore, sensitivity to local cultures and contexts is needed. Amongst others, effective communication and education about the implications of data sharing are crucial. In South Africa, initiatives need to focus on raising awareness and providing resources to help individuals understand their rights and the risks involved. These need to be based on the context and community in which they are undertaken, and must be modifiable where necessary. It is not only research participants who should be considered, but also the knowledge of the researchers themselves.

(b) Uploading information openly online

In terms of open consent, privacy largely comes into play when research participants agree to their information being uploaded online. Once enrolled, research participants are able to control which genetic, health, and trait information they upload to their public profile on the PGP's website and database.³⁸⁷ Additionally, they can submit tissue samples and other specimens for

³⁸² Ibid at 11–2.

³⁸³ Ibid at 12.

³⁸⁴ Ibid at 11.

³⁸⁵ Ibid at 13.

³⁸⁶ Ibid at 13.

³⁸⁷ Trait data is collected through various sources including online questionnaires and personal health records, and includes information on personal medical history, allergies, medications, immunisations, lifestyle, diet, physical traits and measurements, ethnicity, and environmental exposures. The Harvard Personal Genome Project op cit note 374; The Harvard Personal Genome Project 'Participating in the Harvard PGP' available at <https://pgp.med.harvard.edu/participate>, accessed on 17 March 2021; The Harvard Personal Genome Project 'The PGP is not a traditional research study' available at <https://pgp.med.harvard.edu/about>, accessed on 6 June 2022.

research.³⁸⁸ This is shared with the research community and the general public,³⁸⁹ and is intended to be used for various purposes worldwide.³⁹⁰

Given the rise in the sharing of genomic data online – whether for genomics research or as a result of genetic testing – there has tended to be an erosion of the traditional notions of genetic confidentiality and this exposes individuals to the potential for genetic discrimination.³⁹¹ Taking this into account, the PGP is transparent, recognises the realities of genetic discrimination,³⁹² and provides for this in their consent form under the risks associated with the publication of an individual's data.³⁹³ Individuals are encouraged to carefully consider what genetic information they share and how it might potentially be used against them and their relatives.³⁹⁴ The PGP recognises the possible risks that are inherent in having genomic information openly available, but makes research participants aware of these risks and offers advice, where necessary. This means that research participants in the PGP partake in it whilst being aware of these risks.

Based on the 'continuum of privacy interests' that has been established in South African jurisprudence,³⁹⁵ privacy is not static and the degree of protection that it offers differs depending on how far out of the inner sanctum or personal sphere an individual chooses to

³⁸⁸ The Harvard Personal Genome Project op cit note 374.

³⁸⁹ Personal Genome Project 'Participant profiles' available at <https://my.pgp-hms.org/users>, accessed on 19 August 2024.

³⁹⁰ The Harvard Personal Genome Project op cit note 387.

³⁹¹ Resnik op cit note 23 at 45–6.

³⁹² Genetic discrimination occurs when individuals are treated unfairly or differently because they have a particular genetic condition or a higher risk of developing an inherited disorder. Genetic discrimination has become more prevalent with the increased usage of genetic technologies. Although genetic discrimination may occur in a variety of areas such as education, housing, and welfare benefits, two areas most often discussed in relation to genetic discrimination are insurance and employment. This is because 'insurance and employment are the two prime areas where genetic information may be misused'. ASSAf op cit note 29 at 56; Sivan Tamir 'Direct-to-consumer genetic testing: Ethical-legal perspectives and practical considerations' (2010) 18 *Medical Law Review* 227; David F Partlett 'Misuse of genetic information: The common law and professionals' liability' (2003) 42 *Washburn Law Journal* 500.

³⁹³ The PGP states that '[w]hether or not it is lawful to do so, you could be subject to actual or attempted employment, insurance, financial, or other forms of discrimination or negative treatment due to the public disclosure of your genetic and trait information by the PGP or by a third party'. Harvard Personal Genome Project *Consent Form* (2017) 15; Personal Genome Project UK *Informed Consent for Enrolment in the PGP-UK* (2018) 11; Personal Genome Project Canada *Full Consent Form* (2017) 14.

³⁹⁴ Harvard Personal Genome Project *Personal Genome Project Study Material* (2012) 20.

³⁹⁵ *Mistry v Interim National Medical and Dental Council of South Africa* supra note 240 at para 27; *Bernstein* supra note 220 at para 67; *S v Jordan* supra note 244 at para 76; *Hyundai* supra note 229 at para 18; *AmaBhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services; Minister of Police v AmaBhungane Centre for Investigative Journalism NPC* supra note 223 at para 24; *Magajane* supra note 236 at para 46; *Centre for Child Law v Media 24 Limited* supra note 253 at para 45; *Gaertner* supra note 222 at para 49; *Residents of Industry House, 5 Davies Street, New Doornfontein, Johannesburg v Minister of Police* supra note 233 at para 32; *Haze Club (Pty) Ltd v Minister of Police* supra note 237 at para 39; *Minister of Justice and Constitutional Development v Prince (Clarke Intervening); National Director of Public Prosecutions v Rubin; National Director of Public Prosecutions v Acton* supra note 237.

stray. It is also clear that the case of *Botha v Smuts*³⁹⁶ (analysed above) may have important implications for open consent in South Africa, especially where research participants choose to waive their privacy rights and make their genomic data publicly available. It suggests that, in such scenarios, courts may view the privacy protections for this data as limited, depending on the purpose and context of its disclosure.³⁹⁷ The general norm in genomics research has been to protect privacy, but there are individuals who may not value it as highly and choose to forego their privacy rights – this is a motivating factor for open consent. In the case of open consent, because individuals choose to openly share their genomic data and other personal information, they place it into the public realm and therefore opt to forego that right to privacy. This is because genomic data is unique to the individual and contains intimate information about them – something that would traditionally form part of the inner sanctum. However, by publicising it and making it available on the internet, that personal information is now openly accessible and individuals can no longer have a right to privacy over that information. But what about societies, such as South Africa, where values like Ubuntu play a central role in decision-making – and which would be relevant to individual choices concerning privacy?

