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THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH IN THE AGE OF GENE EDITING

A dissertation submitted in pursuance of the requirements for the degree of Master of Laws

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I, Michaela Rae Steytler, declare that

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ABSTRACT

The right to freedom of scientific research is largely omitted, or merely given lip service, in legal and ethical arguments surrounding heritable human gene editing (HHGE) in the context of CRISPR-Cas9 technology. The international ethical and foreign legal attitude towards the right to freedom of scientific research, even when constitutionally protected, is generally dismissive. Debates and arguments which omit this fundamental value are ill-informed and are inappropriate for application in the South African context. The omission of a relevant constitutional right in analyses is cavernous. The practical application of the right to freedom of scientific research must be brought into the light and viewed as an equal among other constitutional rights. This is because the right is constitutionally protected in South Africa and serves important purposes — which are also served by the well-established right to freedom of expression — such as the promotion of individual self-fulfilment and the search for truth. The right to freedom of scientific research plays a valuable role in the advancement of science and the diffusion of knowledge. The right is of particular importance to science in the South African context, where the burden of disease necessitates the pursuit of innovative and contextually appropriate scientific solutions. The right to freedom of scientific research has the potential to influence legislation on HHGE and CRISPR-Cas9, thereby advancing the improvement of healthcare in South Africa. This is a benefit which South Africa cannot afford to overlook, and which should drive the consideration of the right to freedom of scientific research. The right to freedom of scientific research should not be limited by public opinion or ethical arguments, but rather only through regulations which establish constitutionally justified limitations.

TABLE OF ABBREVIATIONS

ASSAf	Academy of Science of South Africa
Cas	CRISPR-associated proteins
CRISPR	Clustered Regularly Interspaced Palindromic Repeat
DoH	Department of Health
ESHG	European Society of Human Genetics
ESHRE	European Society of Human Reproduction and Embryology
HHGE	Human heritable gene editing
HPCSA	Health Professions Council of South Africa
ICESCR	International Covenant on Economic, Social and Cultural Rights
MRC	Medical Research Council
NHA	National Health Act 61 of 2003
POPIA	Protection of Personal Information Act 4 of 2013
SA MTA	South African Material Transfer Agreement
UDHR	Universal Declaration of Human Rights

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CHAPTER ONE:

INTRODUCTION TO CRISPR-CAS9 AND THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH

I BACKGROUND

The purpose of science is to solve problems but, in order to do so, scientific research must be contextually appropriate.[1] In a country facing unique issues, such as South Africa, scientific research must be directed towards achieving appropriate goals in order to better society at grassroots level. Eurocentric thinking can no longer dominate science in an African context.[2] In order for it to meet the specific needs of South African people, scientific research must be regulated in a way that allows it to address issues from a uniquely South African perspective.

This dissertation addresses the regulation of a specific and fast-evolving area of scientific research — CRISPR-Cas9 gene editing in human embryos. CRISPR-Cas9 is a mechanism that enables a specific strand of DNA to be cut, edited or replaced.[3] It holds great potential to improve healthcare and medicine, showing promise in the prevention and treatment of genetic diseases such as cancer, cystic fibrosis and Huntington's disease.[4] CRISPR-Cas9 can be applied to two different types of cells — somatic cells, or germline cells. While somatic cells do not contribute to the genetic makeup of offspring, germline cells do.[5] This has an impact on how gene editing in the two different types of cells is treated both legally and ethically — germline gene editing is the more controversial of the two and raises greater concerns.[6]

A note on terminology: When referring to germline gene editing in a clinical context, the term 'heritable human gene editing' (HHGE) is used. The terms 'gene editing in human embryos,' and 'HHGE basic research' are used interchangeably in reference to the context of

[1] L Nordling 'How decolonization could reshape South African science' (2018) 554 *Nature* 159 at 161.
[2] Ibid.
[3] Jennifer A Doudna & Samuel H Sternberg *A Crack in Creation* (2017) 13.
[4] Ibid at 16; Q Bu 'Reassess the law and ethics of heritable genome editing interventions: Lessons for China and the world' (2019) 34(2) *Issues in Law & Medicine* 115 at 119; KE Ormond, DP Mortlock & DT Scholes et al 'ASHG Position Statement: Human Germline Genome Editing' (2017) 101 *The American Journal of Human Genetics* 167 at 168.
[5] KE Ormond, DP Mortlock & DT Scholes et al 'ASHG Position Statement: Human Germline Genome Editing' (2017) 101 *The American Journal of Human Genetics* 167 at 169.
[6] BM Knoppers, MT Nguyen, F Noohi & E Kleiderman 'Human Genome Editing Ethical and Policy Considerations Policy Brief' (2018) 3.

CRISPR-Cas9 basic laboratory research utilising embryos. In the context of gene editing, the term 'gene' is interchangeable with 'genome.'

Over the many years of research into gene editing technologies, theologians, scientists, lawyers and bioethicists have engaged in debates over the safety, legal and ethical issues surrounding HHGE. The flames of this ethical debate were stoked by the announcement made by scientist He Jiankui.[7] The scientist announced that he had utilised CRISPR-Cas9 technology to disable the *CCR5* gene in two embryos, which were implanted in their mother's womb and carried to term.[8] This experiment was described as 'monstrous'[9] and 'unethical.'[10] This is because He Jiankui had done something highly controversial that had never been reported before — he had engaged in HHGE.

The debate which followed this experiment covered aspects such as the possibility of off-target results, mosaicism, as well as the safety and efficacy of the technology.[11] Other considerations include human dignity, social justice and access. While these concerns are justified and deserve consideration, the global discourse on these issues has, thus far, largely overlooked a fundamental value — freedom of scientific research. This dissertation aims to address this vacuum by illuminating the right to freedom of scientific research as a worthy consideration among other rights and interests.

The right to freedom of scientific research is an enumerated constitutional right in South Africa,[12] Fiji,[13] Kenya[14] and Zimbabwe.[15] Scientific research is also recognised as a legal freedom in many other jurisdictions.[16] Some academics argue that jurisdictions which do not

[7] O Holland & S Wang 'Chinese scientist claims world's first gene-edited babies, amid denial from hospital and international outcry' (2018) available at *https://edition.cnn.com/2018/11/26/health/china-crispr-gene-editing-twin-babies-first-intl/index.html*, accessed on 20 August 2019.
[8] D Cyranoski & H Ledford 'Genome-edited baby claim provokes international outcry' (2018) 563 *Nature* 607 at 607.
[9] H Regan, R Wright & A Field (2018) 'The scientist, the twins and the experiment that geneticists say went too far' available at *https://edition.cnn.com/2018/11/30/health/gene-edited-babies-he-jiankuiintl/index.html*, accessed on 22 August 2019.
[10] Ibid.
[11] Q Bu 'Reassess the law and ethics of heritable genome editing interventions: Lessons for China and the world' (2019) 34(2) *Issues in Law & Medicine* 115 at 122; H Ma, N Marti-Gutierrez & S Park 'Correction of a pathogenic gene mutation in human embryos' (2017) 548 *Nature* 413 at 414; Ormond et al note 5 op cit 168; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 411; Knoppers et al note 6 op cit at 4.
[12] S 16(1)*(d)*, Constitution of the Republic of South Africa, 1996.
[13] S 17(1)*(d)*, Constitution of the Republic of Fiji, 2013.
[14] Art 33(1)*(c)*, Constitution of Kenya, 2010.
[15] S 61(1)*(b)*, Constitution of Zimbabwe, 2013.
[16] These jurisdictions include, but are not limited to; Albania, Bahrain, China, Cuba, Egypt, Estonia, Finland, Greece, Hungary, Jordan, Kuwait, Kyrgyzstan, Latvia, Lithuania, Palestine, Poland, Portugal, Qatar, Slovakia, Slovenia, South Sudan, Tunisia, and Yemen.

expressly protect the right to freedom of scientific research, such as Canada and the United States of America (USA), provide for such under general freedom of expression clauses.[17]

Further, the right is addressed in international law. The Universal Declaration of Human Rights (UDHR) provides for a right to share in scientific advancement and the benefits thereof.[18] It also protects the interests of producers of scientific materials.[19] While the UDHR is not directly legally binding, it has been argued that it is binding as customary international law.[20] The UDHR led to the development of the International Covenant on Economic, Social and Cultural Rights (ICESCR).[21] Section 15(1)*(b)*, which Beiter notes is 'one of the more forgotten provisions of the ICESCR,'[22] gives everyone the right to 'enjoy the benefits of scientific progress and its applications.'[23] The ICESCR contains an undertaking that State Parties will respect 'the freedom indispensable for scientific research,'[24] protecting the right to science.[25] This right is interpreted by Boggio as consisting of three components:

> '(1) the right of everyone to benefit from and contribute to scientific and technological progress (the "right to science" sensu stricto); (2) the right of scientists, for instance, to do research and push forward science and technology (the "rights of science"); and (3) countries' duty to provide an enabling environment.'[26]

In order to realise the right to science, State Parties to the ICESCR must refrain from, and prevent, its violation.[27] Further, the right must be promoted and advanced.[28] The right to science has been identified as 'arguably the least known, discussed, and enforced of the rights recognized in the ICESCR.'[29]

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[17] A Santosuosso, V Sellaroli & E Fabio 'What constitutional protection for freedom of scientific research?' (2007) 33(6) *J Med Ethics* 342 at 342; Kerry Lynn Macintosh 'The Regulation of Human Germline Genome Modification in the United States' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 103–28 at 107.
[18] Art 27(1), Universal Declaration of Human Rights, UN General Assembly (10 December 1948) 217 A (III).
[19] Art 27(2), ibid.
[20] Australian Human Rights Commission 'What is the Universal Declaration of Human Rights?' available at *https://humanrights.gov.au/our-work/what-universal-declaration-human-rights*, accessed on 12 Nov 2020.
[21] Ibid.
[22] KD Beiter 'Where Have All the Scientific and Academic Freedoms Gone? And What is Adequate for Science? The Right to Enjoy the Benefits of Scientific Progress and its Applications' (2019) 52(2) *Israel Law Review* 233 at 234.
[23] S 15(1)*(b)*, International Covenant on Economic, Social and Cultural Rights, UN General Assembly (16 December 1966) UNTS 993.
[24] Art 15(3), ibid.
[25] A Boggio, BM Knoppers & J Almqvist 'The Human Right to Science and the Regulation of Human Germline Engineering' (2019) 2(3) *The CRISPR Journal* 134 at 136.
[26] Ibid at 136.
[27] Ibid at 135.
[28] Ibid.
[29] Ibid.

On the importance of the freedom of science, Beiter quotes Edwin G Conklin:

> 'The increase and diffusion of knowledge depend entirely upon freedom to search, experiment, criticise, proclaim. Without these freedoms, there can be no science.'[30]

If policy is not considered with freedom of science in mind, it is likely that we will see the fall of modern science as we know it.[31] Other than the state's encouragement and promotion of science, it should play a very limited role in other aspects.

With protection in South Africa's Constitution, foreign constitutions, and international law, one would expect freedom of scientific research to feature more prominently in legal and ethical arguments on HHGE and gene editing in human embryos. From an international perspective, it is important to include freedom of scientific research in debates as it is protected by international human rights instruments. From a South African perspective, it is necessary to include material discussions on freedom of scientific research as a constitutionally protected human right.

Arguments which fail to include this important aspect of the debate are ill-informed. Freedom of scientific research is a fundamental value on which modernity was built and should be given due cognisance in debates on HHGE and gene editing in human embryos. This freedom has a telling history and an important role to play in modern societies — it should not be forgotten.

(a) The societal role of science

In order to appreciate the necessity of scientific freedom, one must understand its importance. Thaldar argues that science has given humanity 'everything that differentiates us from our cave-dwelling ancestors.'[32] He aims to illustrate that:

> 'Science is a principal contributor to the improvement of the human condition and enabler of greater individual autonomy and self-actualisation in society, and hence an essential promoter of human dignity.'[33]

This dissertation focuses on basic research using CRISPR-Cas9 gene editing in human embryos. Basic research is committed to advancing knowledge and developing an understanding of nature and is motivated by the expansion of knowledge in man's

[30] Beiter note 22 op cit at 235.
[31] Ibid at 236.
[32] D Jordaan *Medical Biotechnology Law in South Africa: A Human Rights Analysis of Selected Topics* (PhD thesis, University of Cape Town, 2012) at 68 [the author has changed his surname to Thaldar.]
[33] Ibid.

understanding of natural phenomena.[34] It provides the basis of knowledge for applied science, which focuses on providing solutions to problems.[35]

(b) Foreign literature on freedom of scientific research

A brief discussion of foreign literature is necessary as the study will compare the way in which multiple jurisdictions view, protect and treat freedom of scientific research. This discussion will create an understanding of the interpretation of freedom of scientific research. Freedom of scientific research is 'an acquired right, generally approved by society as necessary for the advancement of knowledge from which society may benefit.'[36] Of course, the freedom is not unlimited — it goes hand-in-hand with responsibility of scientists. On freedom of scientific inquiry, Metzger quotes the 1940 *Statement of Principles on Academic Freedom and Tenure*, stating that 'such freedom is the breath in the nostrils of all scientific activity.'[37] Metzger recommends a framework for scientific freedom that would include the discussion of limits of research and a process for addressing unfair restrictions on research. [38]

One of the arguments utilised against DNA research is that some knowledge is better left unknown. Singer responds to this argument in three points.[39] First, the world is very competitive, and there is no way to ensure that other states will also prohibit the research.[40] This will mean that the knowledge will be attained and spread by other nations. Secondly, he argues that banning research creates the image that the truth is being hidden from the public.[41] Thirdly, a ban on certain kinds of research would impede solution development.[42] Metzger supports this view, stating that there is 'no such thing as dangerous knowledge.'[43] It is further supported by Selya, who states that the restriction of science in order to prevent bad science is more risky than bad science itself.[44] It is not the duty of scientists to ensure that the knowledge

[34] JT Edsall 'Scientific Freedom and Responsibility A Report of the AAAS Committee on Scientific Freedom and Responsibility' (1975) available at *https://www.aaas.org/sites/default/files/SRHRL/PDF/1975-ScientificFreedomResponsibility.pdf*, accessed on 1 September 2019 at 1.
[35] Lawrence Berkeley National Laboratory 'Basic vs Applied Research' available at *http://www.sjsu.edu/people/fred.prochaska/courses/ScWk170/s0/Basic-vs.-Applied-Research.pdf*, accessed on 1 September 2019.
[36] Edsall note 34 op cit at 5.
[37] WP Metzger 'Academic Freedom and Scientific Freedom' (1978) 107(2) *Daedalus* 93 at 103.
[38] Ibid at 109.
[39] P Singer 'Ethics and the Limits of Scientific Freedom' (1996) 79(2) *The Monist* 218 at 219.
[40] Ibid.
[41] Ibid.
[42] Ibid.
[43] Metzger note 37 op cit at 103.
[44] R Selya 'Defending Scientific Freedom and Democracy: The Genetics Society of America's Response to Lysenko' (2012) 45(3) *Journal of the History of Biology* 415 at 432.

attained by them is not used for evil purposes, it is the duty of society.[45] The concept of bad science is elucidated in Chapter Two.

In a recent article, Brokowski analyses sixty-one international ethics statements and reports pertaining to gene editing, providing an overview of the global position on HHGE.[46] Nine of the statements expressly suggest a moratorium on HHGE and forty state that HHGE should not be permitted currently.[47] This trend demonstrates that the international position towards HHGE is a cautious one. This is elaborated in Chapter Five's analysis of international ethics statements. The international legal and ethical approaches to both CRISPR-Cas9 and the right to freedom of scientific research are analysed in this dissertation.

(c) CRISPR-Cas9 in South Africa

South Africa does not specifically legislate HHGE or CRISPR-Cas9,[48] but the National Health Act 61 of 2003 (NHA) and its regulations are applicable. Research in South Africa is further guided by medical research ethics guidelines such as those of the Health Professions Council of South Africa, the National Health Research Ethics Council and the South African Medical Research Council. The relevant statutes and regulations, as well as the guidelines, are discussed in detail throughout the dissertation.

The Academy of Science of South Africa (ASSAf) published a consensus study report titled *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications* (the ASSAf Report).[49] The objective of the ASSAf Report is to inform policy, regulations and guidelines due to the limited genetics and genomics legislation in the country.[50] Thaldar et al point out that the ASSAf Report fails to mention the right to freedom of scientific research.[51] Pepper et al did not reply to this critique.[52] I suggest that this demonstrates how the right to

[45] GP II Smith 'The Province and Function of Law, Science and Medicine: Leeways of Choice and Patterns of Discourse' (1987) 10 *UNSW Law Journal* 103.
[46] C Brokowski 'Do CRISPR Germline Ethics Statements Cut It?' (2018) 1(2) *The CRISPR Journal* 115 at 116.
[47] Ibid at 117–19.
[48] Academy of Science of South Africa (ASSAf) 'Human genetics and genomics in South Africa: Ethical, legal and social implications' (2018) available at *http://dx.doi.org/10.17159/assaf.2018/0033,* accessed on 15 Nov 2020 at 20.
[49] Ibid.
[50] Ibid.
[51] D Thaldar, J Kinderlerer & S Soni 'An optimistic vision for biosciences in South Africa: A response to the ASSAf report on human genetics and genomics' (2019) 115(7/8) *S Afr J Sci* available at *https://doi.org/10.17159/ sajs.2019/6146,* accessed on 15 Nov 2020.
[52] MS Pepper, C Dandara & J De Vries et al 'An optimistic vision for biosciences in South Africa: Reply to Thaldar et al' (2019) 115(7/8) *S Afr J Sci* available at *https://doi.org/10.17159/sajs.2019/a0312,* accessed on 15 Nov 2020.

freedom of scientific research is overlooked in academics — this emphasises the need for this study.

Dhai et al indicate that the right to freedom of scientific research can only be limited in terms of section 36 of the Constitution (the limitation clause),[53] which states that limitations on rights must be applied 'only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.'[54] The authors suggest that proving that the NHA restrictions on the right to freedom of scientific research are unreasonable may be a difficult task due to the many different legal positions in other jurisdictions.[55] The authors go no further in attempting to explain why this would have implications for proving that the restrictions placed on South African researchers are unreasonable or too harsh. This lack of deeper analysis of limitations of the right to freedom of scientific research can be observed in many South African writings.

Thaldar questions whether the right to freedom of scientific research is sufficiently protected, or whether it is disregarded as a result of anti-scientific values and the moral status that is attached to the pre-embryo.[56] The example of pre-embryo research is utilised to demonstrate the extent to which South African law is moulded by scientific versus anti-scientific views and values. In order to analyse the legal system on pre-embryo experimentation, Thaldar relies on the conclusion of a previous article in which he explores the legal status of the pre-embryo and determined that it is not inherently worthy of protection.[57] The Medical Research Council's (MRC) ethical guidelines are research-limiting without rational or justified moral reasons for such limitation.[58] Thaldar argues that in the MRC guidelines, 'an individual's interest in procreating is allocated a value far exceeding society's collective interest in scientific progress.'[59] This statement encapsulates one of the reasons that this study is significant — the right to freedom of scientific research has not been afforded the same weight as other constitutional rights.

[53] A Dhai, J Moodley & DJ McQuoid-Mason et al 'Ethical and legal controversies in cloning for biomedical research – a South African perspective' (2004) 94(11) *SAMJ* 906.
[54] S36(1), Constitution.
[55] Dhai et al note 53 op cit.
[56] DW Jordaan 'Science versus anti-science: the law on pre-embryo experimentation' (2007) 124(3) *SALJ* 618 at 618 [the author has changed his surname to Thaldar.]
[57] DW Jordaan 'The legal status of the human pre-embryo in the context of the genetic revolution' (2005) 122(1) *SALJ* 237 [the author has changed his surname to Thaldar.]
[58] Jordaan note 56 op cit at 625.
[59] Ibid.

The right to freedom of scientific research is linked to human dignity.[60] Thaldar submits that the right is part of self-actualisation and autonomy of the individual at the level of the scientist and society as a whole, with the self-actualisation of individual scientists enabling the self-actualisation of individual members of society.[61] On the importance of the right, he states that 'the right to freedom of scientific research is the lifeblood of scientific progress and the conditio sine qua non for the continued improvement of the human condition.'[62]

(d) Liberty

The principles of freedom elucidated in John Stuart Mill's *Essay On Liberty* will be utilised in the interpretation of freedom of scientific research.[63] Mill admits his utilitarian leaning, but qualifies this by stating that his view of utility is, 'in the largest sense, grounded on the permanent interests of man as a progressive being.'[64] While individuals should have liberty in domains which do not concern society, this liberty can be limited in the prevention of harm to others.[65] These arguments will be more thoroughly discussed in Chapter Three, but two aspects of Mill's thinking are highlighted below. The first aspect is encapsulated in Mill's statement that:

> 'Persons of genius, it is true, are, and are always likely to be, a small minority; but in order to have them, it is necessary to preserve the soil in which they grow. Genius can only breathe freely in an *atmosphere* of freedom.'[66]

Mill introduces the idea of the genius needing freedom in order to be autonomous and progressive beings who can 'contribute to the bounty of the species.'[67] Liberty, especially in the context of scientific research, is of utmost importance.

The second aspect is Mill's statement that

> 'the only unfailing and permanent source of improvement is liberty, since by it there are as many possible independent centres of improvement as there are individuals'[68]

[60] Jordaan note 56 op cit at 630.
[61] Jordaan note 32 op cit at 67.
[62] Jordaan note 56 op cit at 632.
[63] JS Mill *On Liberty and The Subjection of Women* (1996) 1–114.
[64] Ibid at 14.
[65] Ibid at 56.
[66] Ibid at 65.
[67] B Donohue 'Rhetoric, Harm, and the Personification of Progress in Mill's *On Liberty*' (2007) 20(2) *Ratio Juris* 196 at 202.
[68] Mill note 63 op cit at 71.

This statement can be applied to the freedom of the individual scientist to pursue research — such freedom would result in individual improvement and the progress of medicine, which is a direct contributor to societal development. Moore engages with this argument, agreeing that individual freedom contributes to society at large.[69] Individuals who are given the freedom to improve their standard of living and better their lives promote societal development.[70] The innovation, creation and thought of individual people is the root of the advancement of humankind.[71] Societal progress is accelerated by the availability of freedom to engage in these activities.[72]

Dworkin justifies freedom of expression as it contributes to society and is an essential aspect of human dignity.[73] Society has an interest in the freedom of expression of individuals, which is especially important in fulfilling the democratic principles of South Africa's constitution.[74] Freedom of expression is central to an open and democratic society[75] in that it recognises individual autonomy and provides 'facilitation of the search for truth by individuals and society generally.'[76] The right is connected with dignity and autonomy,[77] is necessary for the advancement of individuals and society,[78] and the bettering of people's lives.[79]

To supplement South African justifications of freedom of expression, Canadian judgments are considered. The Canadian courts justify constitutional protection of freedom of expression utilising four principles.[80] The first justifying principle is that freedom of expression promotes self-actualisation of individuals.[81] Self-actualisation is not only important to those expressing themselves, but to their audience too.[82] The second is that it is necessary for the attainment of truth,[83] which is 'an inherently good activity.'[84] In accordance with Mill's

[69] TG Moore 'Freedom and Progress' in TG Moore *On Progress: Its Reality, Desirability, and Destiny* (1994) 1–24 at 15.
[70] Ibid.
[71] Ibid.
[72] Ibid at 16.
[73] I Currie & J De Waal *The Bill of Rights Handbook* 6 ed (2013) 339.
[74] *S v Mamabolo* [2001] ZACC 17, 2001 (3) SA 409 (CC) para 37.
[75] *Van Breda v Media 24 Ltd; National Director Of Public Prosecutions v Media 24 Ltd* [2017] ZASCA 97, 2017 (2) SACR 491 (SCA) para 10.
[76] *South African National Defence Union v Minister of Defence* [1999] ZACC 7, 1999 (4) SA 469 (CC) para 7.
[77] Ibid at 8; *Khumalo v Holomisa* [2002] ZACC 12, 2002 (8) BCLR 771 (CC) para 14.
[78] *Phillips v Director of Public Prosecutions, Witwatersrand Local Division* [2003] ZACC 1, 2003 (3) SA 345 (CC) para 23.
[79] *Masuku v South African Human Rights Commission obo South African Jewish Board of Deputies* [2018] ZASCA 180, [2019] 1 All SA 608 (SCA) para 18.
[80] *Ford v Quebec* [1988] 2 SCR 712 at 765.
[81] *Irwin Toy Ltd v Quebec (Attorney General)* [1989] 1 SCR 927 at 976.
[82] *Ford* supra note 80 at 765.
[83] Ibid.
[84] *Irwin Toy Ltd* supra note 81 at 976.

philosophy, freedom of expression provides a test of the truth on an examination of how widely certain ideas are accepted by society.[85] Thirdly, it ensures that individual members of society participate in the democratic system,[86] with expression that conflicts with underlying societal values also being worthy of protection.[87] Individual participation in decision-making should be promoted.[88] The connection between freedom of expression and such participation is seen as essential to the protection of freedom of expression because it allows the airing of all ideas in order for the best option to be decided upon.[89] Lastly, freedom of expression ensures that 'the balance between stability and change in society'[90] is maintained. It is essential as it allows individuals to promote changes that will improve their lives and their societies.[91]

The interpretation of the purposes of freedom of expression provides insight for the reasons for the protection of the right to freedom of scientific research. The purposes of the right are elucidated more thoroughly in the study.

(e) Informed consent

Chapter Four is a justification analysis of certain informed consent requirements as limitations on the right to freedom of scientific research. It is important to clarify from the outset of this dissertation that informed consent is generally, in principle, considered to be a justified limitation on the right to freedom of scientific research. Informed consent respects people as autonomous agents,[92] and facilitates autonomous decision-making.[93] The right to privacy protects individual autonomy, and 'some forms of intimate personal decision-making similar to those addressed by informed consent requirements.'[94] The right to privacy allows individuals to choose what information they wish to disclose, as does informed consent in research.[95] Thus, informed consent in research is a prerequisite for the protection of the individual's right to

[85] *R v Secretary of State for the Home Department, Ex parte Simms* [1999] 3 All ER 400 at 408.
[86] *Ford* supra note 80 at 765.
[87] *R v Keegstra* [1990] 3 SCR 697 at 702.
[88] *Irwin Toy Ltd* supra note 81 at 976.
[89] *Thomson Newspapers Co v Canada (Attorney General)* [1998] 1 SCR 877 at 944.
[90] *Ford* supra note 80 at 765.
[91] *Harper v Canada (Attorney General)* [2004] 1 SCR 827 at 841.
[92] RJ Levine 'Informed Consent in Research and Practice: Similarities and Differences' (1983) 143 *Archives of Internal Medicine* 1229 at 1229.
[93] MM Hammami, EA Ak-Gaai & Y Al-Jawarneh et al 'Patients' perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred' (2014) 15(2) *BMC Medical Ethics* 1–12 at 2; Jessica W Berg, Paul S Appelbaum & Charles W Lidz et al *Informed Consent: Legal Theory and Clinic Practice* 2 ed (2001) 279.
[94] Ruth R Faden & Tom L Beauchamp *A History and Theory of Informed Consent* (1986) 7.
[95] Ibid.

privacy.[96] The protection of these invaluable individual rights justifies the limitations that informed consent places on the right to freedom of scientific research.

In South Africa, informed consent is primarily regulated by the NHA[97] and the Regulations Relating to Research with Human Participants.[98] The guidelines of the Health Professions Council of South Africa (HPCSA)[99] and the Department of Health (DoH)[100] also regulate informed consent requirements. The Protection of Personal Information Act 4 of 2013 (POPIA) regulates the processing of personal information. In order to process personal information, one must have a legal ground for the processing — for research purposes, this legal ground is specific consent from participants.[101]

This study is significant in that it will analyse the right to freedom of scientific research from a South African perspective. The requirements of informed consent in terms of the regulatory framework, and of recommended developments, will be analysed as a case study of limitations on the right to freedom of scientific research. Further, the right to freedom of scientific research is considered in the context of CRISPR-Cas9. Thus, not only is light shed on the right, but its possible applications are also explored.

II RESEARCH METHODOLOGY AND OBJECTIVES

The purpose of this study is to analyse the right to freedom of scientific research with the objective of informing debates on HHGE. The research is to respond to the main question: why should freedom of scientific research be considered in discourse and policy development regarding germline gene editing?

In responding to the main question, the following sub-questions must be addressed:

- How is the right to freedom of scientific research applied in South Africa?

[96] Ibid at 21.
[97] S 71(1)*(b)*, National Health Act 61 of 2003 (NHA).
[98] Reg 5, Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014.
[99] Health Professions Council of South Africa (HPCSA) 'Booklet 14: General Ethical Guidelines for Biotechnology Research in South Africa' in Guidelines for Good Practice in the Health Care Professions (2008); HPCSA 'Booklet 13: General ethical guidelines for health researchers' in Guidelines for Good Practice in the Health Care Professions (2008).
[100] National Department of Health 'Ethics in Health Research: Principles, Processes and Structures' (2015).
[101] S11(1)*(a)*, Protection of Personal Information Act 4 of 2013; Footnote forthcoming (DW Thaldar & BA Townsend 'Exempting health research from the consent provisions of the South African Protection of Personal Information Act' (2020)) provisional page 12.

- How is the right to freedom of scientific research applied as a right and as a freedom in selected comparative foreign jurisdictions?
- When and how should the right to freedom of scientific research be limited?
- How does freedom of scientific research apply to gene editing in human embryos?
- What is South Africa's current legal and ethical position on gene editing?
- What would South Africa's legal and ethical position be if the right to freedom of scientific research were given due cognisance?

This study is a human rights analysis of policy on scientific research. It compares the application of freedom of scientific research in the context of CRISPR-Cas9 HHGE research in multiple jurisdictions. I present the legal comparisons of different jurisdictions in the form of a table (Figure 1). This study comprises of desk-based research. The information for this study is sourced from electronic and print sources. The jurisdictions included in the legal comparisons were chosen using term searches on the Constitute Project website,[102] as well as based on their presence in published jurisdiction comparisons.[103]

III STRUCTURE

The structure of the study is as follows:

In Chapter One I have introduced the dissertation topic and its key concepts. I included a brief elucidation of the concepts of freedom of scientific research and gene editing. This set out the focus of the dissertation as a whole.

In Chapter Two I provide a brief overview of certain concepts to serve as the conceptual backdrop for the subsequent chapters. This chapter explores the meanings of science, scientific research, truth and scientific truth.

In Chapter Three I explore the nature of freedom of scientific research qua specific incidence of the general right to freedom of expression. I consider the constitutions of twenty jurisdictions. I apply the purposes of the general right to freedom of expression — as found in

[102] 'Constitute' available at *https://www.constituteproject.org*, accessed on 1 September 2019.
[103] T Ishii 'Germ line genome editing in clinics: the approaches, objectives and global society' (2015) *Briefings in Functional Genomics* 1; R Yotova 'The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law' (2017); Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020).

classic literature and in case law — to the right to freedom of scientific research. I argue that the right to freedom of scientific research is at the core of the public goods that the general right to freedom of expression is intended to protect.