(c) *The community and privacy*

African social norms, cultural values, and legal traditions influence how privacy is perceived. Thus, simply applying Western concepts of privacy to African contexts may not be suitable.³⁹⁸ As such, Reviglio and Alunge consider whether Ubuntu could support a more relational understanding of privacy.³⁹⁹ A key aspect shared by various definitions of privacy is the idea of having control over personal information and the freedom to make independent choices as moral individuals.⁴⁰⁰ The conflict in terms of privacy revolves around two main ideas: (1) the traditional view of privacy, which is based on individual autonomy; and (2) relational autonomy, which emphasises how autonomy is shaped by relationships and contexts.⁴⁰¹ Relational autonomy leads to the idea of relational privacy, which encompasses various ways of understanding privacy that focus on context and interconnectedness.⁴⁰² Because data

³⁹⁶ 2024 (12) BCLR 1477 (CC).

³⁹⁷ 2024 (12) BCLR 1477 (CC).

³⁹⁸ Patricia Boshe 'A quest for an African concept of privacy' in Lukman Adebisi Abdulrauf & Hlengiwe Dube (eds) *Data Privacy Law in Africa: Emerging Perspectives* (2024) 13; Akpa-Inyang & Chima op cit note 379 at 12.

³⁹⁹ Reviglio & Alunge op cit note 139 at 596.

⁴⁰⁰ Olinger, Britz & Olivier op cit note 361 at 33.

⁴⁰¹ Reviglio & Alunge op cit note 139 at 598.

⁴⁰² Ibid at 598.

collection today tends to focus on groups, the individual element is overlooked.⁴⁰³ This diminishing emphasis on the individual challenges the core principles of Western theories on privacy.⁴⁰⁴

As discussed in Chapter 3, Ubuntu views individuals as being deeply connected to their community, who play a fundamental role in shaping the individual.⁴⁰⁵ It has been defined as ‘a community-based mindset in which the welfare of the group is greater than the welfare of a single individual in the group’.⁴⁰⁶ In terms of Ubuntu, individual rights are only deemed acceptable if they benefit the community, making it challenging to argue for the social advantages of personal privacy.⁴⁰⁷ Furthermore, in Ubuntu societies, privacy has not been regarded as a central value.⁴⁰⁸ As such, some authors argue that Ubuntu offers limited space for privacy to develop in Africa. However, others maintain that Africans desire privacy, even where Ubuntu is central.⁴⁰⁹ There is limited research on privacy in Africa, and the idea of privacy is largely a Western concept rooted in individuality and self-autonomy.⁴¹⁰ This contrasts Ubuntu, which emphasises community and interconnectedness. Africans are typically seen as part of collective groups – such as family or kinship – which leaves little room for individual privacy.⁴¹¹ While Ubuntu values openness and transparency, it does not completely eliminate privacy; rather, it reduces its significance as privacy is seen as an obstacle to the ideals of openness and transparency.⁴¹² However, it has been argued that while privacy may be secondary to relationships in Ubuntu communities, individuals still possess a degree of privacy.⁴¹³ Individuals have unique thoughts and achievements, which can be viewed as private possessions.⁴¹⁴

Reviglio and Alunge suggest that Ubuntu can serve as a foundation for understanding privacy in an African context. It would focus on collective rights that protect the shared interests of the community rather than the rights of each individual.⁴¹⁵ If the individual relies

⁴⁰³ Ibid at 600.

⁴⁰⁴ Ibid at 602.

⁴⁰⁵ Ibid at 603; Boshe op cit note 398 at 31.

⁴⁰⁶ Olinger, Britz & Olivier op cit note 361 at 32.

⁴⁰⁷ Ibid at 35.

⁴⁰⁸ Ibid at 35.

⁴⁰⁹ Reviglio & Alunge op cit note 139 at 604.

⁴¹⁰ Ibid at 606; Olinger, Britz & Olivier op cit note 361 at 34.

⁴¹¹ Reviglio & Alunge op cit note 139 at 606.

⁴¹² Olinger, Britz & Olivier op cit note 361 at 36.

⁴¹³ Reviglio & Alunge op cit note 139 at 607.

⁴¹⁴ Ibid at 607; Olinger, Britz & Olivier op cit note 361 at 36.

⁴¹⁵ Reviglio & Alunge op cit note 139 at 608.

on the community, then safeguarding the community also means safeguarding individuals.⁴¹⁶ Overall, Ubuntu encourages a relational view of privacy, taking into account context and networks when assessing privacy threats. This calls for redefining personal data, fostering group privacy, and promoting a communitarian approach to privacy protection.⁴¹⁷

In line with Ubuntu (discussed in Chapter 3), the interests of the individual and the community are taken into consideration, and one is not seen as more superior than the other.⁴¹⁸ As such, the value of the individual is recognised.⁴¹⁹ Therefore, individuals can make their own decisions provided that it does not result in harm to the community.⁴²⁰ But what happens in the case of open consent, where genetic and trait data is openly accessible online, and where there are privacy implications not only for the individual, but also for their family and the community?

The PGP provides that '[y]ou are strongly encouraged to discuss this study and its potential risks with your immediate family members as well as with your doctor and/or other qualified health care providers'.⁴²¹ While individuals are 'strongly encouraged', discussing the risks of the PGP (including the risks inherent in uploading data to be openly available online) is not mandatory⁴²² – and discussions with the community are not required. However, in South Africa, regulation 3(b) of the Human Research Participant Regulations necessitates consultation with community representatives.⁴²³ Consultation falls under the term 'community engagement'.⁴²⁴ This has been discussed in detail in Chapter 3, but to briefly reiterate, community engagement refers to the process of consulting and collaborating with local authorities and community leaders.⁴²⁵ It highlights the shared interests, goals, and aspirations of a community, emphasising the importance of communication and involvement among its

⁴¹⁶ Ibid at 608.

⁴¹⁷ Ibid at 609.

⁴¹⁸ Bonginkosi Shoji *An Afrocentric Approach to CRISPR-Cas9: Analysing the Use of Genetic Technologies in Human Reproduction Through the Lens of Human Rights and African Values* (unpublished PhD thesis, University of KwaZulu-Natal, 2021) 44.

⁴¹⁹ Ibid at 44.

⁴²⁰ Thaddeus Metz 'Ubuntu as a moral theory and human rights in South Africa' (2011) 11 *African Human Rights Journal* 540.

⁴²¹ Harvard Personal Genome Project *Consent Form* (2021) 13; Personal Genome Project Canada op cit note 393 at 5.

⁴²² Harvard Personal Genome Project op cit note 421 at 13.

⁴²³ Regulation 3(b) of the Human Research Participant Regulations.

⁴²⁴ Tasha Koch, Nabeel Petersen & Lindsey Reynolds 'Towards equity and co-creation' *Medium* 5 December 2023, available at <https://medium.com/@PivotCollective/promoting-participation-and-collaboration-of-communities-in-health-research-in-south-africa-fc758a3fb203>, accessed on 8 August 2024.

⁴²⁵ Zinhle Mthembu, Moses Chimbari & Margaret Macherera 'Facilitating community engagement: Researchers' lived experiences in rural communities in the KwaZulu-Natal Ecohealth Program, South Africa' (2023) 9 *Cogent Social Sciences* 2.

members.⁴²⁶ The fundamental idea is that the knowledge and experiences of a community are shaped by its members, allowing them to identify their own challenges and needs and develop suitable solutions.⁴²⁷ Consequently, all projects should arise from the ongoing realities shaped by the community itself.⁴²⁸ However, consultation cannot only occur with community leaders who make decisions on behalf of the community. Instead, a participatory process is favoured where families, villages, and the wider community are all involved.⁴²⁹ Given this, researchers need to possess the skills, contextual knowledge, and expertise necessary to carry out community engagement properly.⁴³⁰

A positive aspect of the NHREC Ethics Guidelines is a focus on involvement of, and collaboration with, inter alia community representatives and members.⁴³¹ The NHREC Ethics Guidelines define a ‘community’ as ‘a group of people with a shared identity or interest that has the capacity to act or express itself as a collective; it may be territorial, organizational or a community of interest’.⁴³² The NHREC Ethics Guidelines also include a definition of ‘community engagement’, which is defined as ‘a collaborative process whereby researchers involve community stakeholders in an early and sustained manner across the study lifecycle to enhance the scientific and ethical quality of a study; the degree of collaboration may vary depending on the circumstances’.⁴³³ Engaging with community members aims to gather a broad range of perspectives in order to ensure that the outcomes reflect the needs and goals of the community as a whole. This process requires making every effort to include the voices of all individuals, especially those who are vulnerable or marginalised. Researchers must approach this engagement with humility, recognising that the community members are the experts and possess valuable local knowledge.⁴³⁴ The NHREC Ethics Guidelines provide that community engagement should foster partnerships, with an emphasis on respect throughout, particularly in obtaining both community-wide and individual consent.⁴³⁵

⁴²⁶ Ibid at 2.

⁴²⁷ Ibid at 2.

⁴²⁸ Ibid at 2.

⁴²⁹ Helen Acton ‘Meaningful consultation with communities: What does it mean?’ *Good Governance Africa* 7 April 2022, available at <https://gga.org/meaningful-consultation-with-communities-what-does-it-mean/>, accessed on 9 August 2024; Webber Wentzel *Best Practice Guideline on Community Consultation in the South African Extractives Industry* (2024) 9.

⁴³⁰ Koch, Petersen & Reynolds op cit note 424.

⁴³¹ National Department of Health op cit note 190 at 9–10.

⁴³² Ibid at 103.

⁴³³ Ibid at 103.

⁴³⁴ Ibid at 15–6.

⁴³⁵ Ibid at 15–6.

Given the focus on the community, in terms of genomics research, this may mean that individual informed consent is no longer suitable, and instead ‘collective informed consent’ might be more appropriate.⁴³⁶ In South Africa, this would entail the inclusion of family and community members in the consent process.⁴³⁷ Researchers must recognise the cultural nuances of South Africa, where informed consent is seen not just as an individual matter, but as a more collective or communal practice.⁴³⁸ However, in sub-Saharan African, one point of tension between ethics and law is obtaining informed consent in cultures where decision-making is not solely an individual responsibility.⁴³⁹ Legal frameworks typically adopt an individualistic approach to consent, offering little guidance for working in social contexts where this individual-centred idea may not be familiar or applicable.⁴⁴⁰ This needs to be addressed in order to ensure that the manner in which consent is approached is suited to the community, thereby ensuring that such consent is informed and in line with local values. As such, open consent will need to be modified for use in genomics research in South Africa.

Above I also highlighted the familial nature of genomic information, and focused on a more familial approach where results are shared with individuals and their families. This could be applied in terms of privacy in genomics research in South Africa. Given South Africa’s focus on Ubuntu, a more familial approach to genomic information may be more suitable. In terms of genetic testing, this generally means that individuals as well as their families have access to the relevant information, but how would this work in terms of genomics research? It is not just about the privacy of the individual versus the community, but also the privacy of the community versus the public. If information about the community as a collective were to be publicised, this could have an impact on all involved. It has been suggested that that both potential participants and the broader community should receive information about the research. This information should explain the research purpose, alleviate any uncertainties or concerns, and foster greater understanding and confidence.⁴⁴¹

⁴³⁶ Reviglio & Alunge op cit note 139 at 608.

⁴³⁷ Akpa-Inyang & Chima op cit note 379 at 14.

⁴³⁸ Ibid at 15.

⁴³⁹ Busisiwe et al op cit note 380 at 13.

⁴⁴⁰ Busisiwe et al op cit note 380 at 13.

⁴⁴¹ CS Molyneux, N Peshu & K Marsh ‘Trust and informed consent: Insights from community members on the Kenyan coast’ (2005) 61(7) *Soc Sci Med* 1471.

IX RECOMMENDATIONS AND CONCLUSION

This Chapter has thoroughly examined the right to privacy. It began by broadly exploring the nature of genomic data, which included discussions on de-identification and anonymisation, as well as the familial element of genomic data. This Chapter offered general definitions of privacy (including genetic privacy) and confidentiality. It then discussed key philosophical perspectives on the topic. These include individual privacy and personal privacy, restricted access/limited control theory of privacy, relational privacy, categorical privacy, and group privacy. Thereafter, this Chapter considered the meaning of privacy in South Africa through an examination of literature. It then determined how privacy is positioned in South Africa's legal system by analysing various laws, guidelines, and documents.