In Chapter Four I discuss the requirement of informed consent as a case study of a limitation on the right to freedom of scientific research from a South African perspective. The conclusions reached in Chapter Three are utilised in this chapter. I analyse the South African regulatory framework relating to consent and gene editing and analyse recent policy recommendations. I then embark on a justification analysis of consent as a limitation on the right to freedom of scientific research. This serves as an entrée for the next chapter that will engage with gene editing.

In Chapter Five I zoom in on CRISPR-Cas9 gene editing. I begin by providing scientific context and then analyse the ethical issues which emerge. I engage in an analysis of the regulations of twenty foreign jurisdictions in relation to HHGE and gene editing in human embryos. I then analyse the South African legal framework. These discussions are considered through the lens of freedom of scientific research.

In Chapter Six I conclude the dissertation by outlining the main findings of the study and highlighting possible opportunities for future research.

CHAPTER TWO:

SCIENCE, SCIENTIFIC RESEARCH, AND TRUTH

I INTRODUCTION

What is science? And what is scientific research? Do lawyers engage in scientific research when they do legal research? And when a geneticist creates a glow-in-the-dark bunny as a pet for her children, is that scientific research? Science is often said to be a search for the truth. But what is truth? Can science assist in finding the truth, or at least some kinds of truth? While no universally accepted definitions of these concepts exist, it is important to explore the literature with the purpose of clarifying their meanings. In this chapter, I provide a brief overview of these concepts to serve as a conceptual backdrop for the subsequent chapters. I discuss the meaning of science and scientific research, explaining the scientific method. I discuss truth and morality and their role in science.

II SCIENCE AND SCIENTIFIC RESEARCH

Science is '(knowledge from) the careful study of the structure and behaviour of the physical world, especially by watching, measuring, and doing experiments, and the development of theories to describe the results of these activities.'[1] A crucial concept in science is *evidence*. In a letter to his ten-year-old daughter, renowned biologist Richard Dawkins explains that we understand certain things about the world, such as what stars are, thanks to evidence.[2] Evidence is collected through observing or experiencing something that is true, and is thus a 'good reason for believing something.'[3] In science, tradition, authority and revelation are not justifications for beliefs.[4] While scientists often rely on the works of others, this is different to believing something just because an authority said it, because the other scientists have had to collect and convey evidence for their claims.[5] As a result of its dependence on evidence, science is a reliable source of knowledge.

Science, for the most part, proceeds in terms of the scientific method. The scientific method consists, firstly, of the formation of a new and tentative idea (a hypotheses or prediction).

[1] 'Cambridge Dictionary' available at *https://dictionary.cambridge.org/dictionary/english/science*, accessed on 22 January 2020.
[2] Richard Dawkins *A Devil's Chaplain: Reflections on Hope, Lies, Science and Love* (2004) 242.
[3] Ibid at 243.
[4] Ibid.
[5] Ibid at 245.

Conclusions from this idea are reached through logical deduction. The conclusions are contrasted with prior conclusions and statements to determine whether logical relations exist between them.[6] The scientific method proceeds as follows: question — hypothesis — prediction — test by collecting data — analysis of data — determine if prediction is supported by data.[7] A scientist will raise a question based on observations.[8] The question is then formulated as a hypothesis, which is a provisional statement that makes a prediction.[9] The scientist will collect relevant data through experimentation and observation, and then analyse the data to determine whether it supports the hypothesis.[10] However, it must be noted that this is a rather simplified depiction of the scientific method. The scientific method does not always occur in this sequence, nor does it always include each step of the sequence, as it is actually a 'highly variable and creative process.'[11] The scientific method also consists of general principles such as common sense, rationality, logic and the reliance on evidence.[12]

Scientific hypotheses are tested according to different methods.[13] The 'internal consistency of the system'[14] can be checked through contrasting the different conclusions of the theory. The logic of the theory may be tested to establish whether or not it has the characteristics of a scientific theory. The theory may also be compared to other theories. The conclusions of the theory may be empirically applied in order to determine the extent to which they withstand repetition in practice.[15] For as long as a 'theory withstands detailed and severe tests, and is not superseded by another theory in the course of scientific progress, we may say that it is "corroborated" by past experience.'[16]

Popper refers to the rules or conventions which guide scientific research methods.[17] The first methodological convention is that science does not come to an end. Scientific ideas can always be tested further and possibly improved upon — or disproved.[18] A hypothesis may be abandoned or rejected when it has been falsified or replaced with a better theory. The 'supreme

[6] Karl Popper 'Scientific Method' in David Miller (ed) *A Pocket Popper* (1983) 133–42 at 135.
[7] SJ McNaughton 'What is Good Science?' (1999) 13(4) *Natural Resources and Environment* 513 at 513.
[8] Ibid at 514.
[9] Ibid.
[10] Ibid.
[11] Hugh G Gauch, Jr *Scientific Method in Practice* (2003) at 3.
[12] Ibid at 5.
[13] Popper note 6 op cit at 135.
[14] Ibid.
[15] Ibid.
[16] Ibid at 136.
[17] Ibid at 138.
[18] Ibid at 140.

rule'[19] is a ban on the creation of rules that have the effect of preventing the falsification of any statement. Thus, no statement should be protected from being challenged.

Scientific ideas are 'always tentative and open to revision.'[20] Even authoritative theories may be disproven or amended when new evidence provides for such.[21] Ideas must be checked through verification to allow for the rejection and substitution of hypotheses where necessary.[22] Science investigates unanswered questions, reaching provisional conclusions which others are invited to critique.[23] It relies on the transfer of ideas throughout the scientific community, which allows the discourse that enables revision.[24] This approach is similar to critical rationalism's 'device "I may be wrong, and you may be right, and by an effort we may get nearer to the truth."'[25] This indicates that criticism, whether our own or that of others, is vital for finding and correcting errors in scientific thought.[26]

In the introduction to this chapter, I posed the question, 'do lawyers engage in scientific research when they do legal research?' While scientists and lawyers both engage in research, and rely on open debate, there are differences in the two types of research.[27] First, legal research does not tend to strictly follow the scientific method. Secondly, science 'represents a process for proposing and refining theoretical explanations about the world,'[28] while law 'is a specific set of rules that apply to human conduct today.'[29] Thirdly, science is continually reviewed, while dispute resolution in law must be final.[30] These differences may lead to the conclusion that lawyers do not engage in scientific research; however, the answer to this question depends on the manner in which the lawyer engages in legal research.

There are different approaches to the study of law, and in addressing this question, I refer briefly to two main approaches — the natural law approach and the positivist approach. Natural

[19] Ibid at 141.
[20] A Colburn 'The Prepared Practitioner: Defining Science' (2007) 74(6) *The Science Teacher* 12 at 12.
[21] Ibid.
[22] CM Jackson 'What is Science?' (1930) 18(3) *Sigma Xi Quarterly* 77.
[23] K Frazier 'Comment: What is Science?' (1972) 102(9) *Science News* 131.
[24] Colburn note 18 op cit.
[25] Karl Popper *The Open Society & Its Enemies* (2013) 442.
[26] Ibid.
[27] NS Bryson & RJ Mannix 'Good Science, Junk Science, and Regulatory Science: Is There a Role for the Daubert Guidelines in Administrative Rulemaking?' (1998) 8(1) *Environmental Quality Management* 89 at 89.
[28] Ibid.
[29] Ibid.
[30] Ibid.

lawyers hold the view that relationships between humans are governed by a higher order 'emanating from nature, from human reason, or from the will of God.'[31] A natural law approach

> 'must start from the fundamental relation of being and oughtness, of the real and the good. Since the establishment of the natural law further depends upon the doctrine of man's nature, this human element has also to be studied, especially inasmuch as the question of the primacy of intellect or will in man is related to being and oughtness.'[32]

This is in stark contrast with legal positivism, which rejects natural law because

> 'for fixed objective norms it substitutes subjective opinions concerning a juridical oughtness; or that in a dualistic fashion valid legal norms are drawn from a system of norms which is set in contrast to the positive law (ethics, law of reason, reform proposals for new legislation, Roman law as written reason).'[33]

Legal positivism, which Kelsen refers to as 'the science of law,'[34] relies on laws such as statutes and regulations which are 'created and annulled by acts of human beings, thus being independent of morality and similar norm systems.'[35] It is important to note that legal positivism does not ignore the merits of law, however, it does not rely on the justness and fairness of law in order to determine whether the law exists.[36] Thus, legal positivism separates law and morality,[37] contrasting 'people's judgments concerning what morally ought to be and people's judgments concerning what is or was or will be.'[38]

The Constitution allows us to analyse the constitutionality of a law, creating a connection between the *is* (the existing law) and the *ought* (what that law ought to be if it were constitutional). Thus, while all legal research would be constitutionally protected under the right to freedom of thought[39] and the right to freedom of expression,[40] not all legal research would constitute scientific research. Legal research which takes a natural law approach, considering values that are external to the law, such as morality, or the *ought*, would not

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[31] Hans Kelsen *General Theory of Law and State* (1949) 8.
[32] Heinrich A Rommen *The Natural Law: A Study in Legal and Social History and Philosophy* (1998) 141.
[33] Ibid at 219.
[34] H Kelsen 'Law, State and Justice in the Pure Theory of Law' (1948) 57(3) *Yale Law Journal* 377 at 377.
[35] Kelsen note 31 op cit at 9 & 114.
[36] Stanford Encyclopedia of Philosophy 'Legal Positivism' (2003) available at *https://plato.stanford.edu/entries/legal-positivism/*, accessed on 18 Dec 2020.
[37] Jules L Coleman & Brian Leiter 'Legal Positivism' in Dennis Patterson (ed) *A Companion to Philosophy of Law and Legal Theory* 2ed (2010) 228–248 at 228.
[38] Matthew H Kramer *In Defense of Legal Positivism: Law without Trimmings* (1999) 3.
[39] S 15(1), Constitution of the Republic of South Africa, 1996.
[40] S 16(1)*(b) & (d)*, ibid.

constitute scientific research. However, legal research which takes a positivist approach should qualify as (social) scientific research.

And when a geneticist creates a glow-in-the-dark bunny as a pet for her children, is that scientific research? I argue that it is not. First, in her creation of a pet bunny for her children, the scientist does not follow the scientific method. Perhaps she began with a hypothesis that certain combinations of genes would create a glow-in-the-dark rabbit variety, but she did not intend to prove or disprove the hypothesis and publish her results. She intended to create a pet. Thus, creating a pet bunny does not follow the scientific method. Secondly, creating a glow-in-the-dark bunny as a pet does not contribute to the attainment of knowledge and truth in the way that scientific research aims to. Thus, I argue that this is not scientific research.

III GOOD SCIENCE VERSUS BAD SCIENCE

McNaughton argues that in order to identify whether something is good science, one needs to address four questions:

> '[D]oes the process follow the scientific method? Was the process performed in an objective manner? Are the results repeatable? Have the results been published in a peer-reviewed journal?'[41]

If these questions are answered in the positive, the study may be regarded as good science. First, the study should conform to the scientific method discussed above. Secondly, the scientific method must be objectively performed. Scientists sometimes favour of a specific hypothesis, even subconsciously.[42] It is important that bias does not manipulate results.[43] There are methods to ensure that bias does not influence results, including double blind testing, randomisation and variable matching.[44] Thirdly, the results of the research must be replicable.[45] This means that other researchers must be able to follow the same methodology and arrive at the same results.[46] Direct replication entails the following of the same experimental processes, while conceptual replication is the replication of an experiment using different methods.[47] This tests the generalisability of the results of the original experiment.[48] Replication is an important

[41] McNaughton note 7 op cit at 513.
[42] Ibid at 515.
[43] Ibid.
[44] Ibid.
[45] Ibid.
[46] Ibid.
[47] F Romero 'Philosophy of science and the replicability crisis' (2019) 14(11) *Philosophy Compass* 1.
[48] Ibid.

aspect of science — a 'core requirement of the scientific method.'[49] It is a source of scientific authority, a basis on which people support their trust in science.[50] However, there have been claims that science is facing what has been termed a replicability crisis.[51] A survey by *Nature* found that '[m]ore than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments.'[52] A number of studies published across different disciplines, from psychology and biomedicine to chemistry and engineering, have proven to be irreproducible.[53] One of the possible causes of the replicability crisis is publication bias.[54] Publication bias is the 'tendency for journals to publish research demonstrating positive rather than negative outcomes.'[55] Reviewers show publication bias in their preference over statistically significant positive results.[56] Researchers enable publication bias through the disproportionate submission of positive results over negative results.[57] Other possible causes of the crisis are scientific misconduct and questionable research practices.[58]

Although the replicability crisis reveals a need to resolve certain issues in science, Fanelli argues that the 'new "science is in crisis" narrative is not only empirically unsupported, but also quite obviously counterproductive.'[59] In addition, the replicability crisis is not new.[60] Gerlai argues that the crisis is not a result of diminishing scientific standards, but has existed in science throughout history.[61] Rather, the crisis has come to the forefront due to the increase in effective communication and the generation of more data, which has allowed scientists to improve debate surrounding these issues.[62]

Lastly, the research must be published in a peer-reviewed journal. Research is not reliable until 'the merit of the idea, clarity of the hypothesis, design and execution of the test, and

[49] R Gerlai 'Reproducibility and replicability in zebrafish behavioral neuroscience research' (2019) 178 *Pharmacology, Biochemistry and Behaviour* 30.
[50] Romero note 47 op cit.
[51] Ibid; Gerlai note 49 op cit.
[52] M Baker 'Is there a reproducibility crisis?' (2016) 533 *Nature* 452 at 452.
[53] Romero note 47 op cit.
[54] Ibid.
[55] CJ Lee, CR Sugimoto & G Zhang et al 'Bias in peer review' (2012) 64(1) *Journal of the American Society for Information Science and Technology* 2 at 10.
[56] Ibid.
[57] Ibid.
[58] D Fanelli 'Is science really facing a reproducibility crisis, and do we need it to?' (2018) 115(11) *PNAS* 2628.
[59] Ibid.
[60] Ibid; Gerlai note 49 op cit.
[61] Gerlai note 49 op cit.
[62] Ibid.

analysis and interpretation of the results in a broader conceptual framework'[63] have been assessed by other scientists. The importance of peer-review is summarised by McNaughton:

> 'Passing the hurdle of peer-reviewed publication is an assurance that quality control has been exercised in communicating the results to other scientists and, therefore, meets a type of reliability norm that decision-makers can rely on.'[64]

Peer review is a quality-control process which ensures that articles meet the standards required for publication.[65] It has been described as the manner in which published articles hold 'authority and authenticity,'[66] however, the system is not without fault.[67] Velterop summarises that peer review can be 'slow, inefficient, unreliable, highly variable, ineffective, arbitrary, undermining scientific scepticism, confirmation-biased, putting careerism before science, expensive.'[68] The peer-review process, which often requires multiple reviewers for a single article, can take months, even years, to reach its completion.[69] This puts researchers at risk of their competition publishing findings and studies before their articles reach publication.[70] The pressure to publish could incentivise the publication of exaggerated or fraudulent results.[71] It must be remembered that 'peer-reviewed' does not mean 'correct' or 'reliable.'[72] It is not the station of peer-reviewers to decide on the correctness of scientific results and data, but rather to decide whether the article should be published in that particular journal, and whether it contributes to scientific debate.[73] However, the issues that arise from the shortcomings of peer review do have consequences.

Heathers highlights the shortcomings of peer review with an example.[74] In May 2020, The Lancet published an article which claimed that the use of chloroquine or hydroxychloroquine in COVID-19 patients increases the risk of certain heart problems and

[63] McNaughton note 7 op cit at 515.
[64] Ibid.
[65] C Berkenkotter 'The Power and the Perils of Peer Review' (1995) 13(2) *Rhetoric Review* 245.
[66] Ibid at 245.
[67] J Velterop 'Peer review – issues, limitations, and future development' (2015) *ScienceOpen Research* 1.
[68] Ibid at 2.
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid.
[73] Ibid.
[74] J Heathers 'The Lancet has made one of the biggest retractions in modern history. How could this happen?' *The Guardian* 5 June 2020 available at *https://www.theguardian.com/commentisfree/2020/jun/05/lancet-had–to-do-one-of-the-biggest-retractions-in-modern-history-how-could-this-happen?CMP=Share_iOSApp_Other*, accessed on 22 June 2020.

death.[75] As a result of these findings, certain drug trials were urgently stopped.[76] The Lancet retracted the article in early June 2020 as three of its four authors could no longer assure the reliability of the data.[77] Heathers describes this as 'one of the most consequential retractions in modern history,'[78] arguing that the unreliable data slipped through peer review and was published because peer review is not a mechanism for uncovering incongruent data.[79] Retractions such as this one illuminate the impediments of peer review as a whole.[80] Most peer-reviewers do not receive any benefit for their services.[81] This results in a small number of available reviewers, because scientists need to spend their time producing the publications necessary to maintain and advance their careers.[82] The lack of reviewers and the pressure to publish journals results in the hasty, superficial review of articles, which allows unreliable data to slip through the cracks to publication.[83]

Due to COVID-19, scientists are even more immersed in research and there is heightened gravity surrounding health research.[84] This means that publications such as this have direct consequences for decisions in clinical trials and healthcare, and thus have a direct effect on saving lives.[85] Heathers suggests that transparency and more analytical peer review could provide a solution, along with changes to the way in which data is treated by peer-reviewers.[86] He suggests that data should be published in support of articles and that specialist reviewers should review data and statistics.[87]

In addition to the four requirements of good science outlined by McNaughton, good science must be valid. I address four types of validity, namely internal validity, external validity, construct validity and content validity. Internal validity is relevant when a study attempts to establish a causal relationship. It is 'the ability to make inferences concerning causal relationships based on experimental results.'[88] For example, a study of weight loss in

[75] RETRACTED: MR Mehra, SS Desai & F Ruschitzka et al 'Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID–19: a multinational registry analysis' (2020) *The Lancet* 1.
[76] Heathers note 74 op cit.
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] Ibid.
[84] Ibid.
[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] A Nordgren 'Designing Preclinical Studies in Germline Gene Editing: Scientific and Ethical Aspects' (2019) 16 *Journal of Bioethical Inquiry* 559 at 562.

mice may attempt to prove a causal relationship between weight loss and the use of a wheel by the mice. Internal validity may be ensured by random selection of research participants and blinding.[89] External validity refers to the generalisability of findings, or how well the results of a study apply in other settings.[90] For example, if a researcher intended to discover the effects of load shedding on South Africans, but only distributed surveys in suburbs, the results of the study would not be generalisable throughout the country. In order to ensure external validity, researchers must attempt to replicate their study.[91] Construct validity assesses whether a measurement tool represents what the researcher intends to measure.[92] A construct is a characteristic or concept that cannot be directly observed, so it is measured through the observation of indicators associated with it.[93] For example, a doctor researching the effectiveness of a specific surgery in pain relief relies on patients' subjective experiences of pain. The doctor could ask the patients to rate their pain on a scale. Construct validity would assess whether the doctor is measuring pain and not some other factor such as tingling or discomfort. Content validity evaluates whether a study represents all aspects of a construct.[94] For example, in a study on depression, a researcher could ask participants about energy levels, suicidal thoughts and other symptoms. Content validity is diminished if relevant aspects are excluded, or if irrelevant aspects are included.

IV TRUTH

Truth is defined as 'the body of real things, events, and facts,'[95] or 'the state of being the case.'[96] While this may seem simple enough, truth is difficult to define, as demonstrated by philosophers grappling with the concept. Aristotle's definition, '[t]o say of what is that it is, or of what is not that it is not, is true'[97] is a good starting point. This definition, however, is only workable within the correspondence theory of truth, which defines truth as 'a matching of

[89] Ibid.
[90] Ibid.
[91] Ibid.
[92] V Henderson, J Kimmelman & D Fergusson et al 'Threats to Validity in the Design and Conduct of Preclinical Efficacy Studies: A Systematic Review of Guidelines for In Vivo Animal Experiments' (2013) 10(7) *PLoS Medicine* 1.
[93] JD Brown 'What is Construct Validity?' (2000) 4(2) *Shiken: JALT Testing & Evaluation SIG Newsletter* 8.
[94] M Brod, LE Tesler & TL Christensen 'Qualitative Research and Content Validity: Developing Best Practices Based on Science and Experience' (2009) 18(9) *Quality of Life Research* 1263.
[95] 'Merriam-Webster' available at *https://www.merriam-webster.com/dictionary/truth*, accessed on 22 January 2020.
[96] Ibid.
[97] SW Blackburn 'Truth' available at *https://www.britannica.com/topic/truth-philosophy-and-logic*, accessed on 22 January 2020.

words to world.'[98] In order to verify a statement as true, the relationship between the words communicated and the world must be examined.[99] Another philosophical theory of truth, the coherence theory, holds that 'truth derives from coherent relations within a given social, semantic and epistemological framework.'[100] The truth of an idea may only be examined within its framework and context.[101] The social theory 'relies on the understanding of relations of power and control over knowledge and claims to possess truth.'[102] The existence of different theories of truth demonstrates the difficulty associated with defining the concept. While an in-depth discussion of all of the theories of truth is beyond the scope of this study, the meaning of truth is explored further below, with a focus on the correspondence theory as elucidated by Popper.

Popper relies on Tarski's correspondence theory of objective truth.[103] He explains the theory 'as a simple elucidation of the idea of *correspondence to the facts.*'[104] Popper summarises this view: 'A statement is true if it corresponds to the facts. It is nearer to the truth than another statement if it corresponds to the facts more closely than the other statement.'[105] Tarski determines that, in order to understand truth as correspondent to the facts, we must utilise a metalanguage to refer to concepts such as statements and the facts that they correspond to.[106] The correspondence theory treats truth as objective — it is a characteristic of theories, not a subjective experience or belief.[107] Popper describes objective truth by employing the example of a mountain, the top of which is covered in clouds.[108] A mountain climber may never know when he has reached the peak of the mountain as his view may be blocked by the clouds. However, this does not mean that the mountain peak does not exist objectively. The possibility of doubt and error implies that there exists an objective truth.[109]

[98] SD Blum 'Truth' (1999) 9(1/2) *Journal of Linguistic Anthropology* 255 at 255.
[99] Ibid.
[100] Ibid.
[101] Ibid.
[102] Ibid.
[103] Karl Popper 'Truth and Approximation to Truth' in David Miller (ed) *A Pocket Popper* (1983) 181–98 at 182.
[104] Ibid at 183.
[105] Popper note 23 op cit at 492.
[106] Popper note 103 op cit at 183.
[107] Karl Popper 'Karl Popper: "Intellectual Autobiography"' in Paul A Schilpp (ed) *The Philosophy of Karl Popper* (1974) 3–181 at 114.
[108] Popper note 103 op cit at 185.
[109] Ibid.

Truth relativists argue that objective truth does not exist because all claims are perspectival.[110] Searle rejects truth relativism on the basis that if truth is relative, reality must be relative.[111] This is a solipsism — the 'doctrine that the only reality is my reality.'[112] This means that individuals only have access to their own versions of reality.[113] This limits the ability to make epistemically objective claims. Claims such as 'two plus two equals four'[114] rely on a commitment to the existence of an objective truth. Searle thus argues that even from our subjective perspectives, it is possible to make epistemically objective claims about a reality.[115]

On scientific objectivity, Harris refers to Searle's distinction between ontological and epistemic objectivity and subjectivity.[116] Harris describes epistemology as relating to 'how we know,'[117] while ontology relates to 'what there is to know.'[118] Searle refers to epistemology as 'having to do with knowledge'[119] and ontology as 'having to do with existence.'[120] Searle explains that feelings such as pain have a subjective ontology because only conscious experience brings them into existence.[121] For example, the statement 'I have a tickle in my throat' is ontologically subjective because only the person saying it knows if they are truly experiencing a tickle in their throat. Objects such as rocks and atoms have an objective ontology because they exist externally.[122] The statement, 'there is a mountain across the road' is ontologically objective because someone hearing the statement would be able to see if there truly is a mountain across the road. Something is epistemically objective when it can be judged as true or false without consideration of the feelings of witnesses.[123] The statement 'Siya Kolisi played for the Springbok rugby team in 2020' is epistemically objective. We can conclude that it is true without considering attitudes or feelings. When the truth cannot be determined without

[110] J Searle 'Searle vs Lawson: After the End of Truth — part 1' available at *https://iai.tv/articles/objectivity-and-truth-auid-548,* accessed on 17 June 2020.
[111] Ibid.
[112] Ibid.
[113] Ibid.
[114] Ibid.
[115] Ibid.
[116] Sam Harris *The Moral Landscape* (2010) 30.
[117] Ibid at 29.
[118] Ibid.
[119] J Searle 'After the End of Truth' *Philosophy For Our Times* podcast by Institute for Art and Ideas (2016) available at *https://podcasts.google.com/?feed=aHR0cDovL2ZlZWRzLmZlZWRidXJuZXIuY29tL1BoaWxvc29waHlGb3JPdXJUaW1lcw&episode=dGFnOnNvdW5kY2xvdWQsMjAxMDp0cmFja3MvMjgwNzI0Njk5&hl=af&ved=2ahUKEwizorfXhcXnAhWzA2MBHVxpDXQQjrkEegQIBRAE&ep=6,* accessed on 20 March 2020.
[120] Ibid.
[121] Ibid.
[122] Ibid.
[123] Ibid.

the consideration of other opinions and feelings, the statement is said to be epistemically subjective.[124] The statement 'Siya Kolisi is the best rugby player on the planet' is epistemically subjective because we cannot conclude on its truth or falsity without considering the opinions and attitudes of the supporters of other rugby players. Searle argues that the distinction between epistemic and ontological subjectivity and objectivity is fundamental because

> 'the ontological subjectivity of a domain does not preclude epistemic objectivity of a science of that domain. You can have a completely adequate science of consciousness or mental life in general that is epistemically objective even though the entire domain is ontologically subjective.'[125]

Thus, as Harris explains, it is possible to study subjective facts in an objective manner.[126] This means that 'there are right and wrong answers to moral questions.'[127] There are facts that science can discover regarding the well-being of conscious subjects.

V SCIENCE AND TRUTH

Upton cites Aristotle's six characteristics of the principles that science is built upon.[128] The first of these characteristics, and the most important for this discussion, is truth. Aquinas' view is that 'what is not true does not exist, for to be and to be true are convertible. Therefore, anything scientifically known must be true.'[129]

Asimov, an American biochemistry professor, argued that '[s]cience does not purvey absolute truth, science is a mechanism. It's a way of trying to improve your knowledge of nature, it's a system for testing your thoughts against the universe and seeing whether they match.'[130] The method of making hypotheses, finding experiments to prove or disprove the hypotheses, engaging in discourse and dismissing incorrect ideas makes science rather unique.[131] The scientific method means that science has a 'built-in error-correcting machine'[132] which contributes to its successful functioning.[133] Science remains open to ideas on any matter,

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[124] Ibid.
[125] JR Searle 'Theory of Mind & Darwin's Legacy' (2013) 110(2) *PNAS* 10343 at 10344.
[126] Harris note 116 op cit at 30.
[127] Ibid.
[128] T Upton 'Truth vs Necessary Truth in Aristotle's Sciences' (2004) 57(4) *The Review of Metaphysics* 741.
[129] Ibid at 743.
[130] M Popova quoting Asimov in 'What Is Science? From Feynman to Sagan to Asimov to Curie, an Omnibus of Definitions' available at *https://www.brainpickings.org/2012/04/06/what-is-science/,* accessed on 14 January 2020.
[131] Carl Sagan *The Demon–Haunted World: Science as a Candle in the Dark* 2 ed (1997) 252.
[132] Ibid at 34.
[133] Ibid.

retaining the ideas that withstand scrutiny.[134] It is this aspect of science that gives us momentum in 'our quest for the truth.'[135] Science is a balance between open-mindedness and brutal scepticism, and this 'is how deep truths are winnowed from deep nonsense.'[136] New ideas are embraced, and then put through a rigorous testing process of experimentation and investigation in order that the better ideas may be retained.[137]

Massimi poses three questions. The first, 'does science aim at truth?'[138] ignited debate in Van Vraassen's *The Scientific Image.*[139] A scientific realist approach views science's objective as finding out the truth about nature, rather than revealing what can be found from the observed phenomena.[140] Van Vraasen argued that it is often sufficient to account for the observable phenomena without providing an account of the truth.[141] Popper suggests that science is a search for truth, and submits that this goal of science enables us to admit our fallibility and learn from past errors.[142] Fallibility is linked to objective truth because it allows us to recognise mistakes.[143] It implies that we must inspect and criticise our theories in order to find error and come closer to finding truth.[144] Popper emphasises that while we are fallible, we can acquire knowledge through error, and while we cannot always *justify* our theories, we can *develop* them through rational criticism.[145] An example of scientific fallibility is the finding of heavy water and heavy hydrogen.[146] Before this discovery, chemistry was convinced of its knowledge of water, even utilising it to define the unit of mass in the metric system.[147] The discovery of heavy water brought the knowledge that water is not a pure compound and can have varying densities and boiling and freezing points.[148] This discovery demonstrated that we can never be certain of our scientific knowledge.[149] The past has taught us to never expect science to arrive at finality — theories are *always* hypotheses. We can advance, however, through the discovery

[134] Ibid.
[135] Ibid at 252.
[136] Ibid at 287.
[137] Ibid.
[138] M Massimi 'Getting it Right' available at *https://aeon.co/essays/its-time-for-a-robust-philosophical-defence-of-truth-in-science*, accessed on 1 February 2020.
[139] Bas C van Vraassen *The Scientific Image* (1980).
[140] Massimi note 138 op cit.
[141] van Vraassen note 139 op cit.
[142] Popper note 103 op cit at 189.
[143] Roberta Corvi *An Introduction to the Thought of Karl Popper* (1997) 135.
[144] Ibid.
[145] Ibid at 136.
[146] Popper note 23 op cit at 490.
[147] Ibid.
[148] Ibid.
[149] Ibid at 491.

of better theories. In other words, 'we have replaced scientific certainty by scientific progress.'[150]

Fallibilism should not be mistaken as a denial of the existence of truth. In fact, it implies that there is a truth towards which we should aim.[151] Popper asserts that human knowledge is great, but so is human ignorance, and that this contradiction is what develops knowledge.[152] He regards rationality as the rational criticism of theories, linking it to 'the growth of conjectural knowledge.'[153] This growth leads to the attainment of a closer approximation to the truth, which is the goal of the scientist — gaining more knowledge.[154] Thus truth is a regulative principle as it provides a standard — one which we may never meet. However, science does not just seek mere truth, it seeks '*answers to our problems.*'[155] Potential to solve problems is what makes truth relevant in science.