A central aspect of this Chapter was an examination of the meaning of privacy based on South African jurisprudence as well as its links to other rights and values, such as autonomy and human dignity. Based on this, I found that privacy is not a static right, and instead exists on a continuum. The more that an individual interacts in a community setting, the more that their right to privacy is diminished. The same applies when an individual chooses to share personal information with others. What must however be contemplated is the privacy rights of the individual and the interests of the community, and this entails a balancing act that takes both sides into consideration.

Following this, this Chapter considered the outcomes of the analysis in examining privacy in relation to open consent and applied open consent to genomics research in South Africa in terms of privacy, which included informed consent and the provision of information, uploading information openly online, and the community and privacy. Each of these aspects were explored and applied in terms of South Africa.

In this Chapter, I have found that in examining the viability of open consent for genomics research in South African, several critical insights emerge. First, the potential for genetic discrimination poses significant ethical and legal challenges, especially as the sharing of genomic data becomes increasingly common. While the PGP recognises these risks and transparently communicates them, the implications of open access genomic data on privacy must be carefully navigated. Implementing open consent in South Africa requires thoughtful adaptations to address local cultural values, such as Ubuntu. It recognises the relational nature of privacy and the interconnectedness of individuals within their communities, thus fostering a more comprehensive understanding of the risks involved. Ultimately, for open consent to be

effectively applied in genomics research in South Africa, it must be tailored to accommodate diverse cultural contexts, enhance comprehension, and ensure that both individual and community rights are respected. As genomic research continues to evolve, so too must the approaches to consent and privacy, ensuring that they reflect the realities and values of the communities that they aim to serve.

There are two aspects relevant to privacy in South Africa in terms of open consent: (1) in terms of open consent in genomics research, research participants choose to forego their privacy right and share their data publicly; and (2) because the nature of the information is so personal, and as it is shared broadly, in terms of South African case law, it would be public and thus extend to the far side of the ‘continuum of privacy interests’, meaning that there would be little privacy protection available. What is important is that research participants are aware of what they are consenting to, and have been provided with sufficient information on the possible risks involved in uploading and sharing their data openly.

In South Africa, it is not just the individual, but also the community that needs to be taken into consideration. The emphasis on relational autonomy within Ubuntu suggests that privacy cannot be merely an individual right; rather, it must be viewed as a collective concern, interwoven with the fabric of community relationships and cultural values. The challenges presented by genomics research exemplify this tension. In a society where decision-making is communal, traditional concepts of informed consent – which typically focus on individual rights – are inadequate. Instead, adopting a model of collective informed consent can better align with the values and social structures prevalent in many African communities. Moreover, the concerns surrounding the privacy of genomic information extend beyond the individual to the family and community, underscoring the importance of transparency and mutual understanding in research practices. Researchers must navigate these complexities with cultural sensitivity, ensuring that consent processes and the information provided are inclusive and reflective of communal perspectives.

Simply adopting Western concepts of individual privacy fail to accommodate the relational dynamics that shape how privacy is perceived and practiced in many African communities. In South Africa, where community and relational dynamics are central, the PGP’s model of open consent – which often prioritises the individual – may not adequately address the complexities of communal relationships and the shared nature of genomic information. Open consent, which encourages individuals to discuss potential risks with family and healthcare providers, does not go far enough in contexts where decision-making is

inherently communal. I suggest that there are several recommendations to be made in aligning open consent with a South African view of privacy: (1) researchers actively involve families and community representatives. This shift acknowledges that genomic data does not solely belong to individuals; it can have profound privacy implications for their families and broader community; (2) researchers should be trained in the cultural nuances of the communities that they engage with, ensuring that consent processes and the provision of information reflect communal decision-making practices rather than imposing individualistic frameworks; and (2) clear, accessible information about the research and its implications for privacy is crucial. Researchers should facilitate discussions that allow community members to voice concerns and questions, thereby enhancing understanding.

Although, based on South African jurisprudence, research participants who choose to publicly share their genomic information for research are likely to forego their right to privacy, there is also the consideration of the community. An important consideration is the provision of information. It must be clear, comprehensive, understandable, and clearly explain the possible privacy risks involved in openly accessible data. Researchers have a central role to play in informing and educating individuals, their relatives, and the wider community on these aspects of privacy. Embracing a relational understanding of privacy, as rooted in Ubuntu, offers a more nuanced and contextually appropriate framework for addressing privacy issues in South Africa. This approach prioritises the welfare of the community while also recognising the importance of individual rights, paving the way for a more ethical and respectful engagement with privacy in the era of genomics research.

CHAPTER 6

CONCLUSION

I INTRODUCTION

In recent years, genomics research has burgeoned and, with it, questions relating to consent have come to the fore. Open consent is a model of informed consent for genomics research that was pioneered by the PGP in the US.¹ However, as with other modes of consent, it is not without its criticisms and shortfalls. Given that open consent has only be applied in a Western context, throughout this thesis, I explored open consent from a South African perspective. Specifically, I examined whether, from a constitutional perspective, open consent is an acceptable mode of consent for genomics research in South Africa. This was done through an assessment of four salient constitutional rights and/or values: (1) autonomy; (2) Ubuntu; (3) freedom of scientific research; and (4) privacy. Under the headings below, I answer each of my research questions (mentioned in Chapter 1) in turn, summarising the key findings of this thesis. I then consider whether open consent can (or should) be applied to genomics research in South Africa, and consider recommendations for future research.

(a) Is open consent aligned with the constitutional values of autonomy and Ubuntu?

One of the reasons for requiring informed consent for genomics research is to protect autonomy and privacy, as well as foster scientific research and progress. Given that privacy cannot be guaranteed in genomics research, this raises the bar for autonomy and it must be ensured that research participants understand the research and its implications. Does open consent achieve this from a South African constitutional perspective?

Open consent, as defined by the PGP, places emphasis on individual autonomy and informed decision-making.² Individuals are expected to understand the complexities of genomics research and make personal, informed decisions based on their own comprehension of the risks, benefits, and implications of their participation.³ However, this individualistic

¹ The Harvard Personal Genome Project ‘About’ available at <https://pgp.med.harvard.edu/about>, accessed on 22 September 2020. See also, Misha Angrist ‘Eyes wide open: The Personal Genome Project, citizen science and veracity in informed consent’ (2009) 6(6) *Per Med* 3–4.