It is clear that some theories do conform better to the facts than others. For example, a theory could be more detailed, consider more facts, pass more tests or be more accurate than another theory.[156] It is argued that while science seeks truth, this is not its only goal — Popper proposes that the goal of science is 'to find *satisfactory explanations* of whatever strikes us as being in need of explanation.'[157] Satisfactory explanations rely on 'testable and falsifiable universal laws and initial conditions.'[158] The better tested the laws are, the more satisfactory the explanation. The progress of science increases how satisfactory explanations are, resulting in more universal and accurate explanations.[159]

The answer to Massimi's second question, 'does science tell us the truth?'[160] could be found in reference to the history of science.[161] Philosophers of science 'take a well-defined set of facts about nature as responsible for making scientific claims true or false'[162] and the development of science depends on these facts being revealed.[163] This is summarised by

[150] Ibid at 229.
[151] Ibid at 491.
[152] Corvi note 143 op cit at 136.
[153] Popper note 107 op cit at 119.
[154] Ibid.
[155] Popper note 103 op cit at 190.
[156] Ibid at 193.
[157] Karl Popper 'The Aim of Science' in David Miller (ed) *A Pocket Popper* (1983) 162–70 at 162.
[158] Ibid at 164.
[159] Ibid.
[160] Massimi note 138 op cit.
[161] Ibid.
[162] Ibid.
[163] Ibid.

Wittgenstein, as quoted by Massimi, who states that 'the world is the totality of facts.'[164] Fact-constructivists reject that our scientific claims can be affirmed or falsified by facts observed in nature because 'there is not a single, objective way that the world is.'[165] Kuhn rejects the 'naïve view that science aims at or tracks truth'[166] in *The Structure of Scientific Revolutions.*[167] On this view of science as heading towards one goal, Kuhn asks,

> 'Can we not account for science's existence and its success in terms of evolution from the community's state of knowledge at any given time? Does it really help to imagine that there is some one full, objective, true account of nature and that the proper measure of scientific achievement is the extent to which it brings us closer to the ultimate goal?'[168]

He suggests that scientific development can occur 'without the benefit of a set goal, a permanent fixed scientific truth.'[169] In answering her second question, Massimi concludes that science has historically demonstrated that there are reasons to be disillusioned with scientific truth, the philosophy of which should be left for logic to discuss.[170]

To her third question, '[s]hould we *expect* science to tell us the truth?'[171] Massimi responds that it is still the responsibility of the philosophy of science to discuss and engage with the concept of truth.[172] She suggests the American pragmatic manner of considering truth — 'to be true is (to a good approximation) to work successfully.'[173] We know that science creates numerous perspectives which result in scientific progress, but this makes one wonder if truth is perhaps useless to science, or relative to different scientific perspectives.[174] Massimi calls for a defence of truth, submitting that the process starts with 'a commitment to *get things right.'*[175] Science can be expected to tell the truth because 'this is what science ought to do.'[176] Truth is not an aim of science, but a 'normative commitment inherent in scientific knowledge.'[177] This commitment to getting things right is the minimum requirement for something to be classified as scientific knowledge.

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[164] Ibid.
[165] Ibid.
[166] Ibid.
[167] Thomas Kuhn *The Structure of Scientific Revolutions* 3 ed (1996).
[168] Ibid at 171.
[169] Ibid at 173.
[170] Massimi note 138 op cit.
[171] Ibid.
[172] Ibid.
[173] Ibid.
[174] Ibid.
[175] Ibid.
[176] Ibid.
[177] Ibid.

VI EXCURSUS: TRUTH, SCIENCE, AND MORALITY

Is there *moral* truth? Some academics argue not, because 'the statement that some person or persons have a certain feeling is never equivalent to an assertion of moral value and can never prove moral value.'[178] Some philosophers, such as moral sceptic Mackie, argue that moral truth does not exist because moral properties do not exist.[179] Others still have argued against using science-based arguments in discussion of the existence of moral truth, with Kramer arguing that 'anyone who seeks to uphold the reality of moral values will have to have recourse to moral considerations and moral argumentation.'[180] Science and morality are viewed by some as separate domains, but this view has been challenged.

Perhaps the most well-known attempt to marry morality and science is by contemporary author Sam Harris, who proposes that scientific thinking can and should be applied to moral values and that moral truth is indeed attainable.[181] He describes his idea of the moral landscape as a 'hypothetical space…of real and potential outcomes whose peaks correspond to the heights of potential well-being and whose valleys represent the deepest possible suffering.'[182] He argues that 'questions about values — about meaning, morality, and life's larger purpose — are really questions about the wellbeing of conscious creatures.'[183] 'Values,' according to Harris, are

> 'facts that can be scientifically understood: regarding positive and negative social emotions, retributive impulses, the effects of specific laws and social institutions on human relationships, the neurophysiology of happiness and suffering, etc.'[184]

Thus, science is able to identify values and appropriately apply its principles to morality as 'human well-being entirely depends on events in the world and on states of the human brain. Consequently, there must be scientific truths known about it.'[185] Harris argues that a more profound scientific understanding of these truths would enable us to decide which societies have better standards of well-being.[186] An action may be judged as morally wrong or right by

[178] DS Miller 'Moral Truth' (1950) 1(3) *Philosophical Studies: An International Journal for Philosophy in the Analytic Tradition* 40 at 41.
[179] JL Mackie *Ethics: Inventing Right and Wrong* (1991).
[180] Matthew H Kramer *Moral Realism as a Moral Doctrine* (2009) 204.
[181] JW Diller & AE Nuzzolilli 'The Science of Values: The Moral Landscape by Sam Harris' (2012) 35(2) *The Behavior Analyst* 265 at 267.
[182] Harris note 116 op cit at 7.
[183] Ibid at 1.
[184] Ibid at 1–2.
[185] Ibid at 3.
[186] Ibid.

determining its effect on well-being.[187] A scientific approach to morality depends on 'the distinction between "the good life" and "the bad life" and the idea that there are lawful patterns and factors that contribute to each of these outcomes.'[188] On scientific objectivity, Harris adopts Searle's distinction between ontological and epistemic objectivity and subjectivity discussed above.[189]

The gist of Harris' *The Moral Landscape* is that science is able to assist us in understanding 'what we *should* do and *should* want — and, therefore, what *other people* should do and should want in order to live the best lives possible.'[190] A science of morality exists because 'a concern for well-being…is the only intelligible basis for morality and values'[191] and the 'well-being of conscious creatures depends upon how the universe is, altogether,'[192] which is within the domain of science.

VII CONCLUSION

This chapter explored the meanings of science, scientific research, truth and scientific truth. The definitions at which this chapter arrived, while not universally applicable, are relevant to the use of these concepts throughout the rest of this study. In conclusion, science is an empirical and critical process which aims at finding truth and providing solutions to issues through observation and experimentation. Scientific research is an investigation and testing of hypotheses in order to find a closer approximation to the truth. It is clear that the right to freedom of scientific research does not aim to protect frivolous endeavours such as the creation of a glow-in-the-dark bunny as a children's pet. It protects science insofar as it advances *truth*. As argued by Harris, science, truth and morality are interconnected, meaning that science may be able to objectively study subjective moral issues. In the next chapter, I investigate the reasons why many modern societies have come to protect freedom of scientific research.

[187] Ibid.
[188] Diller & Nuzzolilli note 181 op cit at 268.
[189] Harris note 116 op cit at 30.
[190] Ibid at 28.
[191] Ibid.
[192] Ibid.

CHAPTER THREE:

THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH: RATIONALE AND PURPOSE

I INTRODUCTION

In this chapter, I familiarise the reader with the nature of the right to freedom of scientific research as a specific instance of the right to freedom of expression. I start by analysing the purposes of freedom of expression as found in classical literature, as well as South African and foreign case law. I then apply these purposes to freedom of scientific research in order to cast light on the meaning of the right to freedom of scientific research. Finally, I argue that the right to freedom of scientific research is at the centre of the public good that the right to freedom of expression intends to protect.

II FREEDOM OF SCIENTIFIC RESEARCH AS AN INSTANCE OF THE GENERAL RIGHT TO FREEDOM OF EXPRESSION

The right to freedom of scientific research is an enumerated constitutional right in South Africa. It is protected as a specific instance of the more general right to freedom of expression. The relevant section in the Constitution reads as follows:

> '16. (1) Everyone has the right to freedom of expression, which includes—
>
> (a) freedom of the press and other media;
>
> (b) freedom to receive or impart information or ideas;
>
> (c) freedom of artistic creativity; and
>
> (d) academic freedom and freedom of scientific research.'[1]

The constitutions of Fiji,[2] Kenya[3] and Zimbabwe[4] also expressly protect the right to freedom of scientific research as part of their constitutional freedom of expression clauses. The format in which these constitutions and the South African Constitution protect the right is very similar. Each of these countries' constitutions protect the right to freedom of expression, 'which

[1] S 16(1)*(d)*, Constitution of the Republic of South Africa, 1996.
[2] S 17(1)*(d)*, Constitution of the Republic of Fiji, 2013.
[3] Art 33(1)*(c)*, Constitution of Kenya, 2010.
[4] S 61(1)*(b)*, Constitution of Zimbabwe Amendment (No 20) Act 2013.

includes'[5]… 'the right to freedom of scientific research.'[6] In terms of these constitutions, the right to freedom of scientific research is protected under the umbrella of freedom of expression.

Freedom of scientific research is protected in conjunction with freedom of opinion in Bahrain,[7] Jordan,[8] Kuwait,[9] Morocco,[10] and Qatar,[11] while Brazil protects freedom of 'expression of intellectual, artistic, and communication activity.'[12] Countries that constitutionally protect freedom of scientific research separately from freedom expression include Albania,[13] Egypt,[14] Hungary,[15] Latvia,[16] Poland,[17] Qatar,[18] Slovakia,[19] South Sudan,[20] Tunisia[21] and Yemen.[22] Albania, Latvia, Poland, Slovakia and Yemen protect freedom of scientific research together with art and artistic creation.

Tunisia protects freedom of scientific research together with academic freedom. Austria and Palestine[23] protect freedom of scientific research within universities.[24] Austria's constitution states that 'public universities are places of free scientific research.'[25] Palestine grants independence to universities and scientific research centres in order to ensure freedom of scientific research.[26]

[5] Art 33(1)*(c)*, Constitution of Kenya, 2010; S 61(1)*(b)*, Constitution of Zimbabwe Amendment (No 20) Act, 2013; S 17(1)*(d)*, Constitution of the Republic of Fiji, 2013.
[6] Ibid.
[7] Art 23, Constitution of Bahrain, 2002.
[8] Art 15(2), Constitution of Jordan, 1952.
[9] Art 36, Constitution of Kuwait, 1962 (reinst 1992).
[10] Art 25, Constitution of Morocco, 2011.
[11] Art 47, Constitution of Qatar, 2003.
[12] Art 5, Constitution of Brazil, 1988.
[13] Art 58, Constitution of Albania, 1998.
[14] Art 66, Constitution of Egypt, 2014, which also gives the state the duty to 'sponsor researchers and inventors and protect and work to apply their innovations.'
[15] Art X, Constitution of Hungary, 2011, which further removes the right of the State to 'decide on questions of scientific truth; only scientists shall have the right to evaluate scientific research.' It specifically guards the scientific freedom of the Hungarian Academy of Sciences and grants autonomy to institutions of higher education to decide on content and methods of research.
[16] Art 113, Constitution of Latvia, 1922 (reinst 1991).
[17] Art 73, Constitution of Poland, 1997.
[18] Art 47, Constitution of Qatar, 2003.
[19] Art 43, Constitution of Slovakia 1992.
[20] Art 38, Constitution of South Sudan, 2011. South Sudan's National Government has the duty to 'protect the freedom of scientific research within the ethical parameters of research and as shall be regulated by the law.' This art further provides for academic freedom.
[21] Art 33, Constitution of Tunisia, 2014.
[22] Art 27, Constitution of Yemen, 1991.
[23] Art 24, Constitution of Palestine, 2003.
[24] Art 81C, Constitution of Austria, 1920 (reinst 1945); Art 24, Constitution of Palestine, 2003.
[25] Art 81C, Constitution of Austria, 1920 (reinst 1945).
[26] Art 24, Constitution of Palestine, 2003.

Jurisdictions which do not have express constitutional provisions regarding freedom of scientific research, such as the United States of America and Canada, are argued by some academics to provide for such under general freedom of expression clauses.[27]

While some jurisdictions protect freedom of scientific research under the umbrella of freedom of expression, some legal scholars reject the application of the principles of the latter to the former. Green compares freedom of expression to freedom of scientific research,[28] arguing that since freedom of expression does not protect actions such as defamation, freedom of science should not protect scientific experimentation.[29] According to this argument, in order to limit the academic (non-experimental) pursuits of scientists, there would need to be a powerful governmental reason for the restriction, such as a clear imminent danger to others.[30] However, in order to justify restrictions on physical experimentation, 'no more than a rational basis will be required.'[31] According to Green, the scientist has the right to think, hypothesise and publish, but once he enters into the realm of physical experimentation, he is afforded little to no constitutional protection.[32] I suggest that this argument is unfounded because experimentation without manipulation is impossible. Scientific research cannot occur without 'interacting with the object of research.'[33] The protection of scientific freedom would be futile if it did not include experimentation.

Beiter argues that freedom of scientific research must be separated from freedom of expression.[34] This is because scientific freedom necessitates a broader protection than freedom of speech since scientific freedom also implies protection for certain actions.[35] Without protecting the physical experimentation or manipulation necessary to conduct scientific research, the right to freedom of scientific research would be ineffective. The right to academic freedom would protect the academic pursuits of the scientific community. The key differences

[27] A Santosuosso, V Sellaroli & E Fabio 'What constitutional protection for freedom of scientific research?' (2007) 33(6) *J Med Ethics* 342 at 342; Kerry Lynn Macintosh 'The Regulation of Human Germline Genome Modification in the United States' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 103–28 at 107.
[28] HP Green 'The Boundaries of Scientific Freedom' (1977) 20 *Newsletter on Science, Technology, & Human Values* 17.
[29] Ibid at 18.
[30] Ibid.
[31] Ibid.
[32] Ibid.
[33] A Santosuosso, V Sellaroli & E Fabio 'What constitutional protection for freedom of scientific research?' (2007) 33(6) *J Med Ethics* 342 at 343.
[34] KD Beiter 'Where Have All the Scientific and Academic Freedoms Gone? And What is Adequate for Science?' The Right to Enjoy the Benefits of Scientific Progress and its Applications' (2019) 52(2) *Israel Law Review* 233 at 247.
[35] Ibid.

in the protection of freedom of expression and freedom of scientific research are highlighted by Beiter, who states that

> 'scientific and academic speech are subject to quality controls, taking the form of, for example, peer review. In the context of ordinary speech protected by freedom of expression, such controls do not really exist, and would (or should) readily amount to impermissible censorship. However, it is also true that limitations by law to further certain public goals (such as national security) may be imposed more easily with regard to freedom of expression than scientific or academic freedom. This is a consequence of the crucial value attached to the discovery of the truth and the "sophisticated" nature of scientific and academic speech. Scientific and academic freedom may be regulated rather than limited by law.'[36]

Beiter argues that freedom of scientific research and free speech are based on different rationales — free speech promotes democracy, while freedom of scientific research centres on 'discovering the truth and advancing knowledge (even if this is also crucial, eventually, in building a democratic society).'[37] I agree that freedom of scientific research 'entail[s] additional entitlements and more robust speech rights than freedom of expression,'[38] and that it may not serve democracy so directly as freedom of expression does. However, I argue that since freedom of scientific research is expressly included under the right to freedom of expression in the South African Constitution, the two rights do in fact share mutual rationales and purposes. These purposes will be identified in the following sections. While the *principles* and *applications* of freedom of expression may not be directly relevant to the right to freedom of scientific research, the rights are closely linked in that they serve the same *purposes*. The position of the right to freedom of scientific research in the constitutions of countries that expressly protect it demonstrates that the right is an instance of freedom of expression. Thus, in order to better understand the right to freedom of scientific research, it is helpful to consider the justifications of the right to freedom of expression.

In *S v Zuma*,[39] Kentridge AJ quotes Lord Wilberforce — 'a generous interpretation…suitable to give to individuals the full measure of the fundamental rights and freedoms referred to'[40] is called for in constitutional interpretation. Kentridge AJ goes on to quote Dickson J: 'The interpretation should be…a generous rather than legalistic one, aimed

[36] Ibid at 248.
[37] Ibid.
[38] Ibid at 247.
[39] *S v Zuma* [1995] ZACC 1, 1995 (2) SA 642 (CC) at 651.
[40] Ibid, quoting *Privy Council in Minister of Home Affairs (Bermuda) v Fisher* [1979] 3 All ER 21.

at fulfilling the purpose of a guarantee.'[41] South African courts confirm that the interpretation of rights should be purposive in order to ensure that people receive the full benefit of constitutional guarantees.

The Constitutional Court (CC) in *S v Makwanyane* referred to the case of *S v Zuma* and affirmed that a purposive approach is applicable, holding that in order to give meaning to a right, the purpose of the right must first be sought.[42] The goal of a purposive interpretation is to define the scope of the right. Once the purpose of the right is defined, it can be determined what would constitute an infringement on the right. If one applies the instrumental approach to freedom of expression, its purpose could be to promote debate in the political realm.[43] If a purposive approach is applied, the right to freedom of expression is linked to 'the values of personal self-fulfilment and autonomy.'[44] It is clear that South African constitutional law would apply the purposive approach to interpreting the right to freedom of scientific research, considering the right both as an end-in-itself, and instrumentally as a promoter of certain values.

Further, in terms of section 36(1) of the Constitution, the limitation of rights necessitates an analysis of proportionality, meaning that the courts must weigh up the two competing rights.[45] In order to do so, the purpose of the rights must be understood. Thus, in order to determine the scope of the right to freedom of scientific research, in terms of the purposive approach, one needs to determine its purposes. South African courts have not been requested to apply the right to freedom of scientific research, thus there is no case law interpreting the right, so the purposes of freedom of expression will be applied to it. These purposes can be found in case law and classical literature.

III THE PURPOSES OF FREEDOM OF EXPRESSION WITH REFERENCE TO CLASSICAL LITERATURE

The standard classical reference text on freedom of expression is John Stuart Mill's *Essay On Liberty*,[46] which explores civil and social liberty and the manner in which society can wield power over individuals. Mill focuses specifically on the liberty of thought, which he argues is

[41] Ibid, quoting *R v Big M Drug Mart Ltd* (1985) 18 DLR 321 at 3956.
[42] *S v Makwanyane* [1995] ZACC 3, 1995 (6) BCLR 665 (CC) at 777.
[43] Iain Currie & Johan De Waal *The Bill of Rights Handbook* 6 ed (2013) 137.
[44] Ibid.
[45] *Islamic Unity Convention v Independent Broadcasting Authority* [2002] ZACC 3, 2002 (4) SA 294 (CC) para 310.
[46] JS Mill *On Liberty and The Subjection of Women* (1996) 1–114.

inseparable from the freedom to speak and write.[47] *On Liberty* defends freedom of expression with an overarching theory of individual autonomy and freedom.[48] Before discussing Mill's purposes of freedom of expression, his theories of liberty are explored.

Mill is well-known for his utilitarian approach, stating that he views 'utility as the ultimate appeal on all ethical questions; but it must be utility in the largest sense, grounded on the permanent interests of man as a progressive being.'[49] Mill submits that the idea of liberty originated with the necessity of protecting individuals from oppression by political leaders. While the power of political leaders is often formidable, protection of individuals from governmental power is not sufficient. Individuals need protection from the opinions and feelings of society which tends to impose views on individuals, impeding progress and individualism.[50] People tend to believe that their feelings on issues are more important than the reasons that they hold their views. Mill argues that:

> 'Society can and does execute its own mandates and if it issues wrong mandates, or any mandates at all in issues it shouldn't meddle in, it practises a social tyranny more formidable than many kinds of political oppression, since, though not usually upheld by extreme penalties, it leaves fewer means of escape, penetrating more deeply into details of life and enslaving the soul itself.'[51]

According to Mill, there are domains in which society has a limited interest, if any interest at all.[52] The first is the freedom of the individual to thought and opinion. Freedom of expression and the publication of opinions are inextricably linked to freedom of thought.[53] The second private domain is the freedom to plan one's own life, develop one's own character and live as one pleases, without harming others. The third domain is the freedom of groups of people to unite for any reasons, besides to harm others. Mill submits that without these basic liberties, a society cannot be free, stating that:

> 'No society in which these liberties are not, on the whole, respected, is free, whatever may be its form of government; and none is completely free in which they do not exist absolute and unqualified. The only freedom which deserves the name, is that of pursuing our own good in our

[47] Currie & De Wall note 43 op cit at 17.
[48] HH Wellington 'On Freedom of Expression' (1979) 88 *The Yale Law Journal* at 1121.
[49] Mill note 46 op cit at 14.
[50] Ibid at 8.
[51] Ibid.
[52] Ibid at 15.
[53] Ibid at 17.

> own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it.'[54]

The liberty of the individual is not absolute. In line with his utilitarian standpoint, Mill argues that the only justified reason for societal intervention in individual or group behaviour is self-protection. Thus, liberty can be limited when the individual's conduct causes harm,[55] or threatens to cause harm, as the 'case is taken out of the province of liberty, and placed in that of morality or law.'[56] However, in situations that concern only the individual, he should be free to express his opinion and act on them according to his own judgment. Individuality should be supreme in situations that do not concern others. Individuality is a key factor of human contentment and the main factor of progress. An individual's ability to create his own rules of conduct is one of the primary elements of human happiness and individual and societal progress. Liberty, especially in the context of scientific research, is of utmost importance. This is encapsulated in Mill's opinion that:

> 'Persons of genius, it is true, are, and are always likely to be, a small minority; but in order to have them, it is necessary to preserve the soil in which they grow. Genius can only breathe freely in an *atmosphere* of freedom.'[57]

A more contemporary author, Dworkin, states that the justifications for freedom of expression fall into one of two groups.[58] The first group is the protection of free speech instrumentally, because permitting individuals to freely express themselves contributes to society.[59] The second group protects freedom of expression not just because it makes a valuable contribution, but because it is 'an essential and "constitutive" feature of a just political society'[60] which treats citizens as 'responsible moral agents.'[61] Responsible moral agents demand to make their own decisions on right and wrong, and truth and falsity.[62] The censorship of opinions by an authority disregards the dignity of individuals by limiting their abilities to consider and decide upon an opinion themselves.[63] The responsible moral agent will not only have the responsibility to make decisions, 'but to express these to others, out of respect and concern for them, and out of a compelling desire that truth be known, justice served, and the

[54] Ibid at 16.
[55] Ibid at 56.
[56] Ibid at 82.
[57] Ibid at 65.
[58] Ronald Dworkin 'Why Must Speech Be Free?' in *Freedom's Law* (1996) 195–213 at 199.
[59] Ibid.
[60] Ibid.
[61] Ibid.
[62] Ibid.
[63] Ibid.

good secured.'[64] Government limitation on freedom of expression 'denies that aspect of moral personality.'[65]

Matisonn summarises the purposes of freedom of expression set out by Emerson as follows:

'i) developing individual self-fulfilment, intrinsic to the highly prized value of authenticity;

ii) advancing knowledge;

iii) discovering truth;

iv) strengthening the ability to participate in decision-making;

v) maintaining a stable community, reasonably balanced with social change through rational open decision-making processes, and balanced open discussion.'[66]

An important justification of liberty is the search for the truth. Mill states that people 'would be more likely to recognize truth if they were permitted to hear all available views, even those thought by many or most to be false.'[67] He views censorship as obstructing human advancement and the development of knowledge because of the fallibility of the censor.[68] The process of rational judgment to find the truth relies on the freedom to express all opinions. Emerson discusses the relevance of the term 'truth' as used by Mill, stating that 'truth' can be replaced with 'judgment' in today's society. This is because 'modern man may not agree with Mill's assumption that an objective truth exists,'[69] but freedom of expression is still a necessity for 'advancing knowledge and enabling an autonomous man to reach a considered decision.'[70]

Mill holds the view that people are fallible, so we can never be certain of the truth of a view or opinion.[71] To deny a person of the right to hear all sides of an issue is to 'equate one's own certainty with absolute certainty,'[72] and to deny that person of the chance to develop. This is why freedom of expression is important — even the most controversial views could hold an element of truth and the suppression of such views would rob society of this truth.[73] Although humans are prone to making mistakes, 'free discussion and argument tend to pry errors loose,

[64] Ibid.
[65] Ibid.
[66] Lynn Joy Matisonn 'Human Cloning: Separating Science from Fiction' (LLM thesis, University of Natal, 2002).
[67] Richard Moon *The Constitutional Protection of Freedom of Expression* (2000) 9.
[68] Ibid.
[69] TI Emerson 'Communication and Freedom of Expression' (1972) 227 *Scientific American* at 164.
[70] Ibid.
[71] Wendy Donner & Richard Fumerton *Mill* (2009) 59.
[72] KC O'Rourke *John Stuart Mill and Freedom of Expression* (2001) 108.
[73] Donner & Fumerton note 71 op cit at 59.

to expose them in the light of day.'[74] Reasonable individuals admit their fallibility, airing their views with the intention that others will challenge them, and only feel confident in views that survive such challenges.[75]

Mill argues that if a person is barred from expressing their opinion, they are not the only one affected.[76] The opponents of the opinion, and the current and future generation are too robbed, since they lose the opportunity for learning.[77] Even false opinions and views should not be stifled. This is because if the silenced opinion is correct, opponents are robbed of the occasion for their errors to be corrected.[78] Those who oppose the opinion may deny its truth and wish to suppress it, but they are not in the position to hold their opinions as universal and applicable to all mankind.[79]

Human beings have the ability of judgment and reasoning, and the withholding of free expression is in contradiction to this ability. If the silenced opinion is incorrect, the holder loses the opportunity to be imparted with a more accurate version of the truth which they will only obtain if their incorrect opinion is expressed and opposed.[80] In order to arrive at truth, individuals must be given the freedom to air their views and to contradict the views of others. Mill argues that rationality dominates mankind due to our ability to learn from our errors. Through experience and the exploration of different views, we are able to correct ourselves.[81] However, experience alone cannot completely achieve this learning. Discussion and public debate enhances 'the progress of public knowledge…through the synthesis of competing ideas.'[82] The truth can only be understood when it is decided upon through open debate between members of society. The consideration of competing ideas allows one to utilise reason to decide on what is true and false.[83]

Moon considers the limitations of Mill's argument, given that the reason of the general public cannot be relied upon indiscriminately in all contexts.[84] For this reason, freedom of expression cannot be absolute, and the costs of expression should be balanced with the possible

[74] Ibid.
[75] Ibid at 60.
[76] Mill note 46 op cit at 19.
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] Moon note 67 op cit at 9.
[83] Ibid at 10.
[84] Ibid.

benefit to the advancement of truth. Once we have arrived at truth, we might see a need to suppress further opposing ideas in order to protect it.[85]

Freedom of expression is further justified in the context of the welfare of individuals.[86] Mill argues that freedom of expression fosters individual development and self-fulfilment. In line with his view that in circumstances only related to the individual, individuality should reign, Mill argues that freedom to progress as an individual is a requirement for human well-being and a 'necessary part and condition'[87] of 'civilisation, instruction, education, culture.'[88] He quotes Wilhelm von Humboldt, who wrote, 'the end of man…is the highest and most harmonious development of his powers to a complete and consistent whole'[89] and that man must 'ceaselessly direct his efforts'[90] towards 'the individuality of power and development.'[91] Individuality develops with the ability to make one's own decisions and live as one pleases.[92] The development of each individual contributes to diversity within society as a whole. One cannot be independent without the freedom to consider all aspects of an issue, or all opinions on an issue, and make a decision based on their understanding of this. Freedom of thought cannot be as beneficial without the corresponding freedom of expression.[93]

Mill argues that as individuality develops, individual self-worth increases.[94] This in turn makes the individual more valuable to others and increases the number of valuable people in society.[95] Emerson echoes Mill's view that freedom of expression is a necessity for a person to develop their 'character and potential as a human being'[96] and a 'vital part of his being and becoming.'[97] He states that the honour and dignity of humans is infringed by limits on freedom of expression.[98] The dignity argument views freedom of expression as an inherent to individual autonomy.[99] As people choose their own paths in life they express their feelings and views and in doing this they 'realise their personality and find meaning within their world.'[100]

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[85] Ibid at 11.
[86] Ibid at 19.
[87] Mill note 46 op cit at 57.
[88] Ibid.
[89] Ibid at 58.
[90] Ibid.
[91] Ibid.
[92] O'Rourke note 72 op cit at 78.
[93] Ibid.
[94] Mill note 46 op cit at 59
[95] Ibid at 65.
[96] Emerson note 69 op cit at 163.
[97] Ibid at 163.
[98] Ibid at 164.
[99] J Weinrib 'What is the Purpose of Freedom of Expression' (2009) 67 *U Toronto Fac L* 165 at 177.
[100] Ibid.

Freedom of expression preserves the autonomy of both the person expressing their views and those receiving the information. If one limits the expression of a writer in order to prevent the reader from making a certain decision, the reader is robbed of their autonomy to use their reasoning and judgment to make choices.[101] The writer is robbed of their autonomy when they are not allowed to express views that they perceive to be valuable. This is because of the close link between communication and a person's feelings and ideas.[102] A person develops their feelings and ideas through communication with others. Individuals rely on the expression of their own ideas and the consideration of others' ideas to develop their ability to reason and make sound judgments.[103] Autonomy and individualism are 'core human virtues and excellences,'[104] the development of which requires freedom of expression. However, one must also consider autonomy and self-realisation outside of the context of individuals. The communication of feelings and ideas is 'a social process, something that takes place between individuals and within a community.'[105] Moon suggests that freedom of expression plays a role in ensuring autonomy, '[i]f by autonomy we mean a capacity to think, judge, and give direction to one's life and the ability to participate in collective governance.'[106] Further, freedom of expression ensures self-realisation, if self-realisation is the 'emergence of the individual as a conscious and feeling person.'[107] Thus, freedom of expression promotes autonomy and self-realisation because 'individual identity, thought, and feeling emerge in the social realm.'[108]

Mill justifies freedom of expression in that it enhances societal development. With reference to a society overcoming mediocrity, Mill states that 'the only unfailing and permanent source of improvement is liberty, since by it there are as many possible independent centres of improvement as there are individuals.'[109]

Perhaps the most cited purpose of freedom of expression is its aim to enable democracy by allowing all opinions to be heard.[110] The argument for democracy values freedom of expression as an underpinning of democracy.[111] If an authority is to govern on behalf of its citizens, those citizens must be able to 'freely express their preferences on matters of public

[101] Moon note 67 op cit at 19.
[102] Ibid.
[103] Ibid.
[104] Donner & Fumerton note 71 op cit at 58.
[105] Moon note 67 op cit at 21.
[106] Ibid.
[107] Ibid.
[108] Ibid.
[109] Mill note 46 op cit at 71.
[110] Ibid at 164.
[111] Weinrib note 99 op cit at 176.

importance.'[112] Freedom of expression is a requirement for the functioning of democratic government.[113] It acts as a limitation on the will of the majority in support of the principle that 'public issues shall be decided by universal suffrage.'[114] Democracy necessitates the aeration of different ideas on public issues.

The fourth purpose of freedom of expression is that it 'enables a society to find the proper balance between stability and change.'[115] It ensures that societal development does not become stagnant and enables transformation. It provides balance by enabling the analysis of hypotheses through discussion rather than through 'trial and error.'[116]

The purposes of freedom of expression identified in the literature provide a philosophical basis for the understanding of the right to freedom of scientific research. To complement the philosophical foundation of this analysis, the purposes of freedom of expression in terms of South African and foreign case law will be explored.

IV SOUTH AFRICAN CASE LAW

South African courts have recognised all of the justifications for freedom of expression set out by Mill and Emerson. In *Democratic Alliance v African National Congress*, Cameron J described freedom of expression as 'valuable both for its intrinsic importance and because it is instrumentally useful.'[117] Each of the justifications will be discussed in turn below.

(a) Democracy

In her majority decision in *South African National Defence Union v Minister of Defence,* O'Regan J held that '[f]reedom of expression lies at the heart of democracy.'[118] This has been

[112] Ibid.
[113] Moon note 67 op cit at 14.
[114] Mill note 46 op cit quoting Meiklejohn.
[115] Emerson note 69 op cit at 164.
[116] Ibid.
[117] *Democratic Alliance v African National Congress* [2015] ZACC 1, 2015 (2) SA 232 (CC) para 122.
[118] *South African National Defence Union v Minister Of Defence* [1999] ZACC 7, 1999 (4) SA 469 (CC) para 7.

confirmed by the CC in many cases since.[119] South Africa's historical landscape, with its aggressive governmental control over the thoughts, speech and actions of its citizens, makes freedom of expression fundamental to our Constitution.[120] The apartheid era brought with it governmental censorship of books, music and political activity, as well as the forcing of its views of morality on citizens.[121] Political and artistic expression were especially restricted.[122] These constraints 'were not only a denial of democracy itself, but also exacerbated the impact of the systemic violations of other fundamental human rights in South Africa'[123] and were inconsistent with a democracy which promotes openness. Considering this,

> '[i]t could actually be contended with much force that the public interest in the open marketplace of ideas is all the more important to us in this country because our democracy is not yet firmly established and must feel its way. Therefore, we should be particularly astute to outlaw any form of thought-control, however respectably dressed.'[124]

The right to freedom of expression is connected to the right to vote and participate as a candidate in elections.[125] These rights were withheld from the majority of South African citizens, which makes them crucial for South Africa now. The right to freedom of expression is indispensable to the fulfilment of these rights as '[a]n election without as much freedom to speak as is constitutionally permissible would be stunted and inefficient.'[126] Freedom of

[119] See *Masuku v South African Human Rights Commission obo South African Jewish Board of Deputies* [2018] ZASCA 180, 2019 (2) SA 194 (SCA) para 17; *NM v Smith* [2007] ZACC 6, 2007 (5) SA 250 (CC) para 66; *Le Roux v Dey* [2011] ZACC 4, 2011 (3) SA 274 (CC) para 47; *Print Media South Africa v Minister of Home Affairs* [2012] ZACC 22, 2012 (6) SA 443 (CC) para 93; *Islamic Unity Convention* supra note 45 para 26; *Qwelane v South African Human Rights Commission* [2019] ZASCA 167, 2020 (2) SA 124 (SCA) para 41; *South African Broadcasting Corporation Limited v National Director of Public Prosecutions* [2006] ZACC 15, 2007 (1) SA 523 (CC) para 119; *Mail and Guardian Media Ltd v Chipu NO* [2013] ZACC 32, 2013 (6) SA 367 (CC) para 50; *De Reuck v Director of Public Prosecutions (Witwatersrand Local Division)* [2003] ZACC 19, 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] ZACC 6, 2008 (5) SA 31 (CC) fn 34; *Dikoko v Mokhatla* [2006] ZACC 10, 2006 (6) SA 235 (CC) para 138; *Nova Property Group Holdings Ltd v Cobbett* [2016] ZASCA 63, 2016 (4) SA 317 (SCA) para 43; *The Citizen 1978 (Pty) Ltd v McBride* [2011] ZACC 11, 2011 (4) SA 191 (CC) para 141; *Phillips v Director of Public Prosecutions* [2003] ZACC 1, 2003 (3) SA 345 (CC) para 23.

[120] *S v Mamabolo* [2001] ZACC 17, 2001 (3) SA 409 (CC) para 37; *Le Roux v Dey* [2011] ZACC 4, 2011 (3) SA 274 (CC) para 47; *The Citizen 1978 (Pty) Ltd v McBride* [2011] ZACC 11, 2011 (4) SA 191 (CC) para 142; *Print Media South Africa v Minister of Home Affairs* [2012] ZACC 22, 2012 (6) SA 443 (CC) para 94; *Islamic Unity Convention* supra note 45 para 26; *Qwelane v South African Human Rights Commission* [2019] ZASCA 167, 2020 (2) SA 124 (SCA) para 41; *Phillips v Director of Public Prosecutions* [2003] ZACC 1, 2003 (3) SA 345 (CC) para 23.

[121] *Print Media South Africa v Minister of Home Affairs* [2012] ZACC 22, 2012 (6) SA 443 (CC) para 94.

[122] *Islamic Unity Convention* supra note 45 para 27.

[123] Ibid; *Johncom Media Investments Limited v M* [2009] ZACC 5, 2009 (4) SA 7 (CC) para 28.

[124] *S v Mamabolo* [2001] ZACC 17, 2001 (3) SA 409 (CC) para 37.

[125] *Democratic Alliance* supra note 117 para 124.

[126] Ibid.

expression is vital to the ability of citizens to make political decisions and to contribute to public life.[127]

Freedom of expression safeguards democracy 'by informing citizens, encouraging debate and enabling folly and misgovernance to be exposed.'[128] It is the 'lifeblood of democracy'[129] and serves to enlighten debate. Further, it can serve as a check against the abuse or misuse of public power, with citizens and the media being free to expose such wrongdoing. Freedom of expression allows citizens to be informed of the actions of government and to hold members of the government accountable.[130] The freedom of citizens 'to speak out, to educate, to sing and to protest, be it through waving posters or dancing, is an important tool to challenge discrimination, poverty and oppression.'[131]

Further, freedom of expression plays a role in the provision of open justice. The judicial process is a matter of public concern, so adjudication should be transparent.[132] This transparency ensures that the public is aware of what occurs in court so that 'people can discuss, endorse, criticise, applaud or castigate the conduct of their courts.'[133] Open discussion about the judicial process 'promotes impartiality, accessibility and effectiveness, three of the important aspirational attributes prescribed for the judiciary by the Constitution.'[134] This open discussion also acts as a constitutional check on the judiciary's exercise of public power.[135]

(b) Social Stability and Development

The Supreme Court of Appeal (SCA) in *National Media Ltd v Bogoshi* held that freedom of expression is essential for societal progress and the advancement of humankind.[136] It has been a basis of the development of western society.[137] The CC has acknowledged the function of freedom of expression in maintaining a balance between change and stability in society. Open discussion of the judicial process demonstrates that 'the legal process is preferable to

[127] *Khumalo v Holomisa* [2002] ZACC 12, 2002 (5) SA 401 (CC) para 21.
[128] *Masuku v South African Human Rights Commission obo South African Jewish Board of Deputies* [2018] ZASCA 180, 2019 (2) SA 194 (SCA).
[129] *Van Breda v Media 24 Limited; National Director of Public Prosecutions v Media 24 Limited* [2017] ZASCA 97, 2017 (2) SACR 491 (SCA) para 9 quoting *R v Secretary of State for the Home Department, Ex Parte* Simms [1999] 3 All ER 400; *Moyo v Minister of Police; Sonti v Minister of Police* [2019] ZACC 40, 2020 (1) BCLR 91 (CC) para 26.
[130] *Mthembi-Mahanyele v Mail & Guardian Ltd* [2004] ZASCA 67, 2004 (6) SA 329 (SCA) para 65.
[131] *Print Media South Africa* supra note 121 para 93.
[132] *S v Mamabolo* supra note 124 para 29.
[133] Ibid.
[134] Ibid.
[135] Ibid para 30.
[136] *National Media Ltd v Bogoshi* [1998] ZASCA 94, 1998 (4) SA 1196 (SCA) para 1208B.
[137] Ibid.

vengeance.'[138] It provides reassurance that there are rules and a reliable manner of their enforcement.[139]

(c) Individual Self-Fulfilment, Dignity and Autonomy

Freedom of expression has been justified by the significance it holds for the individual. It is an element of human dignity[140] and individual autonomy.[141] Individuals are encouraged to develop through the free sharing and discussion of opinions and viewpoints.[142] The right to freedom of expression, along with its connected rights such as the right to human dignity and the right to privacy, is nestled in the 'constitutional celebration of the possibility of morally autonomous human beings independently able to form opinions and act on them.'[143] The South African Constitution promotes moral autonomy.[144] A morally autonomous person will consider differing opinions and decide upon his own opinion, based on his own reasoning.[145] Without freedom of expression, this is impossible.[146] Freedom of expression defends individual moral agency by allowing people to form opinions freely.[147] We need to express ourselves 'to fulfil our capacity to be individually human.'[148] Free expression encourages individual self-fulfilment and is central to human development and human life.[149] The CC held that freedom of expression is a requirement for individuals' realisation of their potential without the influence of authority, and is 'foundational to each individual's empowerment to autonomous self-development.'[150] The development of a person's individuality, personality and humanity

[138] *S v Mamabolo* supra note 124 para 31.
[139] Ibid.
[140] *Khumalo* supra note 127 para 21; *Masuku* supra note 107 para 18.
[141] *Khumalo* supra note 127 para 21.
[142] *NM v Smith* [2007] ZACC 6, 2007 (5) SA 250 (CC) para 145.
[143] Ibid.
[144] Ibid.
[145] Ibid.
[146] Ibid para 146.
[147] *South African National Defence Union* supra note 118 para 7; *Masuku* supra note 128 para 17; *Islamic Unity Convention* supra note 45 para 26; *South African Broadcasting Corporation Limited v National Director of Public Prosecutions* [2006] ZACC 15, 2007 (1) SA 523 (CC) para 119; *Print Media South Africa* supra note 121 para 53.
[148] *Democratic Alliance* supra note 117 para 123.
[149] *Van Breda v Media 24 Limited; National Director of Public Prosecutions v Media 24 Limited* [2017] ZASCA 97, 2017 (2) SACR 491 (SCA) para 9 quoting *R v Secretary of State for the Home Department, Ex Parte* Simms [1999] 3 All ER 400 at 408.
[150] *Case v Minister of Safety and Security, Curtis v Minister of Safety and Security* [1996] ZACC 7, 1996 (3) SA 617 (CC) para 26.

is essential for human dignity.[151] In order to further this development and maintain human dignity, a person must be free — '[f]reedom and dignity are inseparably linked.'[152]

(d) Truth and Knowledge

The CC also recognised the 'truth-seeking' purpose of freedom of expression,[153] which aids in 'the search for the truth by both individuals and society generally'[154] and allows the truth to be revealed by promoting debate and exposure.[155] The CC echoed Mill's theory that if opinions deemed to be controversial or inappropriate are silenced by society, they cannot be proved wrong.[156] Thus free discussion 'enhances truth-finding and enables us to scrutinise political argument and deliberate social values.'[157] Truth is best found in a free marketplace of ideas.[158] The free marketplace of ideas is hugely important in a South African context as we are recovering from a past of suppression by government. All available information is necessary for the decision-making process.[159] Restriction on the spread of information

> 'may lead to the wrong government being elected, the wrong policies being adopted, the wrong people being appointed, corruption, dishonesty and incompetence not being exposed, wrong investments being made and a multitude of other undesirable consequences.'[160]

Authorities cannot decide which information should be supplied to the public, because even though 'false information will not benefit a society,'[161] there are likely to be errors in deciding what information is true and false.

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[151] *Ferreira v Levin NO; Vryenhoek v Powell NO* [1995] ZACC 13, 1996 (1) SA 984 (CC) para 49; *Shoprite Checkers (Pty) Limited v Member of the Executive Council for Economic Development, Environmental Affairs And Tourism, Eastern Cape* [2015] ZACC 23, 2015 (6) SA 125 (CC) para 44.
[152] *Ferreira v Levin NO; Vryenhoek v Powell NO* [1995] ZACC 13, 1996 (1) SA 984 (CC) para 49.
[153] *South African National Defence Union* supra note 118 para 7; *Masuku* supra note 128 para 17; *Democratic Alliance* supra note 117 para 122; *Van Breda v Media 24 Limited; National Director of Public Prosecutions v Media 24 Limited* [2017] ZASCA 97, 2017 (2) SACR 491 (SCA) para 9 quoting *R v Secretary of State for the Home Department, Ex Parte* Simms [1999] 3 All ER 400 at 408; *South African Broadcasting Corporation Limited v National Director of Public Prosecutions* [2006] ZACC 15, 2007 (1) SA 523 (CC) para 119.
[154] *Democratic Alliance* supra note 117 para 122.
[155] Ibid.
[156] Ibid; *Masuku* supra note 128 para 18.
[157] Ibid.
[158] *Case* supra note 150 para 26.
[159] *S v Hoho* [2008] ZASCA 98, 2009 (1) SACR 276 (SCA) para 29.
[160] Ibid.
[161] Ibid.

V FOREIGN CASE LAW

To supplement South African justifications of freedom of expression, American, Canadian, Indian, Kenyan and Zimbabwean judgments are considered. Foreign judgments refer to the purposes of freedom of expression set out above.[162]

The Zimbabwean CC in *In Re Munhumeso* identified four purposes of freedom of expression:

> '(i) it helps an individual to obtain self-fulfilment; (ii) it assists in the discovery of truth; (iii) it strengthens the capacity of an individual to participate in decision-making; (iv) it provides a mechanism by which it would be possible to establish a reasonable balance between stability and social change.'[163]

This list of purposes is referred to by other foreign judgments.[164] I discuss the judgments of foreign courts on each purpose in turn.

(a) Democracy

The necessity of freedom of expression to democracy has been recognised by courts in Canada[165] India,[166] Kenya,[167] the United States of America (USA)[168] and Zimbabwe.[169]

In the Indian SC matter of *Indibility Creative Pvt Ltd v Govt of West Bengal*, Chandrachud J referred to Dworkin's argument that the only legitimate way to enact laws is through a democratic process, which necessitates freedom of citizens to express their views on

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[162] *Ford v Quebec* [1988] 2 SCR 712 at 765.
[163] *In re Munhumeso* 1994 (1) ZLR 49 (S) at 130.
[164] See *Madzingo v Minister of Justice, Legal and Parliamentary Affairs* (2005) ZWSC 100; *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office* (2004) ZWSC 140; *Retrofit (PVT) LTD v PTC* 1995 (2) ZLR 199 (S); *Biti v Minister of Home Affairs* (2002) ZWSC 9 at 4; *Bennet Coleman v Union of India* 1973 SCR (2) 757; *The Secretary, Ministry of Information & Broadcasting v Cricket Association of Bengal* 1995 SCC (2) 161; *Indian Express Newspapers v Union of India* 1985 SCR (2) 287 para 12; Union of India v Jindal 2004 SCC 43.
[165] *Ford* supra note 162 at 765; *Thomson Newspapers Co v Canada (Attorney General)* [1998] 1 SCR 877 at 28.
[166] *Bennet Coleman v Union of India* 1973 SCR (2) 757; *Indibility Creative Pvt Ltd v Government of West Bengal* 2019 SCC OnLine SC 520 para 13; *Indian Express Newspapers v Union of India* 1985 SCR (2) 287 para 12; *In Re Ramlila Maidan Incident v Home Secretary* 2012 (2) SCALE 682 para 10; *Saxena v Hon'Ble The Chief Justice of India* 1996 SCALE (5) 233 at 15.
[167] *Okoiti v Attorney General* [2020] eKLR para 305; *Andama v Director of Public Prosecution* [2019] eKLR para 45; *Andare v Attorney General* [2016] eKLR para 83; *Alai v The Hon Attorney General* [2017] eKLR para 31; *Nairobi Law Monthly Company Limited v Kenya Electricity Generating Company* [2013] eKLR para 32; *Kahiu v CEO, Kenya Film Classification Board* [2018] eKLR para 62; *Okuta v Attorney General* [2017] eKLR at 5.
[168] *DeJonge v Oregon* 299 US 353 (1937) at 365.
[169] *Madanhire v Attorney General* (2014) ZWCC 2; *Mutambara v Attorney General* (2015) ZWCC 11; *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office* (2004) ZWSC 140; *Capital Radio v Broadcasting Authority of Zimbabwe* (2003) ZWSC 65; *Zimbabwe Lawyers for Human Rights v President of the Republic of Zimbabwe* (2003) ZWSC 12.

these laws.[170] In *Cyprian Andama v Director of Public Prosecution* the Kenyan High Court quoted the Canadian case of *Edmonton Journal v Alberta*, in which it was held that '*a democratic society cannot exist without that freedom to express new ideas and to put forward opinions about the functioning of public institutions.*'[171] In the same matter, Okwany J quoted from the Indian case of *Manika Ghandhi v Union of India* in which it was held that open discussion of public issues is necessary for an individual's ability to 'intelligently exercise his right of making a choice.'[172] Freedom of expression promotes 'well-informed and politically sophisticated electoral debate'[173] and ensures the circulation of the information and opinions which allow citizens to make the informed decisions that are essential to democracy.[174] The Zimbabwean CC referred to the South African case of *S v Hoho*, in which it was held that 'suppression of available information and of ideas can only be detrimental to the decision-making process of individuals.'[175] In order for citizens to make informed decisions, they must have access to all of the relevant knowledge and information.[176]

Freedom of expression ensures that individual members of society participate in the democratic system,[177] with expression that conflicts with underlying societal values also being worthy of protection.[178] Individual participation in decision-making should be promoted.[179] Free expression and debate 'provide an opportunity for citizens to know what their Government is doing, but also to contribute to it by voicing support or opposition.'[180] This is the only way in which citizens can make criticism known to government[181] and be empowered to publicly hold authorities accountable.[182]

The court in *Dejonge v Oregon* accepted the purpose of democracy, stating that free expression allows the government to hear and react to the views of society.[183] The court in

[170] *Indibility Creative Pvt Ltd v Government of West Bengal* 2019 SCC OnLine SC 520 para 14.
[171] *Andama v Director of Public Prosecution* [2019] eKLR para 45 quoting *Edmonton Journal v Alberta* [1989] 45 CRR 1 at 1336.
[172] Ibid para 46 quoting *Manika Ghandhi v Union of India* [1978] 2 SCR at 77.
[173] *Saxena v Hon'Ble The Chief Justice of India* 1996 SCALE (5) 233 at 14.
[174] *Okoiti v Attorney General* [2020] eKLR para 305; *Andama* supra note 171 para 46 quoting *Manika Ghandhi vs Union of India* [1978] 2 SCR at 77; *Retrofit (PVT) LTD v PTC* 1995 (2) ZLR 199 (S).
[175] *Madanhire v Attorney General* (2014) ZWCC 2 quoting *S v Hoho* supra note 159 para 29.
[176] *Bennet Coleman v Union of India* 1973 SCR (2) 757.
[177] *Ford* supra note 162 at 765.
[178] *R v Keegstra* [1990] 3 SCR 697 at 702.
[179] *Irwin Toy Ltd v Quebec (Attorney General)* [1989] 1 SCR 927 at 976.
[180] *Communications Commission of Kenya v Royal Media Services Limited* [2014] eKLR para 162.
[181] *Alai v The Hon Attorney General* [2017] eKLR para 31.
[182] *Okoiti v Attorney General* [2020] eKLR para 305; *Nairobi Law Monthly Company Limited v Kenya Electricity Generating Company* [2013] eKLR para 32.
[183] *DeJonge* supra note 168 at 365.

Stromberg v California expressed that ensuring that government responds to the wishes of its society is essential to the country.[184]

(b) Social Stability and Development

Freedom of expression promotes social stability by ensuring that 'the balance between stability and change in society'[185] is maintained. It is essential as it allows individuals to promote changes that will better their lives and their societies.[186] The court in *Retrofit v PTC* held that '[t]he experience of participation makes it easier for those whose views are rejected or criticised to accept and abide decisions reached through an open, objective and non-coercive process.'[187] This process necessitates the unfettered discussion of ideas and opinions.[188] Thus freedom of expression promotes peace and stability.

If free expression is restricted, this reduces the occurrence of rational debate, rendering society unable to adapt to change.[189] This is because freedom of expression allows citizens to peacefully communicate the changes they wish for.[190] This promotes stability and is 'an insurance against violent upheavals,'[191] allowing 'peaceful social transformation under rule of law.'[192]

(c) Individual Self-Fulfilment, Dignity and Autonomy

The benefits of freedom of expression for the individual have been acknowledged in foreign judgments. The United States (SC) in *Whitney v California* held that the people who won the USA's freedom and independence 'believed that the final end of the State was to make men free to develop their faculties.'[193] They believed freedom to be the 'secret of happiness, and courage to be the secret of liberty.'[194] In the USA case of *Bose Corp v Consumers Union* the court held that 'the freedom to speak one's mind is ... an aspect of individual liberty — and thus a good unto itself.'[195] It is a foundation of liberty and individuality.[196] The court in *Johar*

[184] *Stromberg v California* 283 US 359 (1931) at 369.
[185] *Ford* supra note 162 at 765.
[186] *Harper v Canada (Attorney General)* [2004] 1 SCR 827 at 841.
[187] *Retrofit (PVT) LTD v PTC* 1995 (2) ZLR 199 (S) at 11.
[188] Ibid.
[189] Ibid at 10.
[190] *Saxena* supra note 173 at 15.
[191] *The Secretary, Ministry of Information & Broadcasting v Cricket Association of Bengal* 1995 SCC (2) 161 para 192.
[192] *Saxena* supra note 173 at 14.
[193] *Whitney v California* 274 US 357 (1927).
[194] Ibid.
[195] *Bose Corp v Consumers Union* 466 US 485 (1984) at 503.
[196] *Okuta v Attorney General* [2017] eKLR at 6.

v Union of India quotes Mill, who states that self-expression is imperative, as the uniqueness of an individual is deeply important to them.[197] The Canadian SC in *Irwin Toy Ltd v Quebec (Attorney General)* held that freedom of expression allows self-actualisation of individuals.[198] In *Ford v Quebec* it was held that self-actualisation is not only important to those expressing themselves, but to their audience too.[199]

Kenyan courts have acknowledged the necessity of freedom of expression for individual progress and development.[200] The Indian SC summarised that freedom of expression enables self-expression, which allows self-fulfilment and the development of self-conscience.[201] Limitations on the right to freedom of expression 'are an infringement of an individual's autonomy or dignity — either as a speaker or a listener, or both.'[202]

(d) Truth and Knowledge

Canadian,[203] Indian,[204] Kenyan,[205] USA[206] and Zimbabwean[207] courts have applied the search for truth as a justification of freedom of expression. Mill's argument that the 'search for truth is the sine qua non of the freedoms of speech and press'[208] found its way into the USA SC in *Abrams v United States*.[209] Gressman points out that Brandeis J 'continued this "truth-seeking" dialogue in his concurrence' in the US case of *Whitney v California.*[210] In *Ford v Quebec* it was held that freedom of expression is necessary for the attainment of truth,[211] which is 'an inherently good activity.'[212] The court in *R v Secretary of State for the Home Department, Ex parte Simms* supported Mill's philosophy that freedom of expression provides a test of the truth on an examination of how widely certain ideas are accepted by society.[213] In the case of *Saxena v Hon'Ble The Chief Justice of India*, Ramaswamy J held that '[t]he end of the State is to secure

[197] *Johar v Union of India* 2018 10 SCC 1 para 1.
[198] *Irwin Toy Ltd* supra note 179.
[199] *Ford* supra note 162 at 765.
[200] *Nairobi Law Monthly Company Limited v Kenya Electricity Generating Company* [2013] eKLR para 32; *Okuta* supra note 196 at 5.
[201] *The Secretary, Ministry of Information & Broadcasting* supra note 191 para 34 & 44; *Saxena* supra note 173 at 14.
[202] *Indibility Creative* supra note 170 para 13.
[203] *Ford* supra note 162 at 765; *Irwin Toy Ltd* supra note 179 at 976.
[204] *Indibility Creative* supra note 170 para 13; *Bennet Coleman* supra note 176; *Saxena* supra note 173 at 15.
[205] *Okoiti v Attorney General* [2020] eKLR para 305; *Andare v Attorney General* [2016] eKLR para 83.
[206] *Bose Corp* supra note 195 at 502.
[207] *Retrofit* supra note 187 at 10.
[208] E Gressman 'Bicentennializing Freedom of Expression' (1990) *Seton Hall Law Review* 378 at 381.
[209] Ibid.
[210] *Whitney* supra note 193.
[211] *Ford* supra note 162 at 765.
[212] *Irwin Toy Ltd* supra note 179 at 976.
[213] *R v Secretary of State for the Home Department, Ex Parte* Simms [1999] 3 All ER 400 at 408.

the citizen's freedom to develop his faculties'[214] through freedom of expression in order to advance the discovery of truth and the fulfilment of human rights.[215] It promotes 'debates of social and moral issues,'[216] catalysing the spread of ideas which advances our discovery of truth.[217]

In the USA case *Abrams v United States,* Holmes J held that 'the ultimate good desired is better reached by free trade in ideas — that the best test of truth is the power of the thought to get itself accepted in the competition of the market.'[218] In the case of *Red Lion Broadcasting Co v Federal Communications Commission,*[219] the court held that the aim of the First Amendment (the freedom of expression clause) is to promote a free market of views so that truth may prevail.[220] This metaphor entails that free trade in opinions results in truth, while limits on freedom of expression hamper society's advancement toward truth.[221] The 'marketplace of ideas' justification of freedom of expression is a form of the truth argument and was referred to by Kenyan,[222] Indian[223] and Zimbabwean[224] courts.

In the Zimbabwean case of *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office*, freedom of expression was held to be important as '[k]nowledge is interwoven with the concept of man.'[225] A citizen should be granted the opportunity of

> 'knowing the elements of his environment, the intellectual and scientific achievements of his fellow men, the facts and the developments that affect or may affect his life and generally all those elements and facts which enable him not only to survive but also freely to develop his personality.'[226]

[214] *Saxena* supra note 173 at 14.
[215] Ibid.
[216] *The Secretary, Ministry of Information & Broadcasting* supra note 191 para 34 & 44.
[217] Ibid.
[218] *Abrams v United States* 250 US 616 (1919) at 630.
[219] *Red Lion Broadcasting Co Inc v FCC* 395 US 367 (1969).
[220] Ibid at 390.
[221] Weinrib note 99 op cit at 174.
[222] *Okoiti v Attorney General* [2020] eKLR para 305; *Andare v Attorney General* [2016] eKLR para 83.
[223] *Bennet Coleman* supra note 176; *Saxena* supra note 173 at 14.
[224] *Retrofit* supra note 187 at 10.
[225] *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office* (2004) ZWSC 140 quoting András Sajó *Rights of Access to the Media* (1995) at 3.
[226] Ibid.

VI APPLICATION TO THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH

The purposes of freedom of expression that have been set out will now be applied to the right to freedom of scientific research. The application of the purposes to freedom of scientific research will aid in understanding the scope and limitations of the right through limitations analysis in Chapter Four. The right to freedom of expression achieves certain purposes, namely; democracy, individual self-fulfilment, societal development and the search for the truth.

The achievement of freedom of expression's purposes of individual self-fulfilment, societal development and the search for the truth is supported by freedom of scientific research. Billingsley states that freedom of scientific research 'promotes the core values associated with freedom of expression,'[227] arguing that 'genuine scientific experimentation and research certainly embody'[228] the values of the attainment of truth and individual self-fulfilment.

In order to appreciate the necessity of scientific freedom, one must understand the importance of scientific research. On the importance of science, Thaldar states:

> 'The list of science's gifts to humanity is endless: anaesthetics, organ transplants, motorcars, information and communication technology — in short everything that differentiates us from our cave-dwelling ancestors.'[229]

(a) Individual Self-Fulfilment, Dignity and Autonomy

As held in *Ferreira*, '[f]reedom and dignity are inseparably linked.'[230] Freedom of scientific research is linked to dignity, both for scientists and society. Thaldar discusses dignity as a value and as an individual right, linking the right to freedom of scientific research to the right to human dignity.[231] He states that

> 'science is a principal contributor to the improvement of the human condition and enabler of greater individual autonomy and self-actualisation in society, and hence an essential promoter of human dignity.'[232]

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[227] B Billingsley & R Caulfield 'The Regulation of Science and the Charter of Rights: Would a Ban on Non-Reproductive Human Cloning Unjustifiably Violate Freedom of Expression' (2004) 29(2) *Queen's Law Journal* 647 at 661.
[228] Ibid at 662.
[229] D Jordaan *Medical Biotechnology Law in South Africa: A Human Rights Analysis of Selected Topics* (PhD thesis, University of Cape Town, 2012) at 68 [the author has since changed his surname to Thaldar.]
[230] *Ferreira* supra note 152 para 49.
[231] DW Jordaan 'Science versus anti-science: the law on pre-embryo experimentation' (2007) 124(3) *SALJ* 618 at 630 [the author has since changed his surname to Thaldar.]
[232] Jordaan note 229 op cit at 68.

Science has played an enormous role in human evolution. It is a good that promotes the advancement of knowledge and therefore the development of society. History has proven that science is a hugely important source of ideas and solutions. Science and technology have 'freed a significant portion of humanity from ignorance, poverty and disease.'[233] Smith supports this view through the argument that science is seen to be 'not only of overwhelming benefit to society, but… an essential attribute of human achievement and progress.'[234]

Therefore, conducting scientific research in a chosen field could be an individual scientist's 'path to obtaining self-fulfilment from a scientific, academic and intellectual context.'[235] The right to freedom of scientific research is part of self-fulfilment and autonomy of the individual at the level of the scientist and society as a whole, with the self-actualisation of individual scientists enabling the self-actualisation of members of society.[236] Thaldar states that 'the right to freedom of scientific research is the lifeblood of scientific progress and the *conditio sine qua non* for the continued improvement of the human condition.'[237]

Mill's statement that 'the only unfailing and permanent source of improvement is liberty, since by it there are as many possible independent centres of improvement as there are individuals'[238] can be applied to the freedom of the individual scientist to pursue research. This freedom would promote individual improvement and the progress of medicine, which are direct contributors to societal development.

Mill's justification that freedom of expression enhances societal development is also directly applicable to freedom of scientific research. Through the development of individual scientists, the field of science is advanced, which promotes technological and academic development of society as a whole. It is clear that freedom of scientific research enables self-actualisation of individuals and improves society, in line with Mill and Emerson's justifications of freedom of expression.