² Jeremy Walter ‘General FAQ’ 18 April 2019 *GitHub*, available at <https://github.com/PGPHarvard/FAQ/wiki/General-FAQ#why-do-i-have-to-get-100-on-your-eligibility-questionnaire-before-i-can-join>, accessed on 5 May 2022.

³ Harvard Personal Genome Project ‘Consent form’ 12 July 2021 available at https://my.pgp-hms.org/static/PGP_Consent_2021-07-12_online.pdf, accessed 25 October 2021 20.

model of consent presents challenges when applied to the South African context, where autonomy is viewed more relationally and is intricately tied to communal values, such as Ubuntu. The relationship between autonomy and Ubuntu in South African law reveals a nuanced approach that integrates individual decision-making with a broader sense of community responsibility in a relational context.⁴

The South African view of autonomy demands that researchers not only respect individual decisions, but also actively involve the community in the consent process. While individual autonomy is important, it cannot be exercised in isolation, especially in contexts where decisions about participation in genomics research are intertwined with family, cultural, and community concerns. Thus, open consent, in its current form, does not fully align with the South African understanding of autonomy and Ubuntu. Instead, it requires modification to ensure that community input is woven into the consent process, promoting collective understanding and respect for the values that underpin South Africa's more relational conception of autonomy.

Moreover, the inclusion of Ubuntu highlights that autonomy is not about unqualified individual choice but about making decisions within a framework of social interconnectedness.⁵ This necessitates greater emphasis on community engagement, consultation, and education to ensure that consent is truly informed in a manner that respects both individual and collective rights.⁶ Therefore, open consent in its current iteration is misaligned with South African values unless it incorporates elements of relational autonomy and community involvement, aligning it with Ubuntu.

(b) Is open consent aligned with the constitutional right to freedom of scientific research?

The analysis of the right to freedom of scientific research in South Africa, in conjunction with open science and open consent, demonstrates a clear and compelling alignment between open consent and the right to freedom of scientific research. Through an exploration of the South African constitutional framework and case law surrounding the right to freedom of expression, it becomes evident that the right to freedom of scientific research is a fundamental aspect of freedom of expression. The three key purposes underlying the right to freedom of expression

⁴ See, *AB v Minister of Social Development* 2017 (3) SA 570 (CC) and *S v Makwanyane* 1995 (3) SA 391.

⁵ Bonginkosi Shoji *An Afrocentric Approach to CRISPR-Cas9: Analysing the Use of Genetic Technologies in Human Reproduction Through the Lens of Human Rights and African Values* (unpublished PhD thesis, University of KwaZulu-Natal, 2021) 50.

⁶ Syed M Ahmed & Ann-Gel S Palermo 'Community engagement in research: Frameworks for education and peer review' (2010) 100(8) *Am J Public Health* 1380.

– the search for truth, the exercise of autonomy, and the promotion of democracy – all have direct applications in the realm of scientific research.

Open consent aligns strongly with the right to freedom of scientific research. The key elements of transparency, autonomy, and democratic participation inherent in open consent support and promote the right to freedom of scientific research by removing traditional barriers to data sharing, increasing trust, and ensuring that research can be conducted more freely and comprehensively. South Africa’s legal framework, while lacking direct jurisprudence on the right to freedom of scientific research, offers a strong foundation through its protections for freedom of expression. Open consent, as a tool that facilitates data sharing and participant autonomy, serves to bolster the principles of this constitutional right.

(c) Is open consent aligned with the constitutional right to privacy?

The alignment of open consent with the right to privacy requires a nuanced examination, as it involves balancing individual autonomy with the collective values embedded within South African society. Open consent primarily involves participants voluntarily sharing their personal genetic and health data publicly.⁷ This presents unique challenges, particularly with regards to privacy.

In the context of genomics research, participants may willingly forego their privacy rights by consenting to the public sharing of their genetic data, acknowledging the risks associated with genetic discrimination. However, privacy in South Africa is not a static concept; it exists on a continuum.⁸ This continuum reflects the evolving degree of privacy protection depending on the extent to which an individual interacts within a community or shares personal information.⁹ As genomic data is inherently personal and family-related, its disclosure could also infringe upon the privacy of not just the individual but their family and community as well.¹⁰ Therefore, the erosion of privacy protections through open consent must be carefully considered within South African law, particularly as it pertains to the intersection of individual and collective rights.

⁷ Jeantine E Lunshof, Ruth Chadwick, Daniel B Vorhaus et al ‘From genetic privacy to open consent’ (2008) *Nature Reviews Genetics* 5.

⁸ *Mistry v Interim National Medical and Dental Council of South Africa* 1998 (4) SA 1127 (CC) para 27.

⁹ *S v Jordan (Sex Workers Education and Advocacy Task Force as Amici Curiae)* 2002 (6) SA 642 (CC) para 76.

¹⁰ Gemma A Bilkey, Belinda L Burns, Emily P Coles et al ‘Genomic testing for human health and disease across the life cycle: Applications and ethical, legal, and social challenges’ (2019) 7 *Front Public Health* 7; Muhammad Naveed, Erman Ayday, Ellen W Clayton et al ‘Privacy in the genomic era’ (2015) 48(1) *ACM Comput Surv* 3.

South African society is deeply influenced by Ubuntu, which places greater emphasis on communal values and interdependence rather than individual autonomy.¹¹ Ubuntu's relational autonomy framework complicates the traditional Western understanding of privacy, which prioritises individual autonomy and self-determination.¹² In a society where decision-making is communal, privacy is viewed less as an individual right and more as a collective concern, shaped by the individual's relationship with their community.

Open consent tends to centre on the individual, giving them the right to share their genomic data publicly.¹³ However, this may not align well with South African cultural norms. In a South African context, where collective decision-making prevails, open consent may not sufficiently accommodate the communal concerns surrounding privacy. Decisions about sharing genomic information cannot be made in isolation and, as such, the current individualistic focus of open consent may fail to fully consider the potential impact of this decision on the family and community as a whole.