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[233] G Corbellini 'Scientists, Bioethics and Democracy: The Italian Case and Its Meanings' (2007) 33(6) *Journal of Medical Ethics* 349 at 351.
[234] GP, II Smith 'Biotechnology and the Law: Social Responsibility or Freedom of Scientific Inquiry' (1988) 39 *Mercer Law Review* 437 at 440.
[235] JA Singh 'Freedom of Expression: The Constitutionality of a Ban on Human Cloning in the Context of a Scientist's Guaranteed Right to Freedom of Scientific Research' (1999) 62(4) *Tydskrif vir Hedendaagse Romeins–Hollandse Reg (Journal for Contemporary Roman–Dutch Law)* 577 at 582.
[236] Jordaan note 229 op cit at 67.
[237] Jordaan note 231 op cit at 632.
[238] Mill note 46 op cit at 71.

Knowledge of the natural world 'facilitates human survival and individual and collective achievement in the world.'[239] Thus, freedom of scientific research promotes individual self-fulfilment and human development.

Freedom of scientific research fosters individual self-fulfilment and development. The individual scientist, given freedom of scientific research, is free to seek progress and individuality within his profession. With this progress and development of individuality comes self-worth and self-fulfilment of individual scientists. This is valuable to society, given that self-fulfilled scientists are more likely to produce scientific data.

(b) Truth and Knowledge

As 'science is the search for truths about the natural world,'[240] freedom of scientific research is 'generally approved by society as necessary for the advancement of knowledge from which society may benefit.'[241]

Lederberg points out that there is 'an age-old impulse to control "dangerous knowledge"'[242] — 'rampant technology'[243] can be associated with 'social ills and change in every sphere.'[244] For example, the Cold War and climate change are considered to be results of science and technology. However, science's contributions to society are far greater than its dangers. Thus, against the backdrop of suspicion and control, 'the dispassionate search for truth through science became a counterrevolution.'[245]

On the importance of the freedom of science to truth and knowledge, Beiter quotes Edwin G Conklin: 'The increase and diffusion of knowledge depend entirely upon freedom to search, experiment, criticise, proclaim. Without these freedoms, there can be no science.'[246]

In the same manner that freedom of expression protects the sharing of opinions and information, freedom of scientific research protects the ability of scientists to conduct research and publicise the results thereof. This allows free criticism of the study by other scientists.

[239] Billingsley note 227 op cit at 662.
[240] J Lederberg 'The Freedoms and the Control of Science: Notes from the Ivory Tower' (1972) 45 *Southern California Law Review* 596 at 599.
[241] JT Edsall (1975) 'Scientific Freedom and Responsibility A Report of the AAAS Committee on Scientific Freedom and Responsibility' available at *https://www.aaas.org/sites/default/files/SRHRL/PDF/1975–ScientificFreedomResponsibility.pdf*, accessed on 1 September 2019 at 5.
[242] Lederberg note 240 op cit at 596.
[243] Ibid at 597.
[244] Ibid.
[245] Ibid.
[246] Beiter note 34 op cit at 235.

Lederberg states that for science, an 'essential freedom which must be assured is the open exposure of new knowledge'[247] and that the critique of technology and science should be by 'a whole community of critical experts.'[248] Philosophers, including Mill and Popper, have recognised that 'mutual criticism'[249] is essential. Mutual criticism ensures that scientific findings are valid and reliable, or scientifically true. This allows society 'to hear all available views,'[250] or access all scientific publications and arguments. Free publication, access and criticism of scientific research 'tend to pry errors loose, to expose them in the light of day.'[251] Mankind is dominated by rationality, as argued by Mill, because we learn from our mistakes. Science is an embodiment of this human characteristic. Freedom of scientific research is a core aspect of knowledge advancement, creating 'optimal conditions for our collective search for knowledge.'[252] As held in *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office,* '[k]nowledge is interwoven with the concept of man.'[253] If citizens are to access knowledge, scientific research must be free in order to discover and distribute scientific knowledge.

Wilholt adapts Mill's 'truth-seeking' argument to apply it to freedom of scientific research, stating that scientists need freedom to choose their research topics and their methods so that the different choices will result in a diverse range of approaches and topics, some of which will 'lead to new knowledge.'[254]

One of the arguments utilised against DNA research is that some knowledge is better left unknown. Singer responds to this argument in three points.[255] First, the world is very competitive, and there is no way to ensure that other states will also prohibit the research. This would mean that the knowledge would be attained and spread by other nations. Secondly, he argues that banning research creates the image that the truth is being hidden from the public. Thirdly, a ban on certain kinds of research would impede solution development.[256] Metzger supports this view, stating that there is 'no such thing as dangerous knowledge.'[257] It is further

[247] Lederberg note 240 op cit at 601.
[248] Ibid.
[249] T Wilholt 'Scientific Freedom: Its Grounds and Their Limitations' (2010) 41 Studies in History and Philosophy of Science 174 at 5.
[250] Moon note 67 op cit at 9.
[251] Ibid.
[252] Ibid at 3.
[253] *Association of Independent Journalists v Minister of State for Information and Publicity in the President's Office* (2004) ZWSC 140 quoting András Sajó *Rights of Access to the Media* (1995) at 3.
[254] Wilholt note 249 op cit at 4.
[255] P Singer 'Ethics and the Limits of Scientific Freedom' (1996) 79(2) *The Monist* 218.
[256] Ibid at 219.
[257] WP Metzger 'Academic Freedom and Scientific Freedom' (1978) 107(2) *Daedalus* 93 at 103.

supported by Lederberg (as quoted by Selya): 'the suppression of scientists is a far greater threat than the attempted perpetration of bad science.'[258] It is not the duty of scientists to ensure that the knowledge attained by them is not used for evil purposes, it is the duty of society.[259]

VII CONCLUSION

The right to freedom of expression protects certain public goods, namely democracy, individual self-fulfilment, societal development and the search for the truth. The promotion of these public goods is recognised as justification for freedom of expression in classical and contemporary literature and in South African, American, Canadian, Indian, Kenyan and Zimbabwean courts. Freedom of scientific research is a core aspect of achieving the public goods of individual self-fulfilment and the search for truth protected by freedom of expression. The rights aim to protect mutual goods and achieve mutual purposes. Understanding the purposes of the right to freedom of scientific research will assist in the case study in Chapter Four.

[258] R Selya 'Defending Scientific Freedom and Democracy: The Genetics Society of America's Response to Lysenko' (2012) 45(3) *Journal of the History of Biology* 415 at 432.
[259] GP II Smith 'The Province and Function of Law, Science and Medicine: Leeways of Choice and Patterns of Discourse' (1987) 10 *UNSW Law Journal* 103.

CHAPTER FOUR:

LIMITING THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH: THE CASE OF RESEARCH PARTICIPANT CONSENT

I INTRODUCTION

In this chapter I consider the extent to which consent by human research participants can be a limitation on the right to freedom of scientific research. I begin by considering the existing South African legal framework surrounding consent, focusing on the provisions of the Protection of Personal Information Act 4 of 2013 (POPIA) regarding specific consent. I then analyse proposed developments regarding consent in the context of genetic research. For this section I utilise the report published by the Academy of Science of South Africa (ASSAf), entitled *Human genetics and genomics in South Africa: Ethical, legal and social implications,* ('the Report') as an example of such proposed developments. Finally, I embark on a justification analysis, first analysing consent in terms of POPIA, and then consent in terms of the recommendations of the Report, as limitations on the right to freedom of scientific research.

Before jumping into the substance of this chapter, it is important to clarify that informed consent is generally, in principle, considered to be a justified limitation on the right to freedom of scientific research. Its justification is evident in the purpose that it serves — informed consent recognises the respect-for-persons principle, which considers individuals as autonomous agents.[1] It is underpinned by interests in bodily integrity,[2] individual autonomy and well-being,[3] and facilitates autonomous decision-making.[4] Informed consent is a 'requirement to foster the best interests of research subjects.'[5] Further, it is 'a means of reducing inequalities of knowledge and power in the researcher-subject relationship.'[6] This can be

[1] RJ Levine 'Informed Consent in Research and Practice: Similarities and Differences' (1983) 143 *Archives of Internal Medicine* 1229 at 1229.
[2] Jessica W Berg, Paul S Appelbaum & Charles W Lidz et al *Informed Consent: Legal Theory and Clinic Practice* 2 ed (2001) 11.
[3] Ibid at 14.
[4] MM Hammami, EA Ak-Gaai & Y Al-Jawarneh et al 'Patients' perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred' (2014) 15(2) *BMC Medical Ethics* 1 at 2.
[5] BH Gray 'Complexities of Informed Consent' (1978) 437 *Annals of the American Academy of Political and Social Science* 37 at 45.
[6] Berg et al note 2 op cit at 279.

observed in its history — informed consent emerged as a departure from beneficent paternalism in response to the Nuremberg Trials[7] and the cases of abuse of human subjects in the United States of America.[8] It was developed as a method to ensure that individuals are able to exercise autonomous decision-making to protect themselves from abuses by unscrupulous researchers and practitioners.[9] Thus, the requirement of informed consent protects personal individual decision-making and promotes respect for individual autonomy.

Individual autonomy is also promoted by the right to privacy. The right to privacy may be interpreted as binding others to 'abstain from interference with one's intended course in life.'[10] Faden and Beauchamp argue that 'some forms of intimate personal decision-making similar to those addressed by informed consent requirements…are protected by the constitutional right to privacy.'[11] The right to privacy allows individuals to choose what information they wish to disclose, as does informed consent in research.[12] Thus, informed consent in research is a prerequisite for the protection of the individual's right to privacy.[13] In its respect of individual decision-making, informed consent promotes individual interests in privacy, autonomy and bodily integrity.[14] The protection of these invaluable individual rights strikes a balance which justifies the limitations that informed consent places on the right to freedom of scientific research. Having clarified this chapter's position on informed consent, the next section is an exploration of the existing legal framework of consent in South Africa, and how exactly the right to freedom of scientific freedom is delimited by consent requirements.

II CONSENT IN TERMS OF SOUTH AFRICAN LAW

In this section I pinpoint the provisions relating to consent in South African legislation. Included in this discussion are the National Health Act 61 of 2003 and its regulations, the ethics

[7] The Nuremberg Code was developed as a result of the Nuremberg War Crimes Trials, where the ghastly conduct of Nazi physicians and researchers was revealed.
[8] From the 1930s until the 1970s, hundreds of African American men, who were misled to believe they were being treated, were experimented on for research on untreated syphilis. The practitioners and researchers did not inform the men of the syphilis treatments that were available. The men had not given informed consent as they were not provided with sufficient information to make informed decisions. This unethical experiment was brought to an end in 1972; Berg et al note 2 op cit at 20.
[9] Berg et al note 2 op cit at 20.
[10] Ruth R Faden & Tom L Beauchamp *A History and Theory of Informed Consent* (1986) 7.
[11] Ibid at 40.
[12] Ibid.
[13] Ibid at 21.
[14] Ibid at 173 quoting OM Ruebhausen & OG Brim, Jr 'Privacy and Behavioral Research' (1966) 21 *American Psychologist* 423; Berg et al note 2 op cit at 11 & 14; Hammami et al note 4 op cit at 2.

guidelines of the Health Professions Council of South Africa and the Department of Health, the South African Material Transfer Agreement and POPIA. I focus specifically on POPIA, comparing it to the the General Data Protection Regulation. This discussion aims to synopsise the South African position on consent and highlight the requirements that researchers must adhere to in this regard.

(a) The National Health Act and its Regulations Relating to Research with Human Participants

The National Health Act (NHA) requires informed consent for research. It allows the conduct of research on human beings only 'with the 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.'[15] The NHA's Regulations Relating to Research with Human Participants echo this requirement,[16] providing a list of the information that must be explained to participants in order for their consent to qualify as informed consent.[17] Among other things, participants must be informed of the purpose[18] and the methods[19] of the research, as well as the potential risks involved in participation.[20]

Neither the NHA nor its Regulations distinguish between the different types of consent or explicitly recommend specific consent, nor prohibit blanket consent. However, it can be argued that these pieces of legislation impliedly prohibit blanket consent in their requirement that research participants must be informed of the 'objects' or 'purposes' of the research.[21] In this light, tiered consent cannot include an option to consent to all forms of research, but broad consent appears to be acceptable in as far as different studies can have the same purpose.[22]

(b) Health Professions Council of South Africa guidelines

The Health Professions Council of South Africa (HPCSA) *General Ethical Guidelines for Health Researchers* (HPCSA guidelines) provide that, in obtaining informed consent, researchers must provide research participants with information in a manner which enables

[15] S 71(1)*(b)*, National Health Act 61 of 2003 (NHA).
[16] Reg 5, Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014.
[17] Reg 5(a)–(n), ibid.
[18] Reg 5(a), ibid.
[19] Reg 5(b), ibid.
[20] Reg 5(d), ibid.
[21] Footnote forthcoming (DW Thaldar & BA Townsend 'Exempting health research from the consent provisions of the South African Protection of Personal Information Act' (2020)) provisional page 6.
[22] Ibid.

understanding, taking into consideration the participants' home language and literacy levels.[23] Researchers must provide enough information 'about the nature and effect of the research — in particular the effect of the research on the participants including its consequences, risks and benefits — to enable them to make an informed choice about their participation.'[24] Similarly, the HPCSA's *General Ethical Guidelines for Biotechnology Research in South Africa* state that in order for consent to be informed, the participant must be notified of and must understand, inter alia,[25] the aims, risks and benefits of the research.[26] While neither of these guidelines suggest one type of consent, both of them impliedly prohibit blanket consent in their requirements that the aim and nature of the research be provided to the participants. Further, it appears that dynamic consent is supported by the HPCSA's guidelines in that it is stated that 'the consent process should be reinforced during the trial.'[27]

(c) National Department of Health Ethics Guidelines

The Department of Health's (DoH) *Ethics in Health Research: Principles, Processes and Structures* (DoH guidelines), as pointed out by Thaldar and Townsend, are legally binding on researchers.[28] The Regulations Relating to Research with Human Participants require health research to 'comply with the Department of Health national ethical guidelines for research with human participants at a minimum.'[29] This gives the DoH guidelines the force of law at a secondary legislation level.[30]

The DoH guidelines require informed consent, as necessitated by the principle of respect-for-persons.[31] In order for consent to be informed, the guidelines hold that participants must be informed of certain matters such as the purpose and method of the research, the possible risks involved and the respective responsibilities of the researcher and the participants.[32] The

[23] 6.3.5, Health Professions Council of South Africa (HPCSA) 'Booklet 13: General ethical guidelines for health researchers' in *Guidelines for Good Practice in the Health Care Professions* (2008) available at *https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf*, accessed on 30 September 2020.
[24] 6.3.1, ibid.
[25] 2.6.4.1(a)–(t), HPCSA 'Booklet 14: General Ethical Guidelines for Biotechnology Research in South Africa' in *Guidelines for Good Practice in the Health Care Professions* (2008) available at *https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf*, accessed on 30 September 2020.
[26] 2.6.4, ibid.
[27] 6.3.9, HPCSA note 23 op cit.
[28] National Department of Health 'Ethics in Health Research: Principles, Processes and Structures' (2015) available at *https://www.ul.ac.za/research/application/downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf*, accessed on 29 September 2020; Thaldar & Townsend note 21 op cit.
[29] Reg 2(a), note 16 op cit.
[30] Thaldar & Townsend note 21 op cit.
[31] 3.1.9, National Department of Health note 28 op cit.
[32] Ibid.

information provided must be of a suitable nature and quality — the DoH guidelines require informed consent forms to be written clearly and jargon-free.[33] Before requesting a decision regarding participation, researchers must allow time for prospective participants to consult with family members or their communities.[34]

In line with this recognition of communal decision-making, the DoH guidelines state that in conducting research on 'collectivities,' researchers must request permission from the representatives of the collectivity to approach individuals, as well as informed consent from each individual participant.[35] The DoH guidelines define a collectivity as a group which is distinguishable from other communities and groups by

- 'common beliefs, values, social structures and other features that identify them as a separate group
- customary collective decision-making according to tradition and beliefs
- the custom that leaders express a collective view
- members of the collectivity being aware of common activities and common interests.'[36]

It is not clarified, however, whether the above distinguishing criteria must all be present, or if just one can be present, to classify a community as a collectivity. The DoH guidelines classify research as involving a collectivity where

- 'property or information private to the group as a whole is studied or used
- permission of people occupying positions of authority, whether formal or informal, is required
- participation of members acknowledged as representatives is involved.'[37]

There is no indication of whether all three of these conditions, or only one, is required in order to classify research as involving a collectivity. The DoH guidelines require research involving collectivities to implement certain measures to ensure, among other things, that representatives grant permission for researchers to approach individuals, an informed consent process for each individual and 'respectful negotiation with the collectivity or its leaders.'[38]

[33] Ibid.
[34] Ibid.
[35] 3.2.9 ibid.
[36] Ibid.
[37] Ibid.
[38] Ibid.

The DoH guidelines define specific, tiered and broad consent. Specific consent is referred to as 'narrow (restrictive) consent,'[39] and is defined as consent where 'the donor permits use of the biological specimen for single use only; no storage of leftover specimen; and no sharing of data or specimen.'[40] Tiered consent is defined as consent where the 'donor provides consent for the primary study and chooses whether to permit storage for future use, sample and data sharing.'[41] Broad consent is defined as the permission of the donor for 'use of the specimen for current research, for storage and possible research purposes, even though the precise nature of future research may be unclear at present.'[42] In the case of broad consent, any possible future research must be described in as much detail as is possible. The DoH guidelines remind research ethics committees that the H3Africa Initiative recommends that, as secondary use of data promotes the advancement of health, consent should be broad enough to ensure secondary use.[43] Thaldar and Townsend point out that the DoH guidelines were 'strongly influenced'[44] by H3Africa, 'as is evident from an explicit endorsement and a dozen references throughout the document.'[45] However, they argue that, as H3Africa does not have a democratic mandate in South Africa, it is inappropriate for South African authorities to have allowed themselves to be influenced by H3Africa's recommendations.[46] The point is: While H3Africa's recommendation that consent should be broad enough to allow for secondary use is obviously in the interest of the research consortia represented by H3Africa, is this recommendation truly in the interests of South African research participants?

Secondary use of stored samples for research raises a dilemma concerning the re-consent of research participants with regard to secondary use of materials.[47] The DoH guidelines recommend that, in the absence of broad consent, the initial consent should be considered to determine whether the secondary use falls within its scope.[48] If it does not, new consent is required. New consent is not required in cases where the samples are anonymous, and where the research results would pose no risk to participants.[49] Further, new consent is not required

[39] 3.3.6, ibid.
[40] Ibid.
[41] Ibid.
[42] Ibid.
[43] Ibid.
[44] Thaldar & Townsend note 21 op cit at 6.
[45] Ibid.
[46] BA Townsend & DW Thaldar 'Navigating uncharted waters: Biobanks and informational privacy in South Africa' (2020) 35(4) *SAJHR* 329 at 339.
[47] 3.3.7, National Department of Health note 28 op cit.
[48] Ibid.
[49] Ibid.

where identifiers are not provided to the researchers who will make secondary use of the data, and where the research results would pose no risk to participants.[50]

Although the DoH guidelines do not define dynamic consent, they seem to lean in this direction as it is stated that informed consent must be 'affirmed during the course of the study, as part of the commitment to an ongoing consent process.'[51] The DoH guidelines do not require a certain type of consent, but recommend against the use of blanket consent. Thus, specific, tiered, dynamic and broad consent are acceptable in terms of the DoH guidelines. The DoH guidelines also provide conditions to allow exemption from consent requirements for research purposes.

(d) South African Material Transfer Agreement

The South African Material Transfer Agreement (the SA MTA) defines informed consent as a formal agreement that the donor permits the donation of materials[52] 'after being informed about the project.'[53] The term 'project' is defined as 'the health research project for which the Materials will be used,'[54] but there is no elucidation concerning how specifically defined the project should be. However, as the transfer of materials is only allowed in relation to a project that has been approved by a health research ethics committee,[55] it can be presumed that a definition of a project specific enough to be approved by a health research ethics committee is sufficient.

Support of dynamic consent is displayed in that the SA MTA states that informed consent '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…'[56] Researchers must also obtain informed consent for secondary use 'where reasonably possible.'[57] Further, the researcher who provides data or materials for secondary use must 'inform the Donor of developments or progress made by the Recipient in the Project and which is relevant to the Donor(s) Informed Consent.'[58] As pointed out by Labuschaigne et al, '[t]his is specific to secondary uses related to the research project for which the materials will be used

[50] Ibid.
[51] 2.3.6, ibid.
[52] 2.13, Material Transfer Agreement for Human Biological Materials in GN 719 GG 41781 of 20 July 2018 (MTA).
[53] 2.12, ibid.
[54] 2.15, ibid.
[55] 3.2, ibid.
[56] 2.12, ibid.
[57] 4.3, ibid.
[58] 10.4, ibid.

in accordance with the conditions stipulated in the SA MTA. This clause does not include the secondary use of materials in perpetuity.'[59] The SA MTA's apparent support of dynamic consent is in conflict with the Department of Health's Ethics Guidelines, which state that consent should be broad enough to allow for secondary use.[60] In cases involving the transfer of materials, the SA MTA, as a more recent piece of legislation, takes precedence over the Department of Health's ethics guidelines.

(e) Protection of Personal Information Act 4 of 2013

POPIA aims to promote the right to privacy by implementing justifiable limitations to information processing which balance the right to privacy with other rights, such as the right of access to information.[61] Thaldar and Townsend note that POPIA's stricter data protection is more aligned to the GDPR than the previous legal framework.[62] POPIA provides conditions for the processing of personal information, namely; accountability, processing limitation, purpose specification, further processing limitation, information quality, openness, security safeguards and data subject participation. In the following discussion I focus on the processing limitation, purpose specification and further processing limitation conditions.

Before analysing POPIA's position on informed consent, some definitions must be considered. 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.'[63] An important aspect of this definition is the use of the word 'specific' — POPIA clearly requires specific consent. This has been questioned by some,[64] while others have argued that a purposive interpretation of POPIA allows for broad consent.[65] Thaldar and Townsend argue that a purposive interpretation does not allow the word 'specific' to be replaced with the word 'broad.'[66] This is because a purposive interpretation must be considerate of the original wording of legislation.[67] POPIA defines personal information as 'relating to an identifiable,

[59] M Labuschaigne, A Dhai & S Mahomed et al 'Protecting participants in health research: The South African Material Transfer Agreement' (2009) 109(5) *SAMJ* 353 at 355.
[60] 3.3.6, National Department of Health note 28 op cit.
[61] S 2(a)*(i)*, Protection of Personal Information Act 4 of 2013 (POPIA).
[62] Townsend & Thaldar note 46 op cit at 330.
[63] S 1, POPIA note 61 op cit.
[64] Academy of Science of South Africa (ASSAf) 'Human genetics and genomics in South Africa: Ethical, legal and social implications. Pretoria' (2018) available at *http://dx.doi.org/10.17159/assaf.2018/0033* at 11 R6(d).
[65] 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) *SAMJ* 468.
[66] Thaldar & Townsend note 21 op cit at 7.
[67] Ibid.

living, natural person, and where it is applicable, an identifiable, existing juristic person.'[68] This includes the biometric information of the person, which is classed as special personal information.[69] Biometric information is information attainable through 'a technique of personal identification that is based on physical, physiological or behavioural characterisation including blood typing, fingerprinting, DNA analysis, retinal scanning and voice recognition.'[70] Processing is 'any operation or activity or any set of operations, whether or not by automatic means, concerning personal information,'[71] and includes, among other things, the collection, storage and dissemination of information. Having considered the relevant definitions, the following is an overview of the three relevant conditions.

The processing limitation condition[72] requires a legal ground for the processing of personal information.[73] For research purposes, the legal ground required is specific consent from participants.[74] Actions such as collection of data, recording a DNA analysis of a sample donated by a participant, storage of information, the conduct of research on such information and the sharing of information must be specifically consented to by the participant.[75] This process is more burdensome on researchers than the previous position where participants could give broad consent for all of these actions.[76]

The purpose specification condition[77] applies to the collection and storage of personal information.[78] Collection must occur for a 'specific, explicitly defined and lawful purpose.'[79] Information must not be stored for longer than is necessary to achieve the purpose for which it was collected,[80] however, the storage of information for research purposes is allowed if the researcher has taken appropriate safeguards to ensure the privacy of the information.[81]

[68] S 1, POPIA note 62 op cit.
[69] Ibid.
[70] S 26(a), ibid.
[71] S 1, ibid.
[72] S 9–12, ibid.
[73] Thaldar & Townsend note 21 op cit at 12.
[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] S 13–14, POPIA note 61 op cit.
[78] Thaldar & Townsend note 21 op cit at 12.
[79] S 13–14, POPIA note 61 op cit.
[80] S 14(1), ibid.
[81] S 14(2), ibid; Thaldar & Townsend note 21 op cit at 13.

The further processing limitation condition[82] entails that further processing of information must be compatible with the purpose for which the information was collected.[83] The further processing is deemed to be compatible with the original purpose if it is for historical, statistical or research purposes, but identifiable information may not be published.[84] If the original collection was obtained using broad or tiered consent, it was not collected for a specific, explicitly defined and lawful purpose.[85] This implies that further processing of this type of information would be unlawful.[86]

POPIA prohibits the processing of special personal information,[87] but includes exemptions for research purposes. For research purposes, processing of special personal information is allowed if (i) the processing is necessary for a purpose which serves a public interest, or (ii) obtaining consent would be impossible or 'would involve a disproportionate effort'[88] and safeguards are implemented to ensure that the data subject's privacy is not disproportionately affected.[89] The processing of personal information concerning inherited characteristics is prohibited,[90] as is the processing of the personal information of a child.[91] However, similar to the prohibition on the processing of special personal information, both of these prohibitions are accompanied by exemptions for processing for the purpose of research.[92] In the case of processing of the personal information of a child, processing for research purposes (i) 'must be necessary for a purpose which serves a public interest,'[93] or (ii) obtaining consent would be impossible or 'would involve a disproportionate effort,' and safeguards must be implemented to ensure that the data subject's privacy is not disproportionately affected.[94] The Information Regulator is empowered to grant exemptions from adherence to any of the conditions of processing.[95] In order to grant such an exemption, the Regulator must be satisfied that

[82] S 15, POPIA note 61 op cit.
[83] Thaldar & Townsend note 21 op cit at 13; This is similar to the recommendation of the DoH Guidelines in 3.3.7, National Department of Health note 28 op cit.
[84] S 15(3)*(e)*, POPIA note 61 op cit; Thaldar & Townsend note 21 op cit at 13.
[85] Thaldar & Townsend note 21 op cit at 13.
[86] Ibid.
[87] S 26, POPIA note 61 op cit.
[88] S 27(1)*(d)*(i) & (ii), ibid.
[89] Ibid.
[90] S 32(5), ibid.
[91] S 34, ibid.
[92] S 34(b) & s 35(1)*(d)*(i), ibid.
[93] S 35(1)*(d)*(i), ibid.
[94] S 35(1)*(d)*(ii), ibid.
[95] S 37(1), ibid.

'(a) the public interest in the processing outweighs, to a substantial degree, any interference with the privacy of the data subject that could result from such processing; or

(b) the processing involves a clear benefit to the data subject or a third party that outweighs, to a substantial degree, any interference with the privacy of the data subject or third party that could result from such processing.'[96]

In terms of the above, the public interest includes, among other things, 'historical, statistical or research activity.'[97] Thaldar and Townsend argue that while this exemption

> 'would clearly assist health researchers over the first hurdle to qualify for an exemption, the second hurdle still poses a significant challenge, namely that such public interest must, when balanced against the privacy interest of the data subject, be found to outweigh the individuals' privacy interest to a *substantial* degree. This suggests that mere inconvenience (or lack of expediency) to the researcher of complying with the existing conditions will not suffice as a reason for granting an exemption.'[98]

The research community has expressed apprehensions regarding the specific informed consent required by POPIA.[99] The worry is that this may

> 'drastically restrict and impede information-based medical and genetic research utilising aggregated datasets housed in biobanks or databanks — to uphold ethical ideals of data protection at the expense of practicality and expediency.'[100]

Thaldar and Townsend contemplate whether 'specific, informed consent has appropriate application in the collection and use of human biological material and related data for research.'[101] Less restrictive access to data for secondary use is more affordable and allows genetic and genomic data to be used to its full potential in research.[102] Some advocate for less restrictive or even no consent requirements in the context of Big Data.[103] However, Thaldar and Townsend conclude that these arguments overlook the foundations of informed consent — autonomy and privacy rights.[104] The Report states that arguments against informed consent which are based on the financial and logistical difficulties of reconsenting participants are

[96] S 37(1)*(a)–(b)*, ibid.
[97] S 37(2)*(e)*, ibid. Interestingly, s 37(2)*(f)* includes the interest in freedom of expression as a public interest.
[98] Thaldar & Townsend note 21 op cit at 14.
[99] Townsend & Thaldar note 46 op cit at 330.
[100] Ibid.
[101] Ibid at 336.
[102] Ibid.
[103] Ibid.
[104] Ibid at 337.

'somewhat expedient'[105] and 'avoid addressing the main reason for informed consent which is to respect the autonomy of persons.'[106]

Broad consent limits the control that participants have over their data, while specific consent 'ensures a greater degree of control by participants, who are capable of making individual choices and decisions as autonomous agents with regard to their specific data usage.'[107] The right to privacy is weightier than issues such as finances and convenience for researchers.[108] Constitutional rights should always take precedence over such considerations.[109]

There are convincing arguments for the higher standards of privacy in relation to genetic data.[110] For example, '[a] participant's genetic data present highly sensitive information regarding their traits, genetic conditions and pre-dispositions to certain diseases.'[111] Disclosure of this information could lead to stigmatisation and discrimination.[112] This information could have consequences for the participants' families and communities.[113] Further, due to possible secondary use, it is uncertain as to what may be discovered or gained from the data at a later stage.[114] The protection of privacy rights in terms of POPIA can contribute to the improvement of research programmes and the promotion of research participation.[115] POPIA may also promote a relationship of trust between researchers and participants by protecting privacy rights.[116] This in turn boosts participation in research.[117]

In summary, POPIA requires specific consent.[118] Processing of information must be justified by a legal ground which, in the case of research, is specific consent.[119] Collection of information must be for a specific purpose and storage of that information must be no longer than is necessary to achieve that purpose.[120] There is an exemption for the storage limitation

[105] ASSAf note 64 op cit at 50.
[106] Ibid.
[107] Townsend & Thaldar note 46 op cit at 337.
[108] Ibid.
[109] Ibid at 339.
[110] Ibid at 335.
[111] Ibid.
[112] Ibid.
[113] Ibid.
[114] Ibid.
[115] AER Prince 'Comprehensive Protection of Genetic Information — One Size Privacy of Property Models May Not Fit All' (2013) 79(1) *Brooklyn Law Review* 175 at 218.
[116] Townsend & Thaldar note 46 op cit at 334.
[117] Ibid.
[118] S 1, POPIA note 61 op cit, which defines consent as 'any voluntary, specific and informed expression of will.'
[119] S 9–12, ibid; Thaldar & Townsend note 21 op cit at 12.
[120] S 13–14, POPIA note 61 op cit.

for research purposes if the information is sufficiently protected.[121] Secondary use, or further processing, is allowed if the purpose of the secondary use is compatible with the purposes of the initial collection.[122] An exemption is granted for research purposes if certain conditions are met.[123] The processing of special personal information, information concerning inherited characteristics and the information of children are prohibited, but exemptions are granted for research if certain conditions are met.[124] POPIA prohibits the processing of special personal information,[125] but includes exemptions for research purposes.

(f) Comparative snapshot with the General Data Protection Regulation

The General Data Protection Regulation (GDPR) aims to protect the rights and freedoms of individuals, particularly the right to protection of personal data.[126] It calls for a balance of the right to the protection of personal data and the right to freedom of expression, including academic expression.[127] Consent is defined as a 'freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data…'[128]

Similar to POPIA, the GDPR provides principles for the processing of personal data, namely; lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality and accountability. I focus on the purpose and storage limitations, which are similar to POPIA's further processing limitation and purpose specification conditions.

The purpose limitation requires the processing of personal data to be lawful, fair and transparent.[129] Personal data must be collected for 'specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.'[130] Researchers find exemption in that further processing for research purposes will be deemed compatible with the initial purpose of collection.[131] Unlike POPIA, the GDPR contains an exemption from the requirement of specific consent for scientific research.[132] This exemption is given since it 'is

[121] S 14(2), ibid.
[122] S 15, ibid.
[123] S 15(3)*(e)*, ibid.
[124] S 27 & s 35, ibid.
[125] S 26, ibid.
[126] Art 1(2), EU General Data Protection Regulation 2016/679 (GDPR).
[127] Art 85(1), ibid.
[128] Art 4(11), ibid.
[129] Art 5(1)*(a)*, ibid.
[130] Art 5(1)*(b)*, ibid.
[131] Ibid.
[132] Art 33, ibid.

often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection.'[133] Thus, data subjects may consent to 'certain areas of scientific research when in keeping with recognised ethical standards for scientific research.'[134] They should be allowed to consent to the processing of their data only in specific parts of the research or research projects.[135] Thus, the GDPR exempts researchers from the specific consent requirement.

The storage limitation, which limits storage to the length of time necessary to achieve the purpose for which the data was collected, holds an exception for the storage of personal data solely for research purposes.[136] For research purposes, personal data may be stored for longer periods, subject to the application of appropriate safeguards to protect data subjects.[137]

The GDPR categorises certain types of personal data as 'special.'[138] This includes data which reveals 'racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership,'[139] as well as genetic and biometric data and 'data concerning health or data concerning a natural person's sex life or sexual orientation.'[140] The processing of such data is prohibited,[141] but an exemption exists for processing for research purposes, provided that there are measures implemented to protect the data subject.[142]

The GDPR enables its Member States to provide exemptions for the processing of personal data for research purposes.[143] Member States may allow for derogation from certain rights of the data subject,[144] subject to safeguards and only if the rights are 'likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.'[145]

The similarities between the GDPR's purpose and storage limitations and POPIA's further processing limitation and purpose specification conditions are clear. This supports the

[133] Ibid.
[134] Ibid.
[135] Ibid.
[136] Art 5(1)*(e)*, ibid.
[137] Ibid.
[138] Art 9(1), ibid.
[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] Art 9(2)*(j)*, ibid.
[143] Art 89(2), ibid.
[144] Including the right to access in terms of art 15, the right to rectification in terms of art 16, the right to restriction of processing in terms of art 18 and the right to data portability in terms of art 20. The right to the right to erasure in terms of art 17 and the right to object in terms of art 21 are not included.
[145] Art 89(2), GDPR note 126 op cit.

argument that POPIA situates itself closer to European privacy standards than the previous legal framework.

III PROPOSED DEVELOPMENTS REGARDING CONSENT

I utilise the ASSAf Report as an example of proposed developments regarding consent and research as it is the most recent multidisciplinary report regarding the implications of genetic research and technologies. As indicated by the Report, there is no South African legislation *specifically* pertaining to genetics and genomics, which leaves these fields, in the view of the authors of the Report, unregulated.[146] The Report aims to provide suitable recommendations concerning policy development in the spheres of genetics and genomics. It purports to consider the ethical, legal and social issues surrounding genetics and genomics in research, healthcare and forensics contexts. These deliberations are largely based on the philosophical approaches of Ubuntu and communitarianism, which are discussed further below. The Report makes recommendations and proposes developments regarding the requirement of consent and Ubuntu in the genetics and genomics context, which are analysed below.

(a) Ubuntu and consent

The Report grounds its recommendations in the philosophical approach of Ubuntu,[147] and is guided by human dignity, respect, equity and distributive justice.[148] It recommends the promotion of Ubuntu in genetics and genomics research.[149] It considers historical approaches to genetic research, indicating that autonomy, privacy, equity and justice, along with Western philosophical theories were adopted in traditional approaches.[150] Western philosophical approaches such as liberal individualism and principalism were foremost and were promoted in ethics guidelines.[151] This brought about obligations towards individualised consent processes and individual rights.[152] The Report goes on to state that, 'genetics and genomics, by definition, involve families, communities and population groups: a genetic disease affects an entire family, not just an individual.'[153] As genetic diagnoses have repercussions for families and communities, 'responsibilities and duties to family members, communities and even

[146] ASSAf note 64 op cit at 20.
[147] Ibid at 9.
[148] Ibid at 17.
[149] Ibid at 66 R5(a).
[150] Ibid at 24.
[151] Ibid.
[152] Ibid.
[153] Ibid. This view is supported by Prince note 115 op cit at 187.

population groups become as important as responsibilities to individuals.'[154] Thus, the Report argues, a communal approach is 'both relevant and applicable'[155] to ethical considerations in genetics and genomics. The Report looks 'through the Ubuntu lens'[156] in its interpretation of respect for persons.

Respect for persons, in Western thought, has a focus on individual autonomy and self-determination, which influenced the development of individualised consent procedures.[157] The Report argues that bioethicists have already reconsidered the paramount position of the individual in ethical considerations.[158] This argument is in reference to an article published by Knoppers and Chadwick in 2006.[159] Knoppers and Chadwick argue that

> 'the understanding of the complexity of genetic factors in common diseases and of the familial and socio-economic impact of genetic information and genetic tests, together with the concomitant expansion of public participation in policy making, have given rise to new trends in ethics.'[160]

The authors consider the question of whether individual rights are paramount in the context of focusing on communal, rather than individual, gain.[161] Reciprocity, mutuality, solidarity, citizenry and universality are named as the new ethics trends which have emerged.[162] The authors argue that these trends signify 'a move away from autonomy as the ultimate arbiter'[163] and a recognition of the importance of participation.[164]

The Report considers the common good approach as 'an emerging trend in bioethics.'[165] Along with this approach, ethical norms such as mutuality, solidarity and citizenry have begun to develop.[166] The common good approach is compared to African philosophy.[167] While each African country is comprised of a richly diverse population, there are similarities between each culture.[168] The Report quotes Murove, who states that these similarities are 'a belief in

[154] ASSAf note 64 op cit at 24.
[155] Ibid.
[156] Ibid at 41.
[157] Ibid.
[158] Ibid at 24.
[159] BM Knoppers & R Chadwick 'Human Genetic Research: Emerging Trends in Ethics' (2006) IV(3) *The Journal of Lifelong Learning in Psychiatry* 416.
[160] Ibid at 416.
[161] Ibid.
[162] Ibid.
[163] Ibid.
[164] Ibid.
[165] ASSAf note 64 op cit at 24.
[166] Ibid.
[167] Ibid at 25.
[168] Ibid.

ancestors, an understanding of an individual as communally constituted, and a relational world view.'[169] Another similarity, which seems to exist under different names in many African countries and communities, is the concept of Ubuntu.[170]

Ubuntu plays a central role in African philosophy.[171] It 'represents notions of universal human interdependence, solidarity and communalism'[172] and embodies many values such as respect, morality and dignity.[173] The Report describes Ubuntu as 'a philosophical notion that refers to the essence or quality of being human.'[174] It holds that in 'an African context, the self only makes sense in relation to the community,'[175] or in the words of Dolamo, '[i]ndividuals cannot survive outside of their respective communities in as much as fish cannot survive outside water.'[176]

The Report supports Metz's argument that research, specifically in genetics and genomics, should be guided by an Ubuntu philosophical approach.[177] This approach promotes secondary use and sharing for research purposes, but also insists on consent for collection and secondary use, 'otherwise, by Ubuntu, there would be a failure of donors and researchers to share in a way of life.'[178] There must be reciprocity — participant and community interests, especially in well-being, must be furthered in some way by the sharing and secondary use of their samples.[179] Reciprocity necessitates the consideration of ensuring that participants and their communities receive benefits, such as 'using the results of research to influence health policy, with the aim of improving health care for and well-being of community members'[180] or the provision of 'more tangible benefits.'[181] The Report recommends the promotion of reciprocal relationships between researchers and the community involved in research, suggesting the utilisation of meetings and a participatory approach to achieve this.[182] There

[169] Ibid quoting Munyaradzi Felix Murove 'African Bioethics: An exploratory discourse' in Murove (ed) *African ethics: An anthology of comparative and applied ethics* (2009) 157.
[170] Ibid at 25.
[171] Ibid.
[172] Ibid quoting Christopher Roederer & Darrel Moellendorf *Jurisprudence* (2004) at 441.
[173] Ibid.
[174] Ibid at 9.
[175] Ibid at 17.
[176] Ibid at 26 quoting R Dolamo 'Botho/Ubuntu: the heart of African ethics' (2013) 112(1) *International Journal of Bible, Religion and Theology in Southern Africa* 1.
[177] Ibid referring to T Metz 'African and Western moral theories in a bioethical context' (2010) 10(1) *Developing World Bioethics* 49.
[178] Ibid at 26.
[179] Ibid.
[180] Ibid at 27.
[181] Ibid.
[182] Ibid at 38 R1(b).

should be an objective evaluation mechanism in place to ensure the success of these deliberations.[183]

According to the Report, community engagement is essential, as well as benefit sharing and the building of trusting, non-exploitative relationships between participants, communities and researchers.[184] The Report recommends that researchers engage with the community involved in research and the public at large separately.[185] The dignity of the community and community structures should be promoted.[186] A researcher engaging with a community aims to develop trust with potential participants and their community.[187] The public is provided with information about the technologies involved in the research with 'a view to promoting acceptance and use of the new technologies. This engagement should however not be coercive in nature.'[188] Other aims of community engagement are the involvement of the community in the design of the research study[189] and the determination of local relevance of the research.[190]

The Report makes two recommendations based on its discussion of Ubuntu. First, that Ubuntu must be promoted in research.[191] Secondly, Ubuntu and autonomy must be viewed as complementary, and 'all fundamental rights should be understood within the matrix of the community.'[192] The heavy reliance of the Report on the concept of Ubuntu necessitates a clear and understandable definition of the term. Thaldar et al suggest that the Report fails to provide such a definition, and argue that 'the lack of specificity in terms of which the ASSAf Report interprets Ubuntu is problematic,'[193] asserting that as a result, the Report 'offers a vague and confused vision for bioscience in South Africa'.[194] Pepper et al[195] replied to Thaldar et al's critique but did not find it necessary to expand on or clarify the concept of Ubuntu in the Report.

The Report's version of Ubuntu focuses on the reliance of the individual on the community in its use of definitions such as the individual '*cannot survive* outside of their

[183] Ibid at 38 R1(c).
[184] Ibid at 26.
[185] Ibid at 38 R1(a).
[186] Ibid at 27.
[187] Ibid at 31.
[188] Ibid.
[189] Ibid.
[190] Ibid at 32.
[191] Ibid at 11 R5(a).
[192] Ibid at 11 R5(b).
[193] D Thaldar, J Kinderlerer & S Soni 'An optimistic vision for biosciences in South Africa: A response to the ASSAf report on human genetics and genomics' (2019) 115(7/8) *S Afr J Sci* available at *https://doi.org/10.17159/ sajs.2019/6146.*
[194] Ibid.
[195] MS Pepper, C Dandara & J De Vries et al 'An optimistic vision for biosciences in South Africa: Reply to Thaldar et al' (2019) 115(7/8) *S Afr J Sci* available at *https://doi.org/10.17159/sajs.2019/a0312.*

respective communities'[196] (emphasis added) and that 'the self *only makes sense* in relation to the community.'[197] (emphasis added) Shozi argues that 'it is both disingenuous and a gross oversimplification'[198] to state that community is always paramount in African ethics.[199] Communitarianism does not imply that the community's interests are a paramount consideration to the interests of the individuals within the community.[200] Shozi refers to Kaphagawani, who argues that communitarianism is not 'a denial of the recognition of the individual human being qua individual.'[201] Individuals are viewed as having an identity which is distinct from the community.[202] While weight is given to the community, humans are not *only* seen as part of a community, in other words, 'the communal relations one has do not account for the entirety of their being.'[203] Gyekye argues that it is an exaggeration to project onto the community moral authority over individuals.[204] Ubuntu recognises the importance of individuality to healthy communal relationships.[205] Gyekye argues that communitarianism may be misconstrued as conceiving

> 'the person as *wholly* constituted by social relationships; that it tends to whittle down the moral autonomy of the person; that it makes the being and life of the individual totally dependent on the activities, values, projects, practices and ends of the community; and consequently, that it diminishes his/her freedom and capability to choose or question or re-evaluate the shared values of the community.'[206]

It is important to consider that while people are communal, they are 'by nature other things as well (i.e. a person possesses other essential attributes.)'[207] If this is not appreciated, the nature of an individual's communality may be exaggerated, 'investing the community with an all-engulfing moral authority to determine all things about the life of the individual person.'[208]

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[196] ASSAf note 64 op cit at 26 quoting R Dolamo 'Botho/Ubuntu: the heart of African ethics' (2013) 112(1) *International Journal of Bible, Religion and Theology in Southern Africa* 1.
[197] ASSAf note 64 op cit at 17.
[198] Footnote forthcoming (B Shozi 'An Afrocentric to Approach to Genome Editing: A South African Approach to Balancing Conflicts between Individual Rights and Public Opinion' (2020)).
[199] Ibid.
[200] Ibid.
[201] Ibid.
[202] Ibid.
[203] Ibid.
[204] Ibid.
[205] Ibid.
[206] Kwame Gyekye 'Person and Community in African Thought' in PH Coetzee & APJ Roux (eds) *Philosophy from Africa: A Text with Readings* 2 ed (2003) 297–312 at 298.
[207] Ibid at 301.
[208] Ibid.

The definitions of Ubuntu adopted by the Report imply an approach of radical communitarianism. Radical communitarians would view individuals as existing 'to serve the communal good, thus all that is ethically permissible is that which serves the interests of the community.'[209] This is in contrast to moderate communitarianism, which views individuals as autonomous while recognising their communality,[210] and where community interests are only prioritised when an individual's decisions threaten important communal goals.[211]

Having discussed the Report's conception of Ubuntu, I move on to discuss its views on informed consent. The Report argues that the informed consent requirements in genetics and genomics research are the same as those in other technically complex research.[212] The principles concerning privacy and confidentiality too are similar, but 'must be balanced by a mechanism for traceability should an actionable incidental finding arise.'[213] The Report refers to specific consent as '[t]he most restrictive model of consent'[214] as no secondary use may occur without reconsenting participants.

The Report supports the idea of dynamic consent, stating that it is important that 'continuous contact with communities from which individuals are recruited'[215] is maintained. This contact would allow researchers to keep participants informed of possible secondary use during the long-term storage process.[216] Dynamic consent models may be useful for genetic and genomic research.[217] The Report suggests that dynamic consent could be appropriate for genetic and genomic research due to constant developments in technology and the possibility of new discoveries long after consent was obtained.[218] Dynamic consent allows participants to maintain control of their samples and data through ongoing communication with researchers.[219] It necessitates 'continuous re-contacting of donors, to provide 'real-time' information about specific research projects and to seek consent to use their samples and data in each new research study.'[220] The Report, and some academics,[221] express doubts that dynamic consent would work in a South African context as it requires electronic communication methods such as social

[209] Shozi note 198 op cit.
[210] Ibid.
[211] Ibid; Gyekye note 206 op cit at 312.
[212] ASSAf note 64 op cit at 46.
[213] Ibid.
[214] Ibid at 50.
[215] Ibid at 46.
[216] Ibid.
[217] Townsend & Thaldar note 46 op cit at 348.
[218] ASSAf note 64 op cit at 43.
[219] Townsend & Thaldar note 46 op cit at 348.
[220] ASSAf note 64 op cit at 53.
[221] Thaldar & Townsend note 21 op cit at 3.

media or e-mail in order to re-contact participants.[222] However, Thaldar and Townsend argue that dynamic consent is possible without the use of such technologies, suggesting text messaging and physical meetings as other methods of contacting participants.[223]

The Report defines informed consent as a 'process by which a patient/research participant learns about and understands the purpose, benefits, and potential risks of a medical, surgical intervention and research study, and then agrees to receive the treatment or participate in the study.'[224] However, the Report later argues that informed consent has a 'dual nature… being individuality versus communitarian in the South African population,'[225] implying that researchers must consult with both the individual participants and their communities.[226] The Report acknowledges that individual consent is always required, even where community consent is required.[227] In doing so, the Report acknowledges that the requirement of community consent must exist above and beyond the requirement of individual consent. This is clearly an extension of the requirements included in the legislation explored above, none of which require community consent in general.

It is interesting to note that, notwithstanding its focus on research on communities and Ubuntu, the Report does not even mention the provisions regarding research on collectivities in the DoH guidelines.[228] Further, the Report states that the DoH guidelines

> 'permit researchers and RECs to use the consent model that is appropriate for the context of a study. Thus, the specific consent, tiered consent or broad consent models may be chosen to optimise collection, storage and re-use of samples and data.'[229]

However, the DoH guidelines are subordinate to POPIA, which rules out the use of broad consent. The Report acknowledges the fact that POPIA requires specific consent but does not mention the exemptions for research purposes.[230] It recommends that the DoH guidelines 'that permit broad, tiered and specific consent models should be fully implemented.'[231] It adds the disclaimer that '[t]he panel recognises however that there is lack of consensus regarding the

[222] ASSAf note 64 op cit at 53.
[223] Thaldar & Townsend note 21 op cit at 3.
[224] ASSAf note 64 op cit at 4.
[225] Ibid at 46.
[226] Ibid.
[227] ASSAf note 64 op cit at 25.
[228] 3.2.9, National Department of Health note 28 op cit.
[229] ASSAf note 64 op cit at 54.
[230] Ibid at 50.
[231] Ibid at 66 R6(d).

impact of the POPI Act (No 4 of 2013) on broad consent, and that the situation may change once clarity is obtained from the Regulator.'[232]

Having explored the recommendations and discussions of the Report on Ubuntu and consent, I summarise the key points. The Report recommends the promotion of Ubuntu in genetics and genomics research based on the argument that familial and communal nature of genetic information makes a communal approach relevant and applicable. [233] The respect-for-persons principle is viewed in context of Ubuntu.[234] The Report takes a radical approach towards Ubuntu, defining individuals as wholly dependent on their communities. Reciprocity, which is important in the context of Ubuntu, necessitates the receipt of benefits by research participants.[235] Reciprocity necessitates community engagement, which the Report recommends should be undertaken with the community involved in the research and the public.[236] Community engagement should not be of a coercive nature.[237] The Report holds that the approach of community engagement in which the community is involved in the design of the research study is 'appealing for genomics research in South Africa.'[238]

Finally, the Report recommends that Ubuntu and autonomy be viewed as complementary, and 'all fundamental rights should be understood within the matrix of the community.'[239] The Report argues that informed consent is both individual and communitarian in South Africa.[240] It acknowledges that individual consent is still a requirement on top of community consent.[241]

(b) Excursus: Public ownership, benefit sharing

Genetic research raises questions surrounding the ownership and custodianship of samples and data. In South African law there remains no regulation of these issues with specific reference to genes or genetic information. The NHA and its Regulations Relating to Research with Human Participants, and POPIA, do not regulate these issues. The SA MTA provides that, in the context of material transfer, the donor of materials remains the owner until the destruction

[232] Ibid.
[233] Ibid at 66 R5(a).
[234] Ibid at 41.
[235] Ibid at 27.
[236] Ibid at 38 R1(a).
[237] Ibid at 31.
[238] Ibid.
[239] Ibid at 11 R5(b).
[240] Ibid at 46.
[241] Ibid at 25.

of the materials occurs.[242] The provider who is responsible for the transfer remains the custodian[243] of the materials even once they are in the possession of the recipient. The DoH guidelines suggest that, when conducting research with collectivities, researchers must ensure that agreement is reached about the ownership of data, but do not suggest how this should be regulated.[244] The Regulations Relating to Artificial Fertilisation of Persons provide clarity regarding the ownership of gametes, zygotes and embryos.[245] Ownership of gametes donated by a male donor resides with the institution which removed the gamete until such time as the institution that intends to use the gamete for artificial fertilisation receives the gametes. Thereafter, this institution becomes the owner.[246] When a male donates gametes for the purpose of artificial fertilisation of his spouse, he retains ownership.[247] When a female donates gametes for the purpose of artificial fertilisation of any recipient, the donor retains ownership.[248] After artificial fertilisation occurs, the recipient is owner of the gametes.[249] The Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes state that any person who receives any tissue or gametes in terms of the NHA and the provisions of the Regulations shall 'acquire exclusive rights in respect thereof.'[250] Mahesh argues that this 'portrays a sense of exclusive property rights from donor to donee, the latter being a researcher, doctor, or research institute, for example.'[251] The conundrum of ownership of genetic data is elucidated by Montgomery, who states that

> 'I cannot easily claim on this basis that I am entitled to treat my genomic information as "belonging" to me because it was given to me rather than created by me. First, what have I *done* to deserve it? Although there is scope for argument and for some divergence, the principles of intellectual property law generally deny the patentability of naturally occurring things on the basis that no intellectual capital has been invested in them. Second, what have *I* done to deserve it? Perhaps my parents created my genome, by contributing the constituent

[242] 3.3, MTA note 52 op cit.
[243] 'Custodian' means 'a person or entity entrusted by the Donor with safeguarding and protecting the Materials.' in 2.6, MTA note 52 op cit.
[244] 3.2.9, Regulations Relating to Research with Human Participants note 16 op cit.
[245] R18, Regulations Relating to Artificial Fertilisation of Persons in GN 174 GG 35099 of 2 March 2012.
[246] R18(1)(a), ibid.
[247] R18(1)(b), ibid.
[248] R18(1)(c), ibid.
[249] R18(2), ibid.
[250] R26, Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes in GN 180 GG 35099 of March 2012.
[251] KP Mahesh 'Laws and regulations associated with ownership of human biological material in South Africa' (2015) 8(1) *S Afr J BL* 1112.

> materials, but the idea that children should be treated as parental property seems grotesque in the modern world.'[252]

The Report argues that in South African law, biological samples are not seen as property,[253] which supports the argument that 'genomic resources should be a common good, i.e. public property which is outside of commerce and thus not open to private ownership.'[254] I argue that the provisions of the SA MTA, the guidelines, the Regulations Relating to Artificial Fertilisation of Persons and the Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes imply that ownership of biological samples is in fact supported in our law.

Montgomery states that public property 'can be used by everyone without exclusion and exhaustion,'[255] for example, air is public property as its availability to one does not exclude its availability to others.[256] He goes on to argue that the human genome is

> 'an example of such a public good. Understanding it as public property explains why it is legitimate for states to take steps to preserve it and to protect its value. Understanding it as public property enables its value to be secured for all and not appropriated by a private owner who then permits access to others only at a price.'[257]

The Report argues that Ubuntu would consider genomic resources as public property.[258] Thus, the State would govern samples and data, and control their use and reuse with 'representative input from donors.'[259] The Report argues that State custodianship of 'natural resources in the form of water and of mineral resources'[260] already occurs in South Africa and that exploitation and fair access are managed by governance systems.[261] Similarly, Montgomery argues that public ownership of genetic information 'recognises obligations of stewardship to preserve and make productive use of the property without limiting the ability to secure a just distribution of the benefits.'[262] Thaldar et al challenge this position, stating that the use of the comparison between genetic data and water or minerals 'is not only flawed, but

[252] J Montgomery 'Data Sharing and the Idea of Ownership' (2017) 23(1) *The New Bioethics* 81 at 83.
[253] ASSAf note 64 op cit at 85.
[254] Ibid.
[255] Montgomery note 252 op cit at 84.
[256] Ibid.
[257] Ibid.
[258] ASSAf note 64 op cit at 27.
[259] Ibid at 85.
[260] Ibid.
[261] Ibid.
[262] Montgomery note 252 op cit at 85.

dangerous.'[263] The recommended state control of genetic information diminishes the rights to privacy and human dignity in that it 'reduces the individual to a mere carrier or container of a state-controlled resource.'[264] Pepper et al responded to these challenges, explaining that as consensus was not reached on this particular issue, the Report had to include the different views.[265] The authors draw attention to recommendation 12 of the Report, which suggests that the issue of ownership of samples must be considered in the adaptation of the 'sociologically informed model.'[266] Pepper et al state that this is their 'balanced consensus view on this complex topic.'[267] It seems that consensus was reached, however, in the statement that '[o]ur view would be to apply the principle of "custodianship" or "DNA on loan" and to avoid the notion of ownership.'[268] The 'DNA on Loan' model, which originated in the context of genomics research involving Canadian aboriginal people, allows donors to control the use and reuse of their information.[269] If researchers intend to share the information or reuse the information, they must approach the community, which makes a decision on the individuals' behalf.[270] The Report argues that this model is appropriate in a South African context.[271] However, I argue that the concept of allowing a community to make decisions regarding the use of an individual's personal, genetic information displays a disregard for individual autonomy and privacy. This recommendation by the Report appears to be a *shortcut to obtaining consent for the reuse of individuals' genetic information without having to approach the relevant individuals*. The authors call for robust discussion of the issues emanating from ownership of samples and data, including benefit sharing.[272] While the authors of the Report did not commit to the view that genetic information should be regarded as public property in terms of Ubuntu, it is a view which must be discussed.

First, the confusion created by the Report must be pointed out. The Report is of the view that genetic data may not be considered to be property.[273] However, it then argues that in the context of the conception of Ubuntu that it promotes, genetic data would be considered as public *property*.[274] Perhaps what the Report had in mind was that genetic data is property which

[263] Thaldar et al note 193 op cit.
[264] Ibid.
[265] Pepper et al note 195 op cit.
[266] ASSAf note 64 op cit at 85.
[267] Pepper et al note 195 op cit.
[268] ASSAf note 64 op cit at 86.
[269] Ibid at 74.
[270] Ibid.
[271] Ibid.
[272] Ibid at 86.
[273] Ibid at 85.
[274] Ibid at 27.

should not be commercialised, or res extra commercium. In light of this position, I argue that while genetic information may well be res extra commercium, the Report incorrectly classifies it as res publica, rather than res omnium communes. Res publica includes public or state property which must be utilised to further the public interest and must be open to the public.[275] Public property is owned, controlled and managed by the state.[276] Roman law classifies things such as bridges, roads and harbours as public property.[277] Res omnium communes includes common property — things which all individuals have the right to access and use of.[278] Things such as air, water and the sea are categorised as res omnium communes.[279] Montgomery supports the consideration of genetic information as 'a form of common property belonging simultaneously to a group of people but with outsiders excluded.'[280] This model validates the co-ownership of genetic information and allows the full use of its value.[281] This model would also allow genetic information to be treated as common property belonging to the community that contributed it, which, I argue, is more in line with the concept of Ubuntu than public ownership. The argument that genetic information is communal and not commercial does not necessitate public ownership — in fact, the concept of community in the context of Ubuntu would likely support the model of genetic information as res omnium communes. Public ownership of genetic information may well deter communities and individuals from participating in research. Individuals have personal interests in their genetic data which could possibly be infringed by public ownership.

Prince describes the implications of defining personal interests in genetic data (property or privacy rights) for individuals, families and societies.[282] The interest of an individual in maintaining control and privacy of their genetic information is 'grounded in protecting the self-identity of a person.'[283] The Report does not explore the possibility of individual property rights over genetic information. Ownership gives an individual the

[275] G Viljoen *Water as Public Property: A Parallel Evaluation of South African and German Law* (Doctor Legum thesis, North–West University, 2016) 70.
[276] Ibid 80.
[277] Ibid 70.
[278] Ibid.
[279] Ibid.
[280] Montgomery note 252 op cit at 84.
[281] Ibid at 85.
[282] Prince note 115 op cit at 185.
[283] Ibid.

> 'exclusive right of the individual owner to decide on the use of the resource in question; the exclusive right to the services of the resource; and the right to exchange or alienate the resource at mutually agreeable terms.'[284]

This position would clearly afford the most control to individual research participants, while posing a limit to access for research purposes.

Researchers require access to the genetic information of large groups of individuals.[285] This entails that genetic information is not only individual and familial, but societal too.[286] As a result of the value of genetic information in the research context, there are arguments that 'society as a whole'[287] should own genetic information, especially due to the public's funding of research such as the Human Genome Project.[288] However, the 'public' that funded the Human Genome Project is not the South African public, but a group of Global North 'publics.' As such, the logical conclusion of this argument would be that the results of the Human Genome Project should belong to the relevant Global North 'publics' to the exclusion of South Africa.