To align open consent with the right to privacy, a more nuanced approach is required. While individuals should retain the right to choose whether to share their genomic data, these choices must be informed by an understanding of the potential consequences for their families and communities. As such, adopting a collective model of informed consent is recommended. This model involves not only the individual but also their family, community representatives, and broader social structures in the consent process. By doing so, the potential risks to privacy, genetic discrimination, and the community's interests can be better addressed.

Additionally, South African jurisprudence suggests that when individuals opt to waive their right to privacy in genomic research, they enter into a public sphere where privacy protections are minimal.¹⁴ This highlights the need for clear communication about the risks involved in sharing genomic data publicly. Ultimately, a more comprehensive approach to

¹¹ *South African Police Service v Solidarity obo Barnard* 2014 (6) SA 123 (CC) para 174.

¹² Francis Akpa-Inyang & Sylvester C Chima 'South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: A cross-cultural qualitative study' (2021) 22 *BMC Med Ethics* 2.

¹³ Lunshof et al op cit note 7 at 5.

¹⁴ *Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd. In re: Hyundai Motor Distributors (Pty) Ltd v Smit* NO 2001 (1) SA 545 (CC) para 18. This was also cited in *AmaBhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services; Minister of Police v AmaBhungane Centre for Investigative Journalism* NPC 2021 (3) SA 246 (CC) para 24. See also, *Mistry v Interim Medical and Dental Council of South Africa* supra note 8 at para 27; *Magajane v Chairperson, North West Gambling Board* 2006 (5) SA 250 (CC) para 46.

consent that incorporates community engagement and cultural sensitivity would help to ensure that the constitutional right to privacy is respected, even in the context of open consent.

II APPLYING OPEN CONSENT TO GENOMICS RESEARCH IN SOUTH AFRICA

Although not a primary focus of this thesis, it is worth briefly considering the practicalities of applying open consent to genomics research in South Africa. While the theoretical alignment of open consent with South African constitutional values is strong, practical considerations present challenges. Language barriers and digital literacy issues may limit effective participation in open consent models, particularly in rural or underserved areas. Moreover, culturally sensitive approaches must be developed to ensure that the principle of Ubuntu is respected, with communities being adequately informed and consulted. These practical challenges must be addressed to fully realise the potential of open consent in genomics research in South Africa.

(a) Autonomy and Ubuntu: Community engagement and education

Autonomy, a cornerstone of informed consent, must be approached differently in South Africa due to the communal nature of decision-making. While individual autonomy is important, it must be understood through the lens of Ubuntu, which emphasises interconnectedness, communal values, and mutual respect.¹⁵ In this context, community engagement is pivotal. Researchers must go beyond informing individual participants to build relationships with entire communities.¹⁶ This includes involving traditional leaders, family structures, and local authorities to ensure that decisions about genomic research align with both individual and collective autonomy.¹⁷

Education plays a crucial role in this process. It is not enough to provide information in a one-size-fits-all manner; researchers must ensure that both the research participants and the broader community understand the implications of genomics research. This includes explaining the data being collected, its potential uses, and the risks involved, in ways that are

¹⁵ H3Africa Community Engagement Working Group for the Human Heredity and Health (H3Africa) Consortium *H3Africa Guidelines for Community Engagement (Version Two)* (2017) 9; Paulina Tindana, Susan Bull, Lucas Amenga-Etego et al 'Seeking consent to genetic and genomic research in a rural Ghanaian setting: A qualitative study of the MalariaGEN experience' (2012) 13(15) *BMC Med Ethics* 4.

¹⁶ Dorothy Maxwell Kazembe, Tigist Mesfin, Abigiya Abebe et al 'A review assessing participants' understanding of informed consent for clinical trials in Africa' (2022) 10(11) *Medical Research Archives* 2.

¹⁷ Paulina Tindana, Jantina de Vries, Megan Campbell et al 'Community engagement strategies for genomic studies in Africa: A review of the literature' (2015) 16(24) *BMC Med Ethics* 6.

culturally appropriate and accessible.¹⁸ This might involve the use of local languages, images, and oral traditions, ensuring the message resonates with all participants.¹⁹ Moreover, informed consent should not be restricted to a one-time event but should foster ongoing discussions, allowing for continuous community input and feedback.²⁰

(b) The informed consent process: Adapting to local contexts

The current practice of open consent, which often relies on online assessments and individual decisions, must be adapted to better fit the South African context. Given challenges such as limited internet access and varying literacy levels, alternative methods must be explored, such as oral consent, face-to-face interactions, and visual aids, to ensure that all participants can fully comprehend the research. Informed consent should thus not only respect individual autonomy, but also acknowledge the importance of social networks in decision-making.

Researchers must also embrace a relational approach to autonomy, one that recognises the collective decision-making process inherent in many South African communities. To facilitate this, the consent process should encourage community-wide discussions and provide space for families and local leaders to be part of the decision-making process.²¹ This approach underscores the importance of transparency, trust, and respect, with an emphasis on ensuring that participants understand the research, the implications of their involvement, and the risks they are undertaking, not just individually but as a collective.²²

(c) Freedom of scientific research: Opportunities and challenges

Incorporating open consent into genomics research in South Africa also intersects with the right to freedom of scientific research. Open consent offers significant opportunities for enhancing transparency and fostering trust between researchers and participants. By making participants fully aware of how their genomic data will be used, shared, and stored, the research community can build public trust, which is vital for ongoing research collaboration.

¹⁸ Ibid at 6.

¹⁹ Kirsten Rowe & Keymanthri Moodley ‘Patients as consumers of health care in South Africa: The ethical and legal implications’ (2013) 14(15) *BMC Medical Ethics* 1-9 cited in Sidney F Engelbrecht ‘Can autonomy be limited – An ethical and legal perspective in a South African context?’ (2014) 32(1) *JFOS* 36; Akpa-Inyang & Chima op cit note 12 at 12.

²⁰ Tindana, de Vries, Campbell et al op cit note 17 at 2.

²¹ Keymanthri Moodley & Shenuka Singh ‘“It’s all about trust”: Reflections of researchers on the complexity and controversy surrounding biobanking in South Africa’ (2016) 17(57) *BMC Med. Ethics* 6.