There is opposition to the property rights model.[289] With regard to property rights in genetic information, the ownership of genetic information by families raises some issues.[290] If a family were to have joint ownership of their genetic information, since it is familial data, there would be problems in the circumstance of disputes.[291] Individual property rights in genetic information may incentivise individuals to participate in research and donate samples.[292] On the other hand, it may also impede research by limiting the use of public datasets.[293] There are possibilities that the privacy and property models may both limit genetic research.[294] However, some prefer the application of privacy rights to genetic information as it does not commodify the human body.[295] The privacy model views genetic information as something we have a personal interest in, rather than as commodifiable parts.[296] The control

[284] Viljoen note 275 op cit at 59.
[285] Prince note 115 op cit at 191.
[286] Ibid.
[287] Ibid.
[288] Ibid.
[289] Ibid at 186; Montgomery note 252 op cit at 84.
[290] Prince note 115 op cit at 188.
[291] Ibid.
[292] Ibid at 192.
[293] Ibid.
[294] Ibid.
[295] Ibid at 186; Montgomery note 252 op cit at 84.
[296] Prince note 115 op cit at 186.

over information ensured by the privacy model 'may help an individual maintain his or her sense of self.'[297]

In light of the above discussion on ownership of genetic information, I move on to the discussion of benefit sharing. Benefits may arise from genetic and genomic research. These may take the form of financial benefits as well as benefits such as healthcare, the generation of knowledge and capacity building.[298] A benefit is something that promotes well-being.[299] The Report notes that participants altruistically donate samples and researchers benefit both financially and personally from the research they conduct on the samples.[300] This imbalance is acknowledged by Haddow et al, who argue that research participants are largely requested to donate samples altruistically and with no prospects of receiving benefits from the donation.[301] Thus, samples are viewed as 'gifts.'[302] Labuschaigne challenges the argument that human genetic research should rely on altruism on the basis that

> 'it seems hypocritical to demand altruistic donations from participants in poor and developing countries, whilst industry-led researchers from developed countries reap all the benefit, especially if the purpose of the "genetic mining" in less developed countries is to produce products aimed solely at affluent populations of industrialised countries.'[303]

Haddow et al 'endeavour to counter the perceived excesses of private profit.'[304] The authors consider the reasons for the public's participation in research, arguing that some people are not motivated to participate and that 'the problem is that the privileging of the wealth interest of some might be impacting negatively on motivations of others to take part.'[305] They propose that the impact of private profit on participation should be reduced, arguing that:

> 'An obvious solution would be to remove the prospect of private profit altogether by denying intellectual property rights, but this would be draconian and ultimately against the public interest if it meant that research was simply not done.'[306]

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[297] Ibid at 187.
[298] ASSAf note 64 op cit at 86.
[299] Ibid at 86.
[300] Ibid at 87.
[301] G Haddow, G Laurie, S Cunningham Burley & KG Hunter 'Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal' (2006) 64 *Social Science and Medicine* 272 at 273.
[302] Ibid.
[303] M Nöthling Slabbert (now Labuschaigne) 'The legal regulation of access and benefit–sharing with regard to human genetic resources in South Africa' (2011) 74 *THRHR* 605 at 612.
[304] Haddow et al note 301 op cit at 278.
[305] Ibid.
[306] Ibid.

The authors thus argue that benefit sharing is a more suitable model to combat 'perceived injustices'[307] in the commercialisation of samples. Further, such a model would show a 'commitment to justice,'[308] which would promote public trust in research. The authors argue that '[n]ew obligations to share could easily be incorporated into the existing ethical approval framework with minimal disruption,'[309] but do not consider the disruption that the introduction of benefit sharing would cause for researchers, who would have increased burdens in the undertaking of research.

The Report argues that if genetic and genomic research is viewed as a common good, research clearly benefits society and benefit sharing agreements are unnecessary.[310] However, if such research is viewed in the same way as other scientific work and uses the gift model, then benefit sharing must be regulated.[311] In discussing a benefit sharing model, the Report refers to tangible benefits such as financial benefits, employment and development.[312] Other benefits, which are not tangible, are capacity and skills development and knowledge generation.[313] It notes that it is important that funds are allocated for benefit sharing.[314] Other examples of benefits are information sharing,[315] access to research results,[316] royalties,[317] technology and materials transfer,[318] capacity development,[319] access to medicine, the advancement of knowledge, or money.[320] Haddow et al's model holds that benefit sharing is essential because DNA is communal, and ownership is prevented while the participants retain control of their samples.[321] The Report argues that this model promotes Ubuntu.[322]

It is important at this point to consider the provisions of South African legislation. The NHA makes *payment for tissue and gametes an offence,* however, the reimbursement of costs incurred is permitted.[323] Thus, it is a crime for a research participant who has 'donated tissue, a gamete, blood or a blood product to receive *any form of financial or other reward* for such

[307] Ibid at 279.
[308] Ibid.
[309] Ibid.
[310] ASSAf note 64 op cit at 87.
[311] Ibid.
[312] Ibid.
[313] Ibid.
[314] Ibid at 71.
[315] 2.2, MTA note 52 op cit.
[316] Ibid; Nöthling Slabbert note 303 op cit at 606.
[317] 2.2, MTA note 52 op cit.; Nöthling Slabbert note 303 op cit at 606.
[318] 2.2, MTA note 52 op cit.; Nöthling Slabbert note 303 op cit at 606.
[319] 2.2, MTA note 52 op cit.; Nöthling Slabbert note 303 op cit at 606.
[320] Nöthling Slabbert note 303 op cit at 606.
[321] ASSAf note 64 op cit at 87 referring to Haddow et al note 300 op cit.
[322] ASSAf note 64 op cit at 87.
[323] S60(4)(a), POPIA note 61 op cit.

donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation'[324] (emphasis added). Despite the provisions of the NHA, the SA MTA provides that the 'sharing of benefits should be discussed and negotiated between the Provider and Recipient before Materials are transferred to the Recipient.'[325] Labuschaigne et al point out that the SA MTA falls short in that 'it does not prescribe what the benefit should entail, or that benefit sharing must take place. It does, however, state that this should be discussed and negotiated prior to transfer.'[326] While the Report and the SA MTA suggest different types of benefits which may be shared, it is important to remember that the NHA outlaws the receipt by donors of '*any form of financial or other reward*.'[327] It seems that this provision prohibits the sharing of *any* benefits, including non-monetary benefits which would classify as a form of 'other reward'[328] in terms of this section. The Report does not expand on how benefits may be allowed in terms of this provision of the NHA.

One argument against benefit sharing is that it could result in coercion or undue inducement. Andanda, writing in the context of research in developing countries, argues that the offer of compensation to research participants may cause a shift in the relationship between researcher and participant.[329] The relationship may become commercialised, and economically disadvantaged research participants 'may conceal important health information in order to become or remain eligible for study.'[330] Economically disadvantaged research participants may be induced to participate in research solely for the purposes of gaining benefits.[331]

Another argument against benefit sharing considers whether research participants are in fact owed benefits in exchange for their participation. The underlying arguments against the altruism of research participants is that they contribute their samples and the information gained therefrom may benefit researchers. However, I consider the labour theory of ownership to challenge this argument. The labour theory holds that the worth of the data can only be utilised as a result of the labour put into the samples, thus the labourer (who extracts and analyses the data) owns the data.[332]

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[324] Ibid.
[325] 7.1, MTA note 52 op cit.
[326] Labuschaigne et al note 59 op cit at 355.
[327] S60(4)(a), POPIA note 61 op cit.
[328] Ibid.
[329] PA Andanda 'Human-tissue-related inventions: ownership and intellectual property rights in international collaborative research in developing countries' (2008) 34 *J Med Ethics* 171 at 173.
[330] Ibid.
[331] D Schroeder 'Benefit sharing: it's time for a definition' (2007) 33 *J Med Ethics* 205 at 207.
[332] Montgomery note 252 op cit at 83.

As indicated by Montgomery, this theory 'may even make the claims of the health service to ownership rights over information more plausible than those of patients.'[333] This can be applied to research — the information obtained through research 'does not exist prior to interactions with'[334] researchers. The contribution of the research participant who donates samples must be balanced against the contributions of the researcher,

> 'who extracts the personal data and makes it intelligible. This contribution is significant and beyond the competence of the patient. Further, the patient loses nothing in the provision of samples or information because they retain the information and can replace the samples.'[335]

In the context of genetic research, a research participant donates their samples. These samples have no value in research until a researcher manipulates them and conducts the research. The value of the samples is only exposed once the researcher has invested time, work and effort into the research. Without the efforts of the researcher, the participant's samples would have no value. Thus, in terms of the labour theory, a participant would not qualify for benefits which result from the efforts of the researcher.

Benefit sharing requirements have implications for the right to freedom of scientific research. Rourke writes in the context of the Convention on Biological Diversity (CBD) and the Nagoya Protocol, both of which are limited to the regulation of non-human genetic resources.[336] Rourke's arguments may nonetheless be applied to benefit sharing in relation to human genetic information. Rourke underlines the way in which the access and benefit sharing provisions of the CBD and Nagoya Protocol limit access to genetic resources.[337] These barriers completely bar the undertaking of some research, which has 'a significant toll on the scientific endeavour.'[338] Rourke emphasises the fact that 'not all uses of genetic resources are intended to generate a product for the marketplace. A distinction can be made between foundational scientific research with academic intent and applied research and development with commercial intent.'[339] Traditionally, the search for scientific knowledge has been viewed as a public good, with researchers sharing and exchanging information and samples among themselves.[340] Scientific journals generally require the sharing of the data on which findings

[333] Ibid.
[334] Ibid.
[335] Ibid at 84.
[336] MF Rourke 'Access and benefit–sharing in practice: non–commercial research scientists face legal obstacles to accessing genetic resources' (2018) 13(1) *Journal of Science Policy & Governance* 1.
[337] Ibid at 2.
[338] Ibid.
[339] Ibid at 5.
[340] Ibid at 10.

are based.[341] Benefit sharing would have an impact on these processes and norms, with the possibility that researchers with less resources, such as researchers in developing countries and unfunded researchers, may not be able to afford benefit sharing. Researchers involved in basic research may not have benefits to share except the contributions made to scientific research as a whole. Accordingly, research participant (or community) expectations of 'tangible' benefit sharing may act as an effective limit on the freedom of scientific research (of less-resourced researchers).

IV CONSENT AS A JUSTIFIED LIMITATION ON THE RIGHT OF FREEDOM TO SCIENTIFIC RESEARCH

POPIA requires the form of consent which is most onerous on researchers — specific consent. In this section I analyse the extent to which this is a limitation on the right to freedom of scientific research. I consider the effect of the exemptions on the limitation, and the extent to which they relieve the burden on researchers. I demonstrate that specific consent, in terms of POPIA, is a justifiable limitation on the right to freedom of scientific research. I then consider the developments proposed by the Report as limitations on the right to freedom of scientific research. For the purposes of the justification analysis, I imagine a law that enforces the proposed developments in research specifically introduced by the model of Ubuntu that is discussed by the Report. I call this hypothetical law 'the X law'. This section takes the form of a human rights justification analysis in terms of section 36 of the Constitution. I utilise South African case law to structure the analysis. The purposes of freedom of scientific research elucidated in Chapter Three play a role in the analysis. I conclude that the X law is an unjustifiable limit on the right to freedom of scientific research.

The Constitution regulates the limitation of rights as follows:

> '36(1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including—
>
> (a) the nature of the right;
>
> (b) the importance of the purpose of the limitation;
>
> (c) the nature and extent of the limitation;

[341] Ibid.

(d) the relation between the limitation and its purpose; and

(e) less restrictive means to achieve the purpose.

(2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights.'[342]

In order for a law to justifiably limit a right, it must be a law of general application (in line with the principle of the rule of law) that is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.[343] South African courts take a two-stage approach to the limitation of rights.[344] I mirror this approach in my justification analysis. In the first stage, I consider whether POPIA limits the right to freedom of scientific research with its requirement of specific consent. I then consider the requirements introduced by the X law as limitations on the right to freedom of scientific research. I conclude that both POPIA and the Report limit the right to freedom of scientific research and undergo an analysis of proportionality in terms of the second stage.

(a) Stage one: has the right to freedom of scientific research been limited by POPIA or the X law?

The first stage involves the determination that a right in the Bill of Rights has been infringed, either by law or conduct. [345] Here the court must interpret the right in order to determine its scope.[346] At this stage, the question is asked

'whether certain activities or interests fall within the scope of the right. This process often requires a court to examine the values that underlie the right and the practices that serve those values. There should be no balancing of competing values.'[347]

I argue that the right to freedom of scientific research is limited by POPIA in the following manner:

- The introduction of the requirement of specific consent. This means that researchers may only collect samples for a specific purpose, which negates the

[342] S 36, Constitution of the Republic of South Africa, 1996.
[343] Ibid.
[344] *S v Makwanyane* [1995] ZACC 3, 1995 (6) BCLR 665 (CC) para 100.
[345] Ibid para 208.
[346] K Iles 'A Fresh Look at Limitations: Unpacking Section 36' (2007) 23(1) *South African Journal on Human Rights* 68 at 72.
[347] Ibid.

use of broad consent and tiered consent models with a 'consent to all future research' tier.[348]

- Samples and information may only be stored for as long as is necessary to achieve the purpose for which they were collected. However, POPIA exempts researchers from this limitation on the condition that researchers implement measures to ensure that the information is not used for purposes other than those for which it was collected. Thus, once researchers have utilised the information for the project or research for which it was collected, they may store the information for possible future research purposes. However, they are burdened with the duty of protecting the information.[349]
- Secondary use of samples and information must be compatible with the purposes of the initial collection. This could be a limitation on the right to freedom of scientific research since one set of information can often be utilised in different types of scientific research with different purposes. However, POPIA deems all research purposes to be compatible with the initial purpose of collection. When using such samples and information in research, researchers may not publish the information in a manner that allows for the identification of participants.[350]
- The processing of special personal information (which includes genetic information) is prohibited. However, researchers may process such information if the processing is necessary for a purpose which serves the public interest, or if it would be disproportionately difficult to obtain consent. In the latter case, researchers must implement measures to ensure that the processing does not disproportionately disrupt the participants' privacy.[351]
- The processing of the information of children is prohibited. However, researchers may process the information of a child for purposes which serve the public interest, or when it would be disproportionately difficult to obtain consent. In the latter case, researchers must implement measures to ensure that the processing does not disproportionately disrupt the participants' privacy.[352]

[348] S 2, POPIA note 61 op cit.
[349] S 14, ibid.
[350] S 15, ibid.
[351] S 27, ibid.
[352] S 27 & s 35, ibid.

In this section I use the Report's conception of Ubuntu and its arguments as to how Ubuntu could affect research requirements in order to outline the limitations of this Ubuntu model. I utilise the Report to create the hypothetical X law, and argue that the right to freedom of scientific research is limited by the X law in the following manner:

- Researchers must promote Ubuntu and view respect for persons communally.[353]
- Researchers must engage with the community involved in research and the public at large.[354]
- Researchers must obtain community consent as well as individual consent.[355]
- Genetic information and resources must be owned and controlled by the state.[356]
- Researchers must share the benefits of their research with the research participants and their community.[357]
- Research must allocate funds to ensure benefit sharing.[358]

(b) Stage two: are the limitations reasonable and justifiable?

The second stage asks whether the limitation is reasonable and justifiable.[359] This determination requires the balancing of the factors included in section 36.[360] Determining reasonableness requires 'the weighing up of competing values, and ultimately an assessment based on proportionality.'[361] On the one hand, the nature and purpose of the right must be considered, and, on the other hand, the importance of the purpose of the limitation of the right must be considered.[362] This analysis is summarised by Jafta AJ in *Johncom Media Investments Ltd as*

[353] ASSAf note 64 op cit at 11.
[354] Ibid at 11 R1(a).
[355] Ibid at 25.
[356] Ibid at 85.
[357] Ibid at 87.
[358] Ibid at 71.
[359] *Johncom Media Investments Ltd v M* [2009] ZACC 5, 2009 (4) SA 7 (CC), 2009 (4) SA 7 (CC) para 22.
[360] S 36, Constitution.
[361] *S v Makwanyane* supra note 344 para 104;
[362] Ibid; *S v Bhulwana* [1995] ZACC 11, 1996 (1) SA 388 (CC) para 18; *Centre for Child Law v Minister of Justice and Constitutional Development* [1995] ZACC 11, 2009 (6) SA 632 (CC) para 51; *Brümmer v Minister for Social Development* [2009] ZACC 21, 2009 (6) SA 323 (CC) para 59; *Johncom Media Investments Ltd* supra note 359 para 24; *Minister of Home Affairs v National Institute for Crime Prevention and the Reintegration of Offenders* [2004] ZACC 10, 2005 (3) SA 280 (CC) para 37; *Twee Jonge Gezellen (Pty) Ltd v Land and Agricultural Development Bank of South Africa T/A The Landbank* [2011] ZACC 2, 2011 (3) SA 1 (CC) para 54; *Phillips v Director of Public Prosecutions* [2003] ZACC 1, 2003 (3) SA 345 (CC) para 345.

> 'the right infringed must be identified, and its nature as well as its importance in a particular context must be considered. The purpose of the limitation must be pin-pointed, together with its extent, so as to determine the relation between the limitation and the purpose it is designed to achieve.'[363]

The party limiting the right must justify the purpose of the limitation.[364] As held by O'Regan J in *S v Bhulwana*, 'the more substantial the inroad into fundamental rights, the more persuasive the grounds of justification must be.'[365] The party must provide material to support justifications which are based on factual or policy concerns.[366] In *Minister of Home Affairs v National Institute for Crime Prevention and the Reintegration of Offenders*, Chaskalson CJ held that a 'legislative choice is not always subject to courtroom factfinding and may be based on reasonable inferences unsupported by empirical data.'[367] However, this does not render legislation unjustifiable or unreasonable — as held by Chaskalson:

> 'If the concerns are of sufficient importance, the risks associated with them sufficiently high, and there is sufficient connection between means and ends, that may be enough to justify action taken to address them.'[368]

(i) The nature of the right to freedom of scientific research

The first of the five factors considered is the nature of the right.[369] Chaskalson P added in *S v Makwanyane* that the importance of the right to 'an open and democratic society based on freedom and equality'[370] must be considered. In the first stage of the analysis I identified the right to freedom of scientific research as being limited by the provisions of POPIA and the X law. The right to freedom of scientific research, an instance of the right to freedom of expression, was explored in depth in Chapter Three. There I concluded that the first purpose of the right to freedom of scientific research is the promotion of individual self-fulfilment, dignity and autonomy. Its second purpose is to enable the advancement of knowledge and the search for truth. It is clear that the right to freedom of scientific research plays an important role in protecting these public goods.

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[363] *Johncom Media Investments Ltd* supra note 359 para 25.
[364] *Moise v Greater Germiston Transitional Local Council* [2001] ZACC 21, 2001 (4) SA 491 (CC) para 19.
[365] *S v Bhulwana* [1995] ZACC 11, 1996 (1) SA 388 (CC) para 18
[366] *Moise* supra note 364 para 19; *Minister of Home Affairs v National Institute for Crime Prevention and the Reintegration of Offenders* [2004] ZACC 10, 2005 (3) SA 280 (CC) para 36.
[367] *Minister of Home Affairs v National Institute for Crime Prevention and the Reintegration of Offenders* [2004] ZACC 10, 2005 (3) SA 280 (CC) para 35.
[368] Ibid.
[369] S 36, Constitution.
[370] *S v Makwanyane* supra note 344 para 104.

(ii) The importance of the purpose of the limitation

The second factor is the importance of the purpose of the limitation, which must promote an open and democratic society based on human dignity, freedom and equality.[371]

The purpose of POPIA is to protect the right to privacy,[372] which includes 'a right to protection against the unlawful collection, retention, dissemination and use of personal information.'[373] The right to privacy is subject to limitations aimed at balancing the right with other considerations such as the right of access to information and interests in the free flow of information.[374] The Constitutional Court (CC) in *Bernstein v Bester* held that the right to privacy protects 'the inner sanctum of a person,'[375] and is recognised '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.'[376] In *De Reuck v Director of Public Prosecutions (Witwatersrand Local Division)*, the CC held that 'constitutional rights are mutually interrelated and interdependent and form a single constitutional value system.'[377]

The CC has drawn links between the constitutional rights to privacy and dignity.[378] In *Khumalo v Holomisa*, O'Regan J held in her majority judgment that the right to privacy '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.'[379] The protection of privacy thus clearly serves to protect human dignity simultaneously. I thus argue that the purpose of POPIA's limitations are important in an open and democratic society based on human dignity, freedom and equality.

The X law's limitations on the right to freedom of scientific research identified above are all recommended for the purpose of promoting Ubuntu. The requirement that research must share benefits is recommended for the purpose of Ubuntu, as well as the purpose of ameliorating the conflict between altruistic donation by research participants and the personal and financial gains of researchers. However, in the case of community consent such as that

[371] S 36, Consitution.
[372] S 14, ibid.
[373] Preamble, POPIA note 61 op cit.
[374] S 2, ibid.
[375] *Bernstein v Bester* [1996] ZACC 2, 1996 (2) SA 751 (CC) para 67.
[376] Ibid.
[377] *De Reuck v Director of Public Prosecutions (Witwatersrand Local Division)* [2003] ZACC 19, 2004 (1) SA 406 (CC) para 55.
[378] S 10, Constitution; *Centre for Child Law v Minister of Justice and Constitutional Development* [1995] ZACC 11, 2009 (6) SA 632 (CC) para 50; *Khumalo v Holomisa* [2002] ZACC 12, 2002 (5) SA 401 (CC) para 27.
[379] *Khumalo v Holomisa* [2002] ZACC 12, 2002 (5) SA 401 (CC) para 27.

envisaged by the 'DNA on Loan' model, I argue that an ulterior purpose of this requirement could be to create a shortcut where individual consent is not required for secondary use of information.

The promotion of Ubuntu is an important purpose. The CC in *Port Elizabeth Municipality v Various Occupiers* held that the

> 'spirit of [U]buntu, 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.'[380]

In his minority judgment in *Dikoko v Mokhatla,* Sachs J held that Ubuntu represents the 'element of human solidarity that binds together liberty and equality to create an affirmative and mutually supportive triad of central constitutional values.'[381] It is clear that the promotion of Ubuntu is of value in an open and democratic society based on human dignity, freedom and equality.

(iii) The nature and extent of the limitation

The third factor is the nature and extent of the limitation.[382] Here, the scope of the limitation is identified.

In terms of POPIA's limitations, researchers must obtain specific consent for the collection of samples and information.[383] POPIA's exemptions for research purposes are important in understanding the extent to which POPIA limits the right to freedom of research. Researchers must protect the information that they store for future research purposes.[384] Researchers may engage in secondary use for any research purpose, as long as they anonymise the published information.[385] Researchers may process special personal information if their research serves the public interest, or if it would be disproportionately difficult to obtain consent, in which case measures must be implemented to protect the participants' privacy from disproportionate disruption.[386] Researchers may also process the information of children on the

[380] *Port Elizabeth Municipality v Various Occupiers* [2004] ZACC 7, 2005 (1) SA 217 (CC) para 37; *Dikoko v Mokhatla* [2006] ZACC 10, 2006 (6) SA 235 (CC) para 113.
[381] *Dikoko v Mokhatla* [2006] ZACC 10, 2006 (6) SA 235 (CC) para 113.
[382] S 36, Constitution.
[383] S 1, POPIA note 61 op cit.
[384] S 14, ibid.
[385] S 15, ibid.
[386] S 27, ibid.

same conditions.[387] POPIA grants leeway to researchers in its exemptions, which only require researchers to implement mechanisms to ensure the anonymisation of information and the adequate protection of research participants' privacy. In order to process special personal information, researchers are required to either prove that their research serves the public interest; or prove that it would be disproportionately onerous to obtain consent. I argue that these limitations only raise issues of convenience, as researchers are already required to comply with standards of participant privacy and confidentiality in terms of research ethics guidelines.

In terms of the X law, researchers must engage with both the community and the public. This is an extension of the current position which only requires consultation with 'representatives from the participating community or other relevant stakeholders, where relevant.'[388] In terms of the X law, researchers must obtain community consent as well as individual consent. This is an extension of the current position which only requires permission from the community to approach individuals when conducting research on collectivities.[389]

In the context of the X law, genetic resources must be public property. This limits the right to freedom of scientific research in that researchers would have to work in conjunction with the state in order to access the information necessary for their research. This could lead to bureaucratic and inefficient data access processes which could impair the research process.

Furthermore, in the context of the X law, researchers must share the benefits of their research with research participants and their communities; and must allocate funds to benefit sharing. This requirement has implications for resource-allocation in research. It would be onerous on unfunded researchers, academic researchers, and those researchers operating in developing countries where resources are scarce. Researchers involved in basic research might not have benefits to share besides their contribution to scientific knowledge. For this reason, benefit sharing requirements could lead to researchers being unable to undertake their projects. Further, the requirement of community engagement and the negotiation of benefit sharing could lead to the community leaders or representatives acting as gatekeepers for specific research in order to gain more attractive benefits. This would be a clear limitation of the right to freedom of scientific research.

[387] S 27 & s 35, ibid.
[388] Reg 3(b), Regulations Relating to Research with Human Participants note 16 op cit.
[389] 3.2.9, National Department of Health note 28 op cit.

(iv) The relation between the limitation and its purpose

The scope of the limitation is used to consider the relation between the limitation and its purpose.[390] The limitation must be proportionate to its purpose — as held in the judgment of Madala J, Sachs J and Yacoob J in *S v Manamela*, a sledgehammer must not be used to crack a nut.[391] Further, the law must not be used for purposes which are not appropriate.[392]

Do the specific consent requirement and the processing conditions in POPIA (the means) serve to protect individual autonomy and the rights to privacy and bodily integrity (the ends)? I answer this question in the affirmative, arguing that the limitation is proportionate. The requirement of specific consent allows individuals to make decisions about whether their information may be used for specific purposes.[393] This protects individuals' privacy and dignity by allowing them to exercise autonomous decision-making.[394] The purpose specification condition on storage protects individuals in that once their information has been processed for the purpose of the initial collection, it may only be stored further for the same purpose. Individual privacy is protected in that researchers must ensure that the information is only used for the purpose which was originally consented to. The rights to privacy and dignity are protected by the further processing limitation. Secondary use is permitted for research purposes, but individuals are protected in that researchers must ensure that no identifiable information is published. While researchers are allowed to process special personal information, individuals are protected in the requirement that the research must have a purpose that serves the public interest. This balances the right to privacy with the public interest. Alternatively, researchers must prove that it would be disproportionately difficult to obtain consent, in which case measures must be implemented to ensure that the processing does not unduly disrupt the participants' privacy. This directly protects the right to privacy. POPIA's exemptions for research allow researchers to achieve their purpose while protecting individual rights to privacy and dignity. I thus argue that the limitation is proportionate to the harm it causes to the right to freedom of scientific research.

Does the public ownership of genetic information (the means) serve to promote Ubuntu (the ends)? I argue that it does not. The requirement of public ownership is not substantiated in the Report, besides the argument that Ubuntu promotes humanness 'by helping others to

[390] S 36, Constitution.
[391] *S v Manamela* [2000] ZACC 5, 2000 (3) SA 1 (CC) para 34.
[392] Ibid.
[393] S 1, POPIA note 61 op cit.
[394] Townsend & Thaldar note 46 op cit at 337.

fulfil their own potential, and also by enabling local researchers to make contributions to their societies.'[395] However, public ownership of genetic data would impact both the researchers' right to freedom of scientific research and individual rights to privacy. I argue that the requirement of public ownership is a drastic measure to achieve the promotion of Ubuntu.

Does benefit sharing (the means) serve to promote Ubuntu (the ends)? The requirement of benefit sharing is argued to promote Ubuntu in that it creates a relationship of reciprocity.[396] I argue that while benefit sharing may promote reciprocity in that it entails the exchange of information necessary for research for benefits, it could also present a breeding ground for coercion. As argued above, the combination of community consent and benefit sharing may lead to gatekeeping and the negotiation of benefits in a commercial manner. Thus, benefit sharing could have harmful results that outweigh the importance of promoting Ubuntu in research.

Do the community engagement and consent requirements (the means) serve to promote Ubuntu (the ends)? I argue that community engagement requirements do serve to promote Ubuntu when applied in appropriate circumstances. Community engagement is already legally required in research 'where appropriate,'[397] and is important in practising ethical research in Africa.[398] In the appropriate contexts, community engagement would promote respectful, trusting relationships which are of great value both in Ubuntu and in research.[399] Community engagement may not be appropriate where research involves intimate personal issues, or issues which may be considered taboo in that community. In these contexts, community engagement may be ineffective as community members may not feel comfortable with discussing such issues outside of a private setting.

Similarly, I argue that community consent is appropriate in certain circumstances. For example, in research concerning the genetic or disease characteristics of the community as a whole, community consent would clearly be appropriate, as the results of the research would have an impact on the community. However, in research concerning individual characteristics, specific diseases, or issues considered taboo, consent should be solely individual in order to

[395] ASSAf note 64 op cit at 27.
[396] Ibid.
[397] Reg 3(b), Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014.
[398] H3Africa 'H3Africa Guidelines for Community Engagement (Version Two)' (2017) available at *https://h3africa.org/wp-content/uploads/2018/05/CE%20Revised%20Guidelines_Final_September%202017%20(1).pdf*, accessed on 1 Dec 2020.
[399] ASSAf note 64 op cit at 31.

ensure that individuals are not barred from, or pressured into, participating. The requirement of informed consent respects individual autonomy[400] and protects individual interests in bodily integrity[401] and well-being.[402] Further, it is a prerequisite for the protection of the individual's right to privacy.[403] The right to privacy is linked to the right to dignity in that it protects 'a right to a sphere of intimacy and autonomy.'[404] Community consent should not be elevated above these individual rights and interests. The community is not always paramount in African ethics,[405] and should not be granted 'an all-engulfing moral authority to determine all things about the life of the individual person.'[406] Moderate communitarianism recognises community members as autonomous individuals,[407] and the requirement of community consent may in some contexts offend this autonomy.

(v) Less restrictive means to achieve the purpose

Finally, the fifth factor — the limitation cannot be proportionate if there are less restrictive means available to achieve the same end.[408]

I argue that there are no less restrictive ways to promote the right to privacy than the requirements of POPIA. The right to privacy is of great importance, and the exemptions in POPIA give sufficient leeway to researchers to ensure that the right to freedom of scientific research is not disproportionately limited.

Are there less restrictive ways in which Ubuntu can be promoted in research? I argue that there are less restrictive methods for the promotion of Ubuntu in research. Community engagement in terms of the DoH guidelines is less restrictive.[409] The DoH guidelines only require permission from the community where research is being conducted on collectivities.[410]

Benefit sharing could be less restrictive if limited to the provision of medical treatment in research where specific diseases are being studied. In circumstances where research will not

[400] Levine note 1 op cit at 1229; Hammami et al note 4 op cit at 2; Berg et al note 2 op cit at 279.
[401] Berg et al note 2 op cit at 11.
[402] Ibid at 14.
[403] Faden & Beauchamp note 10 op cit at 21.
[404] *Khumalo* supra note 379 para 27.
[405] Shozi note 198 op cit.
[406] Gyekye note 206 op cit at 301.
[407] Shozi note 198 op cit.
[408] *S v Makwanyane* supra note 344 para 104; *Twee Jonge Gezellen (Pty) Ltd v Land and Agricultural Development Bank of South Africa T/A The Landbank* [2011] ZACC 2, 2011 (3) SA 1 (CC) para 54; *Centre for Child Law v Minister of Justice and Constitutional Development* [1995] ZACC 11, 2009 (6) SA 632 (CC) para 51; *Johncom Media Investments Ltd* supra note 359 para 24; *Phillips v Director of Public Prosecutions* [2003] ZACC 1, 2003 (3) SA 345 (CC) para 22.
[409] 3.2.9, National Department of Health note 28 op cit.
[410] 3.2.9, ibid.

lead to such benefits, benefit sharing agreements could explain the contribution to knowledge that the research will make, or aims to make. I argue that this promotes Ubuntu in that communities are educated about the contributions to society that their information will make.