²² Joseph Mumba Zulu, Ingvild Fossgard Sandøy, Karen Marie Moland et al ‘The challenge of community engagement and informed consent in rural Zambia: An example from a pilot study’ (2019) 20 *BMC Med Ethics* 8.

Furthermore, open consent could alleviate issues related to data access, enabling more fluid collaboration between researchers. Adopting open consent can facilitate data sharing and accelerate scientific discovery. This is especially relevant in light of South Africa's draft Open Science Policy, which supports open data and scientific collaboration on a national level.²³

However, challenges persist, particularly regarding privacy and confidentiality. Open consent assumes a level of trust and transparency that may be difficult to achieve in communities with limited understanding of data privacy risks.²⁴ To address this, the informed consent process must ensure that participants are not only aware of the potential risks involved in sharing genomic data, but are also fully equipped to make informed decisions based on this understanding. In addition, legal and regulatory frameworks must be developed to balance open science with the protection of research participants' rights.

(d) Privacy: Navigating the tensions

The right to privacy presents another significant challenge when applying open consent to genomics research in South Africa. While the legal framework, particularly POPIA, offers privacy protections, the open consent model requires that research participants' data be shared openly, which can be at odds with privacy expectations. Researchers must ensure that the consent process is transparent and culturally sensitive.²⁵ This could involve community consultations, the use of visual and verbal materials to explain the research, and ongoing dialogue to ensure that privacy concerns are addressed.²⁶

Cultural sensitivity and researcher training are essential in ensuring that the consent process respects local customs and traditions. In South African communities, decision-making is often a collective process, and researchers must be prepared to navigate these dynamics.²⁷ This could involve supporting participants in understanding the broader implications of genomic research, not just for themselves but for their families and communities.

²³ Department of Science and Innovation (DSI) *Draft National Open Science Policy* (2022) 9.

²⁴ Jantina de Vries, Susan J Bull, Ogobara Doumbo et al 'Ethical issues in human genomics research in developing countries' (2011) 12 *BMC Med Ethics* 3.

²⁵ Akpa-Inyang & Chima op cit note 12 at 15.

²⁶ Harriet Nankya, Vincent P Alibu, Enock Matovu et al 'Community engagement conduct for genetics and genomics research: A qualitative study of the experiences and perspectives of key stakeholders in Uganda' (2024) 25 *BMC Med Ethics* 2; Erin Rothwell, Naomi O Riches, Erin Johnson et al 'Evaluating visual imagery for participant understanding of research concepts in genomics research' (2022) 14(1) *J Community Genet* 60.

²⁷ Akpa-Inyang & Chima op cit note 12 at 15.

(e) *Collective consent and ongoing engagement*

A key practical consideration for applying open consent to genomics research in South Africa is the idea that consent goes beyond individual consent to include families and communities in the decision-making process.²⁸ This could be achieved through support systems such as community consultations, workshops, and local advisory boards, which facilitate informed, collective decision-making. By adopting this approach, researchers can ensure that the consent process is not just an isolated event but an ongoing, dynamic dialogue between participants, their communities, and researchers. This would foster a deeper understanding of the research and its implications, while also building trust and mutual respect.

Applying open consent to genomics research in South Africa presents a complex, but feasible opportunity. By prioritising community engagement, adapting consent processes to local realities, and embracing the communal nature of autonomy and privacy, open consent can be successfully implemented. However, this requires careful consideration of cultural values, legal frameworks, and privacy concerns to ensure that the process is ethical, inclusive, and aligned with South Africa's constitutional values.

III RECOMMENDATIONS

Based on my analysis, and a consideration of various constitutional rights and values, open consent may be applied to genomics research in South Africa. However, I do suggest several practical recommendations for its implementation:

1. Prioritise comprehensive community engagement in genomics research to ensure that research participants fully understand the implications of open consent. Researchers should work with community leaders and local health workers to educate research participants in culturally appropriate ways and make information accessible in local languages.
2. Modify the open consent process to better suit the social and cultural realities of South Africa. Instead of relying solely on online assessments, incorporate oral consent, face-to-face meetings, and visual tools, especially in rural areas where

²⁸ Katharine Hall & Zitha Mokomane 'The shape of children's families and households: A demographic overview' (2018) *South African Child Gauge* 32; Racheal Mafumbate 'The undiluted African community: Values, the family, orphanage and wellness in traditional Africa' (2019) 9(8) *Information and Knowledge Management* 8.

access to the internet and literacy may be limited. This would help to ensure that consent is genuinely informed and culturally sensitive.

3. Strengthen South Africa's legal and regulatory frameworks to support open consent in genomics research while safeguarding privacy. Additionally, amend guidelines to reflect the communal nature of consent under Ubuntu, incorporating community-based decision-making models into the regulatory structure of genomics research. By not incorporating a broader African view of autonomy, the NHREC Ethics Guidelines miss an opportunity to reflect the constitutional value of Ubuntu. For example, the NHREC Ethics Guidelines could explicitly acknowledge the role of family and community in participant recruitment, ensuring that decisions are made in harmony with communal norms and values. This would align ethical guidelines with both jurisprudence and societal practices in South Africa.
4. Support open science initiatives that prioritise transparency, making genomic data more accessible to researchers and the public. Encourage the development of platforms that allow researchers to share genomic data in a secure, ethical, and transparent manner, fostering collaboration and innovation.
5. Emphasise relational autonomy in genomics research to ensure that research participants' decisions are supported by their social networks. Involve families and community leaders in the informed consent process, ensuring that decisions align with collective values and interests while respecting individual autonomy.
6. Address privacy concerns by developing secure and culturally sensitive methods of data sharing that comply with South Africa's privacy laws. Implement privacy protection measures that balance the need for openness in genomic research with the constitutional right to privacy, ensuring that participants understand the risks associated with data sharing.

Given that open consent is a fairly new concept in South Africa that has not yet been implemented or tested in genomics research, there are possible areas for further research. These include:

1. What jurisprudential principles guide consent in genomic research in South Africa?
2. Is open consent to be preferred over other modes of consent?
3. Can open consent be practically applied to genomics research in South Africa?

4. What should informed consent in genomics research in South Africa look like?
5. What other mechanisms exist to ensure informed consent for genomics research?
6. Is proper informed consent attainable for genomics research in South Africa?

While this thesis primarily examines the South African constitutional landscape, it is worth noting that international instruments, such as the World Health Organisation (WHO) *Guidance for Human Genome Data Collection, Access, Use and Sharing* (WHO Guidelines)²⁹ and the *Model Law on Health Data Governance* (Model Law),³⁰ offer valuable insights and could serve to guide the manner in which South Africa's legal framework could evolve for genomics research and the various constitutional rights and values.

In terms of autonomy and Ubuntu, the Model Law provides that in the case of community health data, individual consent to the use of such data is insufficient – the community must consent.³¹ Therefore, the Model Law goes further than community consultation, but requires community consent. The Model Law – in terms of privacy – confirms existing rights in terms of POPIA, but goes further by inter alia criminalising attempts to re-identify pseudonymised or de-identified health data, which can strengthen privacy protections in genomics research.³²

The WHO Guidelines underscore global best practices, which could complement South Africa's evolving approach to balancing privacy with the right to freedom of scientific research. The WHO Guidelines emphasise the need for transparency, accountability, and consent.³³ The WHO Guidelines and the Model Law introduce community consent and engagement, which resonates with South African values of Ubuntu. Although South African law acknowledges community consultation in certain contexts, the Model Law's requirement for community consent when dealing with health data could serve as a valuable precedent for strengthening the involvement of communities in genomics research in South Africa.

While South Africa's constitutional principles, such as autonomy and privacy, offer a foundation for the implementation of open consent in genomics research, integrating insights from the WHO Guidelines and the Model Law can assist in addressing potential gaps, particularly in the areas of community consent and privacy safeguards. These international

²⁹ World Health Organisation (WHO) *Guidance for Human Genome Data Collection, Access, Use and Sharing* (2024).

³⁰ Transform Health *Model Law on Health Data Governance* (2024).

³¹ Ibid at 13.

³² Ibid at 15.

³³ WHO op cit note 29 at 9.

perspectives provide useful benchmarks for ongoing legal development in South Africa, specifically in terms of genomics research.

IV CONCLUSION

The answer to the primary question in this thesis – whether, from a constitutional perspective, open consent is an acceptable mode of consent for genomics research in South Africa – is that open consent, as it was developed by the PGP, cannot be applied in its current form in South Africa. However, I suggest that a modified version of open consent, tailored to local cultures and values, can be feasible and may be practically applied in genomics research in South Africa.

While open consent holds great potential for genomics research, it requires significant modifications to align with the constitutional values of autonomy and Ubuntu. This alignment can be achieved by prioritising community engagement, using accessible and culturally relevant information, and adopting a relational approach to autonomy that emphasises collective decision-making. Only by respecting both individual autonomy and community values can open consent truly reflect the ethical principles central to South African society and the constitutional framework that guides it. The application of open consent to genomics research in South Africa requires a shift from the individual-centric model typically employed in Western research frameworks to one that reflects the cultural and legal context of South Africa, where both autonomy and Ubuntu emphasise relational decision-making.

Applying open consent to genomics research in South Africa, in alignment with the right to freedom of scientific research, holds great promise for enhancing transparency, autonomy, and democratic participation in scientific endeavours. However, this approach will require careful consideration of privacy, cultural, and regulatory challenges. With the right investments in infrastructure, ethical guidelines, and public education, open consent can serve as a powerful tool to advance genomics research in South Africa while respecting the rights and autonomy of research participants. By fostering an environment of trust and openness, South Africa can ensure that its scientific research practices align with constitutional protections and contribute meaningfully to the global scientific community.

While open consent provides a valuable framework for genomics research, it requires adaptations in order for it to be successfully implemented in South Africa. Aligning open consent with the right to privacy means embracing collective decision-making, enhancing the

cultural relevance of consent processes, and ensuring transparency regarding the risks of sharing genomic data publicly. By integrating these considerations, open consent can be adapted to respect both the individual's right to privacy and the communal values that are integral to South African society. However, its practical application will require continuous engagement with communities, researchers' cultural competence, and the development of informed consent processes that reflect both personal autonomy and communal responsibility. This would ultimately ensure that the ethical complexities of privacy in genomics research are addressed in a way that aligns with South Africa's constitutional rights and values.

An additional consideration is that while open science and open consent offer promising avenues to enhance collaboration and accelerate genomics research, their application must be understood within the complex socio-political realities of South Africa and the broader Global South context. Critical engagement with concerns around equity, capacity building, and benefit sharing is essential to ensure that open data initiatives do not inadvertently reinforce existing disparities. Furthermore, claims regarding the exceptional honesty of open consent should be tempered with recognition that transparency is a shared ethical commitment across consent models. This acknowledges both the transformative potential and the challenges of open consent in advancing ethical genomics research.

In conclusion, this thesis has demonstrated that open consent, when implemented with careful consideration of South African constitutional values, has the potential to serve as a viable model for genomics research in the country. While challenges remain, particularly in terms of privacy protections and ensuring equitable participation, the alignment with constitutional principles such as autonomy, Ubuntu, and the right to freedom of scientific research makes open consent a promising approach. Future legal and ethical developments, informed by both South African law and international guidelines, will be crucial in shaping the framework for genomic research in South Africa.

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Prof Donrich Willem Thaldar (59413)
School Of Law
Howard College

Dear Prof Donrich Willem Thaldar,

Original application number: 00015127 **Project title:** DSI-Africa LAW

Exemption from Ethics Review

In response to your application received on 3 December 2021, your school has indicated that the protocol has been granted **EXEMPTION FROM ETHICS REVIEW**.

Any alteration/s to the exempted research protocol, e.g., Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through an amendment/modification prior to its implementation. The original exemption number must be cited.

For any changes that could result in potential risk, an ethics application including the proposed amendments must be submitted to the relevant UKZN Research Ethics Committee. The original exemption number must be cited.

In case you have further queries, please quote the above reference number.

PLEASE NOTE:

Research data should be securely stored in the discipline/department for a period of 5 years.

I take this opportunity of wishing you everything of the best with your study.

Yours sincerely,



Mr Simphiwe Peaceful Phungula
obo Academic Leader Research
School Of Law