V CONCLUSION

The requirement of informed consent is a justified limitation on the right to freedom of scientific research. POPIA provides for specific consent, which is more onerous on the researcher than other forms of consent. However, POPIA also provides exemptions for research which justify the limitation of specific consent on the right to freedom of scientific research. The requirement of community consent envisaged by the Report is a limitation on the right to freedom of scientific research which is not justified because there are methods of promoting Ubuntu which would be less restrictive on the right to freedom of scientific research.

CHAPTER FIVE:

HUMAN GERMLINE GENE EDITING AND THE RIGHT TO FREEDOM OF SCIENTIFIC RESEARCH

I INTRODUCTION

This chapter considers the right to freedom of scientific research in the context of gene editing. I begin by placing the reader in the scientific context of CRISPR-Cas9 gene editing. The ethical and safety issues emanating from heritable human gene editing and gene editing in embryos are discussed. I set out the international legal and ethical framework governing gene editing and consider the regulatory approach of twenty foreign jurisdictions. I then analyse the South African legal framework. These discussions are considered through the lens of freedom of scientific research.

II SCIENTIFIC CONTEXT

In this section I provide the scientific context for the discussions in the rest of the chapter. First, a basic explanation of CRISPR-Cas9 is provided, followed by a brief history of the scientific research which led to its discovery. Finally, a more in-depth discussion of CRISPR-Cas9 is provided, including the discussion of specific studies on its application in human embryos, and the safety and efficacy issues which arise.

(a) How does CRISPR-Cas9 work to edit genes?

CRISPR-Cas9 is a relatively simple gene editing technology,[1] which enables the precise and efficient targeted alteration of genes.[2] As indicated by Doudna — '[a]s long as the genetic code for a particular trait is known, scientists can use CRISPR to insert, edit, or delete the associated gene in virtually any living plant's or animal's genome.'[3] CRISPR-Cas9 is compared 'to a word processing program's "find and replace" function.'[4]

[1] Jennifer A Doudna & Samuel H Sternberg *A Crack in Creation* (2017) 13.
[2] Q Bu 'Reassess the law and ethics of heritable genome editing interventions: Lessons for China and the world' (2019) 34(2) *Issues in Law & Medicine* 115 at 119.
[3] Doudna & Sternberg note 1 op cit at 13.
[4] KS Bruce 'Legislative Recommendation for Regulating the Use of Germline Modification Techniques in the United States' (2019) 25 *Boston University Journal of Science and Technology Law* 185 at 190.

CRISPR-Cas9 recognises a specific genetic sequence and targets it to induce a double-strand break in the DNA.[5] The cell then repairs the double-strand break with its 'normal DNA repair machinery'[6] — homologous recombination or non-homologous end-joining.[7] While non-homologous end-joining is more common, it is not suitable for gene editing purposes due to the random introduction of insertions or deletions at the double-strand break.[8] The repair mechanism of homology-directed repair is appropriate as it utilises the non-mutant identical chromosome in the cell or a supplied DNA molecule to 'fill' the double-strand break.[9] This process allows for DNA to be inserted at the target site to repair the removed mutated gene.[10] In this way, CRISPR-Cas9 can be utilised to edit genes.[11] It shows potential for the treatment of diseases such as cystic fibrosis, Duchenne muscular dystrophy, haemophilia, sickle-cell anaemia, HIV and cancer.[12]

(b) History of the key discoveries leading up to CRISPR-Cas9

Gene editing technologies are not a novel phenomenon — by the 1970s, scientists were researching the use of viral vectors to deliver therapeutic DNA to genomes.[13] The germline of mice was successfully edited, with changes being passed onto following generations, allowing for the observation of gene functions.[14] In the 1980s, Capecchi discovered that mammal cells engage in homologous recombination and envisioned the use of the enzymes involved in the process of genetic editing.[15] In 1985, Smithies achieved this by replacing the beta-globin gene in the cells of human bladder tumours with an artificial one.[16]

Around the same time, Szostak discovered the double-strand break made in DNA before homologous recombination.[17] This presented an opportunity for gene editing in mammal cells — scientists could introduce a break at the site of the attempted edit, insert the correct gene and allow cells to repair the break.[18] Jasin performed this process in mice in 1994, concluding

[5] H Ma, N Marti-Gutierrez & S Park 'Correction of a pathogenic gene mutation in human embryos' (2017) 548 *Nature* 413 at 413.
[6] KE Ormond, DP Mortlock & DT Scholes et al 'ASHG Position Statement: Human Germline Genome Editing' (2017) 101 *The American Journal of Human Genetics* 167 at 168.
[7] Ma et al note 5 op cit at 413.
[8] Ibid.
[9] Ibid.
[10] Ormond et al note 6 op cit at 168.
[11] Ibid.
[12] Bu note 2 op cit at 119; Ormond et al note 6 op cit at 168; Doudna & Sternberg note 1 op cit at 16.
[13] Doudna & Sternberg note 1 op cit at 64.
[14] Ibid at 65.
[15] Ibid at 74.
[16] Ibid at 75.
[17] Ibid at 81.
[18] Ibid at 82.

that the use of an enzyme to inflict 'an artificially generated double-strand break enhanced the efficiency of homologous recombination.'[19] She utilised an endonuclease (an enzyme which can snip DNA) found in yeast to target the correct site in the genome.[20] Despite Jasin's success rate, the endonuclease she utilised only targeted the genetic sequence it recognised — it would not be able to target mutated genes.[21] At this point, three requirements for gene editing mechanisms had been identified, as Doudna indicated:

> 'They had to recognize a specific, desired DNA sequence; they had to be able to cut that DNA sequence; and they had to be easily reprogrammable to target and cut different DNA sequences.'[22]

(c) CRISPR — from a bacterial immune system to a method of gene editing

The CRISPR system is observed in bacteria and archaea,[23] such as Streptococcus pyogenes.[24] It consists of repeated genetic sequences (the repeats), interspaced by different genetic sequences which contain 'exotic DNA'[25] (the spacers). Jansen discovered CRISPR-associated genes alongside the CRISPR locus.[26] These genes produce certain enzymes, some of which have the function of 'unzipping the two strands of the DNA double helix or slicing up RNA or DNA molecules, just like the DNA-cutting function of restriction endonucleases.'[27] These enzymes are CRISPR-associated proteins (Cas).[28]

The importance of these proteins for CRISPR was demonstrated by Barrangou et al, who proved that deactivating the gene that codes for Cas5 in Streptococcus thermophilus results in the bacteria being unable to protect itself from viruses.[29] They observed the storage of viral DNA in the spacers of the CRISPR locus, and the resultant immunity of the bacteria.[30] This immunity is passed on to the cells reproduced by the bacteria.[31]

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[19] Ibid at 84.
[20] Ibid.
[21] Ibid at 87.
[22] Ibid.
[23] Tetsushi Sakuma & Takashi Yamamoto 'CRISPR/Cas9: The Leading Edge of Genome Editing Technology' in Takashi Yamamoto (ed) *Targeted Genome Editing Using Site-Specific Nucleases: ZFNs, TALENs, and the CRISPR/Cas9 System* (2015) 25–41 at 26.
[24] Doudna & Sternberg note 1 op cit at 173.
[25] Sakuma & Yamamoto note 23 op cit at 26.
[26] Doudna & Sternberg note 1 op cit at 130.
[27] Ibid.
[28] Sakuma & Yamamoto note 23 op cit at 26.
[29] R Barrangou, C Fremaux & H Deveau et al 'CRISPR Provides Acquired Resistance against Viruses in Prokaryotes' (2007) 315(5819) *Science* 1709; Doudna & Sternberg note 1 op cit at 132.
[30] Doudna & Sternberg note 1 op cit at 130.
[31] Ibid at 131.

CRISPR has been described as a 'molecular vaccination card'[32] as it is an adaptive immune system to protect bacteria and archaea from viral DNA infection.[33] When a virus injects its DNA into the bacteria, the DNA is integrated into a spacer on the CRISPR locus and transcribed as RNA which consists of many sequence repeats with spacers (pre-crRNA).[34] Pre-crRNA then becomes CRISPR RNA (crRNA), which contains one spacer sequence matching the genetic sequence of the viral DNA.[35] The crRNA combines with an RNA molecule called tracrRNA, creating a crRNA-tracrRNA heteroduplex.[36] The crRNA-tracrRNA heteroduplex works with Cas to target viral DNA and introduce a double-strand break in its genetic sequence.[37]

The Cas9 enzyme was first observed in the bacteria Streptococcus pyogenes.[38] Jinek et al discovered that Cas9 attaches to and separates the two strands of the DNA double helix and creates a double-strand break.[39] The CRISPR RNA sequence determines the site targeted and cut by Cas9.[40] The system showed potential for application to living cells as a method of targeted gene editing.[41]

The next question was, '[i]f bacteria could program Cas9 to cut up specific viral DNA sequences, could we, the researchers, program Cas9 to cut up other DNA sequences — viral or not — as we suspected?'[42] Doudna worked to demonstrate that Cas9 and CRISPR RNA could be engineered to target any specified DNA sequence.[43] A breakthrough was reached when the DNA of jellyfish was successfully sliced at target sites by Cas9.[44]

The final piece of the CRISPR puzzle — tracrRNA — was discovered in 2011.[45] TracrRNA, crRNA and Cas9 cause a double-strand break in the viral DNA which is repaired by the cell's repair mechanisms.[46] Also in 2011, Sapranauskas et al demonstrated that CRISPR-

[32] Ibid at 104.
[33] P Liang, Y Xu, X Zhang et al 'CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes' (2015) 6(5) *Protein & Cell* 363 at 363.
[34] Sakuma & Yamamoto note 23 op cit at 26.
[35] Ibid.
[36] Ibid.
[37] E Charpentier & JA Doudna 'Rewriting a genome' (2013) 495 *Nature* 50 at 50.
[38] Ormond et al note 6 op cit at 168.
[39] M Jinek, K Chylinsk & I Fonfara et al 'A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity' (2012) 337 *Science* 816.
[40] Doudna & Sternberg note 1 op cit at 144.
[41] Ormond et al note 6 op cit at 168.
[42] Doudna & Sternberg note 1 op cit at 194.
[43] Doudna & Sternberg note 1 op cit at 194.
[44] Ibid.
[45] E Deltcheva, K Chylinski & CM Sharma et al 'CRISPR RNA maturation by trans-encoded small RNA and host factor RNase III' (2011) 471(7340) *Nature* 602; Bruce note 4 op cit at 192.
[46] Bruce note 4 op cit at 193.

Cas9 could be transferred into cells which do not contain its components, and externally controlled in those cells.[47] In a study published two weeks later, Jinek et al discovered that crRNA and tracrRNA can be fused into a single-guide RNA (sgRNA), simplifying the CRISPR tool.[48] This discovery 'enabled the CRISPR-Cas9 complex to edit genomes of multicellular organisms.'[49]

By 2013 a number of studies demonstrated the preciseness of CRISPR-Cas9 in targeting and cutting specific DNA sequences.[50] Cong et al were the first to successfully utilise CRISPR-Cas9 in the DNA of human and mouse cells, demonstrating the technology's 'easy programmability and wide applicability.'[51]

The first application of CRISPR-Cas9 in human embryos occurred in 2015, when Liang et al engaged in CRISPR-Cas9 editing of the human β-globin (*HBB)* gene.[52] Mutations in this gene can cause a β-thalassemia blood disorder which reduces haemoglobin production.[53] The scientists utilised human tripronuclear embryos,[54] which are non-viable due to fertilisation by two sperm cells, rather than one.[55] These embryos, which are discarded by in vitro fertilisation (IVF) clinics, may serve as a valuable alternative in studies on human embryos.[56] Despite the use of non-viable human embryos in 'a deliberate attempt to head off ethical concerns,'[57] Liang et al's research 'ignited a wide-ranging debate about what types of gene editing research are ethical,'[58] as well as how to publish the findings of such research.[59]

[47] R Sapranauskas, G Gasiunas & C Fremaux et al 'The Streptococcus thermophilus CRISPR/Cas system provides immunity in Escherichia coli' (2011) 39(21) *Nucleic Acids Research* 9275; Bruce note 4 op cit at 194.
[48] Jinek et al note 39 op cit; Bruce note 4 op cit at 194.
[49] Bruce note 4 op cit at 195.
[50] P Mali, L Yang & KM Esvelt, et al 'RNA-Guided Human Genome Engineering via Cas9' (2013) 339(6121) *Science* 823; L Cong, FA Ran & D Cox et al 'Multiplex genome engineering using CRISPR/Cas systems' (2013) 338(6121) *Science* 819; Jinek et al note 39 op cit; SW Cho, S Kim & JM Kim et al 'Targeted genome engineering in human cells with the Cas9 RNA-guided endonuclease' (2013) 31(3) *Nature Biotechnology* 230; Ormond et al note 6 op cit at 168.
[51] L Cong, FA Ran & D Cox et al 'Multiplex genome engineering using CRISPR/Cas systems' (2013) 338(6121) *Science* 819.
[52] Liang et al note 33 op cit.
[53] Ibid at 364.
[54] Ibid at 369.
[55] *M Zhu* '"CRISPR/Cas9-mediated Gene Editing in Human Tripronuclear Zygotes" (2015), by Junjiu Huang et al.' (2017) *The Embryo Project Encyclopaedia* available at *https://embryo.asu.edu/pages/crispr-cas9-mediated-gene-editing-human-tripronuclear-zygotes-2015-junjiu-huang-et-al*, accessed on 29 Oct 2020.
[56] Liang et al note 33 op cit at 364.
[57] D Cyranoski & S Reardon 'Embryo editing sparks epic debate' (2015) 520 *Nature* 593 at 593.
[58] Ibid.
[59] Ibid.

The scientists began by injecting CRISPR-Cas9 into 86 embryos.[60] After 48 hours, 71 embryos remained alive and 54 of those were genetically tested to observe the results.[61] Only 28 of the 54 displayed successful double-strand breaks, and only four of the 28 were able to repair these breaks.[62] For this reason, along with the observation of off-target effects and mosaicism, the scientists concluded that CRISPR-Cas9 was not ready for clinical application.[63] When mosaicism occurs, the embryo contains cells with different genetic sequences — some are genetically edited and other are not.[64] This could result in a person who presents some characteristics of the disease that was intended to be edited out.[65] Off-target mutations are caused when CRISPR-Cas9 creates unwanted cuts at sites other than the target site.[66] This occurs when the off-target site has a similar DNA sequence to the target site.[67] This can cause deletions, inversions and translocations in the DNA sequence.[68] There is a need for further research into the understanding of CRISPR-Cas9 in human cells, particularly the understanding of off-target effects.[69]

CRISPR-Cas9 was applied to viable embryos in 2017.[70] Ma et al fertilised healthy donor oocytes with sperm from a patient who was heterozygous for the *MYBPC3* mutation.[71] This mutation causes hypertrophic cardiomyopathy.[72] The scientists injected sgRNA, Cas9 and single-stranded oligodeoxynucleotide (ssODN DNA) into the embryos.[73] Three days later they sequenced the embryos and observed a 97.1 percent survival rate.[74] A 72.2 percent rate of targeting efficiency was observed.[75] These findings showed that 'CRISPR-Cas9 gene targeting in human zygotes is exceptionally efficient.'[76] To address the concern of off-target effects, the patient's whole genome was sequenced and sixteen potential off-target sites were identified.[77]

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[60] Liang et al note 33 op cit.
[61] Ibid.
[62] Ibid.
[63] Liang et al note 33 op cit at 364; Cyranoski & Reardon note 57 op cit at 593.
[64] K Smith 'Time to start intervening in the human germline? A utilitarian perspective' (2020) 34 *Bioethics* 90 at 99.
[65] Ibid.
[66] T Koo, J Lee & J Kim 'Measuring and Reducing Off-Target Activities of Programmable Nucleases Including CRISPR-Cas9' (2015) 38(6) *Molecules and Cells* 475 at 476.
[67] Ibid.
[68] Ibid.
[69] Liang et al note 33 op cit at 364.
[70] Ma et al note 5 op cit.
[71] Ibid at 414.
[72] Ibid at 413.
[73] Ibid at 414.
[74] Ibid.
[75] Ibid at 415.
[76] Ibid.
[77] Ibid at 417.

These sites in seven of the zygotes were sequenced and scrutinised, and selected zygotes underwent whole genome sequencing.[78] No off-target mutations were observed, establishing that CRISPR-Cas9 has a high specificity rate of targeting in human embryos, and that the avoidance of off-target effects is possible.[79]

As a tool for gene editing, CRISP-Cas9 requires two things — a chimeric RNA that imitates the crRNA-tracrRNA heteroduplex (gRNA), and a Cas9 protein.[80] The gRNA targets sequences which contain the tri-nucleotide protospacer adjacent motif (PAM), and which match the programmed gRNA sequence.[81] Cas9, which is guided to the target site by gRNA, seeks the PAM for targeting.[82] Cas9 then introduces a double-stranded break three to four base pairs from the PAM.[83] The cell repairs this double-strand break through homologous recombination using a supplied DNA molecule.[84] There are multiple different methods to deliver gRNA and Cas9 for gene editing, including transfection and microinjection for cultured cells and animal embryos.[85]

It is appropriate at this point to distinguish between the two types of cells — somatic and germline — which may be genetically edited. Somatic gene editing 'refers to the alteration of cells that cannot contribute to gamete formation and thus cannot be passed on from the individual to offspring.'[86] Thus, the genetic editing of somatic cells 'will be limited to the treated individual and will not affect future offspring.'[87] While somatic gene editing clinical trials are in progress, the gene editing of germline cells is more controversial, and generally banned.[88] This is because it 'occurs in a germ cell or embryo and results in changes that are theoretically present in all cells of the embryo and that could also potentially be passed from the modified individual to offspring.'[89] Since it is heritable, gene editing in germline cells has

[78] Ibid.
[79] Ibid.
[80] Sakuma & Yamamoto note 23 op cit at 26.
[81] Liang et al note 33 op cit at 363.
[82] Sakuma & Yamamoto note 23 op cit at 26; Ormond et al note 6 op cit at 168.
[83] Sakuma & Yamamoto note 23 op cit at 168.
[84] Charpentier & Doudna note 37 op cit at 50; Ma et al note 5 op cit at 413.
[85] Sakuma & Yamamoto note 23 op cit at 33.
[86] Ormond et al note 6 op cit at 169.
[87] BM Knoppers, MT Nguyen & F Noohi et al 'Human Genome Editing Ethical and Policy Considerations Policy Brief' (2018) 3.
[88] Ibid.
[89] Ormond et al note 6 op cit at 169.

more rigorous ethical issues,[90] but its research has potential to improve knowledge of genetic disease and early human development.[91]

This section provided a simplified explanation of the process of CRISPR-Cas9 gene editing. CRISPR-Cas9 shows great potential for the treatment and prevention of disease, however, its application raises many ethical arguments. These ethical issues are discussed in the following section.

III HERITABLE HUMAN GENE EDITING SPARKS GLOBAL DEBATE

In this section I discuss the ethical issues that have been raised in debates on the application of CRISPR-Cas9 and heritable human gene editing (HHGE) in general. HHGE is a polarising issue.[92] To some, its application in any form is 'heinous, a perverse violation of the sacred laws of nature and the dignity of life.'[93] On the other side of the scale are those who 'see the genome simply as software — something we can fix, clean, update, and upgrade — and argue that leaving human beings at the mercy of faulty genetics is not only irrational, but immoral.'[94] For this reason, there are recommendations ranging from a complete prohibition of HHGE, to unrestrained scientific research on the topic.[95] In the following subsections I identify some of the ethics issues raised in discussions on the potential failure, and the potential success,[96] of CRISPR-Cas9.

(a) Issues arising from the failure of CRISPR-Cas9

The application of CRISPR-Cas9 poses safety and efficacy concerns[97] such as mosaicism[98] and off-target mutations.[99] Methods of measuring the occurrence of off-target effects must be

[90] Ibid.
[91] Cyranoski & Reardon note 57 op cit at 594.
[92] Doudna & Sternberg note 1 op cit at 24.
[93] Ibid.
[94] Ibid.
[95] J Doudna 'Embryo editing needs scrutiny' (2015) 528 *Nature* S6.
[96] Ormond et al note 6 op cit 169.
[97] Bu note 2 op cit at 117; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 411; KR Smith, S Chan & J Harris 'Human Germline Genetic Modification: Scientific and Bioethical Perspectives' (2012) 43 *Archives of Medical Research* 491 at 502.
[98] Bu note 2 op cit at 122; Ma et al note 5 op cit at 414; Ormond et al note 6 op cit 168; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 411; Knoppers et al note 87 op cit at 4.
[99] Knoppers et al note 87 op cit at 4; Bu note 2 op cit at 117; Ma et al note 5 op cit at 414; Ormond et al note 6 op cit at 168; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 411; KR Smith, S Chan & J Harris 'Human Germline Genetic Modification: Scientific and Bioethical Perspectives' (2012) 43 *Archives of Medical Research* 491 at 502; Smith note 64 op cit at 99.

developed and standardised to ensure that experimental results can be correctly analysed.[100] However, the assessment of the safety of CRISPR-Cas9 'requires years if not decades of studying how genes play out in a lifespan.'[101] This is due to the heritability of germline edits.[102] Safety can only be determined by creating children through the technology, so if a low level of risk is required before clinical application, such application will never occur.[103] Research must 'establish reliability, validity, safety, and efficacy'[104] of CRISPR-Cas9 before the implantation of an embryo which has been genetically edited.[105]

While it is clear that these safety and efficacy issues must be scientifically addressed before the clinical application of CRISPR-Cas9,[106] they are not 'a valid objection'[107] to gene editing.[108] The known risks of a health intervention should be balanced against the potential benefits.[109] However, the benefits of CRISPR-Cas9 are 'at best hypothetical,'[110] and its risks are partially unknown.[111] Thus, at this time, the hypothetical benefits cannot outweigh the possible risks.[112] Bu argues that once safety has been determined, ethical concerns will likely 'be outweighed by the ethical imperative to avoid disease.'[113]

Those who oppose HHGE due to the safety and efficacy issues discussed above often utilise the precautionary principle in their arguments. The precautionary principle is subject to different interpretations, the strongest of which would entail that we engage in no HHGE at all, notwithstanding any potential benefits, because there is a level of risk involved.[114] This is a flawed argument as it would amount to the decision not to take action whenever the slightest risks are involved.[115] The utilisation of the precautionary principle in this manner is also unsuccessful due to its vagueness.[116] Furthermore, considering the risks involved with any specific technology, one must also account for the risks that could occur *if the technology is*

[100] Doudna note 95 op cit; Ormond et al note 6 op cit at 172.
[101] Bu note 2 op cit at 120.
[102] Ibid.
[103] Smith note 64 op cit at 101.
[104] Ormond et al note 6 op cit at 172.
[105] Ibid.
[106] KR Smith, S Chan & J Harris 'Human Germline Genetic Modification: Scientific and Bioethical Perspectives' (2012) 43 *Archives of Medical Research* 491 at 492.
[107] Ibid.
[108] Ibid.
[109] Ormond et al note 6 op cit at 169; Smith et al note 106 op cit at 502.
[110] Bu note 2 op cit at 120.
[111] Ibid.
[112] Ibid.
[113] Ibid at 122.
[114] Smith et al note 106 op cit at 503.
[115] Ibid.
[116] Ibid.

prohibited and its benefits are not gained.[117] A more moderate version of the precautionary principle would be that risks and benefits must be analysed in order for the most cautious course of action to be employed, or the course of action that 'results in the greatest ratio of benefits to harms.'[118]

A potential critique against this moderate version of the precautionary principle would be that there exist 'unknown or uncertain risks.'[119] How should society deal with such unknown risks inherent in any new technology? One who favours a strong version of the precautionary principle 'tends to advocate a risk-averse approach to unknown consequences and favours precaution in situations where we cannot clearly estimate the outcomes of action.'[120] Smith et al argue that this applies only when 'one believes that the route to moral blamelessness is always to do nothing.'[121] Given the potential benefit of a new technology, a wiser approach, I suggest, would be to explore the safety of the new technology in a cautious, controlled, and gradual fashion, rather than to do forbid it and forgo its potential benefits.

Concerns of the safety of HHGE are valid, but it cannot be expected that technologies must be absolutely risk-free before application or research.[122] Shozi warns of the possible risks involved in an overly cautious approach, which could pose

> 'a danger of delaying good science, and the longer that delay, the more people who are born, suffer and die without benefiting from a therapeutic intervention that could have had a major impact on their lives.'[123]

Even once the safety issues have been addressed, the successful application of CRISPR-Cas9 raises ethical issues. These are addressed in the following subsection.

(b) Issues arising from the success of CRISPR-Cas9

(i) Consent

Informed consent is raised as an ethical issue emanating from HHGE.[124] If a parent were to decide to genetically edit their future child, this would be done without the consent of that

[117] Ibid.
[118] Ibid.
[119] Ibid.
[120] Ibid.
[121] Ibid.
[122] Ibid at 509.
[123] B Shozi 'A critical review of the ethical and legal issues in human germline gene editing: Considering human rights and a call for an African perspective' (2020) 13(1) *SAJBL* 62 at 66.
[124] Bu note 2 op cit at 128.

child.[125] Thus, some argue that parental decisions to genetically edit an embryo infringe the autonomy of the future child and the right to an open future.[126] However, this is true for decisions to utilise other reproductive technologies such as IVF, pre-implantation genetic diagnosis (PGD), artificial insemination and the use of donor embryos.[127] It is widely accepted that parents make medical decisions for their children until they reach the age to make their own decisions.[128] It is assumed that parents will make decisions which are in their children's best interests, since they have 'the most to lose or gain from a decision and will ultimately make decisions that reflect the future values and beliefs of their children.'[129]

Thus, as Smith et al argue, if the potential risks and benefits of such decisions are considered, exposure to a risk of harm is not wrong.[130] While there is a parental obligation not to make decisions that will cause harm to their children, there is also an obligation to make decisions that will potentially benefit them.[131] From a utilitarian perspective, the lack of consent would not classify as a disutility because it is impossible to obtain consent from the future child.[132] A utilitarian approach would not consider the lack of consent from the prospective child, but rather focus on the benefits and harms to the child.[133]

(ii) Potential unforeseen risks for future generations

Being heritable, HHGE poses risks not only to individuals born of the technology, but also to future generations of people emanating from those individuals.[134] Lanphier et al argue that this makes it 'dangerous and ethically unacceptable.'[135] Since HHGE carries a certain level of risk of error, these errors could be passed down from generation to generation.[136] However, as argued by Smith et al, the possible benefits will also be passed down.[137] Further, if HHGE is not employed, the diseases which it could have prevented will also be passed down to future generations.[138]

[125] Bu note 2 op cit at 128; Ormond et al note 6 op cit at 171; Smith et al note 106 op cit at 504.
[126] Smith et al note 106 op cit at 504.
[127] Smith note 64 op cit at 101.
[128] Ormond et al note 6 op cit at 171; Smith et al note 106 op cit at 504.
[129] Ormond et al note 6 op cit at 171.
[130] Smith et al note 106 op cit at 504.
[131] Ibid.
[132] Smith note 64 op cit at 101.
[133] Ibid at 102.
[134] Smith et al note 106 op cit at 504; Bu note 2 op cit at 117; Knoppers et al note 87 op cit at 5; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 410.
[135] E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 410.
[136] Smith et al note 106 op cit at 505.
[137] Ibid.
[138] Ibid.

Some argue that HHGE will affect individuals in future generations, 'in the sense of who they are as well as whether they are made better or worse by our present choices.'[139] This raises the so-called 'non-identity problem,' which is often raised in the context of artificial reproductive technologies. Applied to HHGE, the non-identity problem argument can be formulated as follows: If we decide not to employ HHGE, *certain* people will be born into future generations.[140] If we choose to employ HHGE, *different* people will be born.[141] Individuals born into future generations who are affected by HHGE would *not have existed* had we decided not to employ the technology.[142] We cannot, therefore, argue that they would have had better or worse lives if not for HHGE, because they would not have existed.[143]

Thaldar and Shozi address the non-identity problem, stating that it 'creates a false dilemma.'[144] The court in *Ex Parte KAF* distinguished between 'the mental construct of the prospective child'[145] and embryos. Thus, the court did not have a duty to consider the best interests of embryos as prospective children.[146] Embryos are not to be viewed as prospective children, but as biological material.[147] This demonstrates that 'there is no continuity of identity between any particular in vitro embryo and the identity of the person who is born using that embryo.'[148] The identity of a child 'is continuous with the mental construct of the prospective child and not with the embryo,'[149] thus, if one were to choose one of two embryos, one would not be choosing between two children. The choice of one specific embryo does not equate to the choice of one specific child, as both embryos can result in the same prospective (mentally constructed) child.[150]

The position is summarised by de Miguel Beriain, who argues that

> 'it seems absurd from a moral point of view to consider that a general avoidance of human germ line editing would free us from all types of responsibility to our descendants. Would anyone hold that we would take no moral responsibility for allowing someone to be born with Huntington's

[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] Ibid.
[143] Ibid.
[144] D Thaldar & B Shozi 'Procreative Non-Maleficence: A South African Human Rights Perspective on Heritable Human Genome Editing' (2020) 3(1) *The CRISPR Journal* 32 at 35.
[145] Ibid; Ex Parte KAF 2019 (2) SA 510 (GJ).
[146] Thaldar & Shozi note 144 op cit at 35.
[147] Ibid.
[148] Ibid.
[149] Ibid.
[150] Ibid.

disease if we had a tool to cure him or her? It seems clear that the answer to this question must be a resounding "no."'[151]

(iii) Eugenics

Slippery slope arguments are often utilised in opposition to HHGE.[152] The slippery slope argument is that an action which may seem inoffensive and even beneficial, when undertaken, may have the effect of causing the occurrence of malevolent future acts.[153] For example, one may argue that allowing somatic gene editing will lead us down the slippery slope to the allowance of germline gene editing.[154] This argument relies on the unjustified assumption that germline gene editing is morally or ethically unacceptable.[155] Another example of the slippery slope argument is that allowing somatic gene editing will send us down a slippery slope to eugenics.[156] This type of argument 'derives its power from its appeal to facts and probabilities which it would be pointless to try empirically to prove.'[157] The slippery slope argument is based on the precautionary principle — it would be unethical to attempt human germline gene editing because this could send us down the slippery slope to dystopia.[158] This is an illogical argument as there is no established 'plausible and strong link between the early use of a new technology and the evoked dystopian future.'[159] Lanphier et al express the concern, in the form of a slippery slope argument, that human germline gene editing research 'could be exploited for non-therapeutic modifications.'[160] Non-therapeutic application of HHGE, or genetic enhancement, in particular, brings up concerns of eugenics as it involves the choosing of favourable traits.[161] This is likely a result of the connection between genetics and eugenics in history.[162]

While slippery slope arguments do not carry much weight in bioethical arguments, the concern that human germline gene editing could lead to the implementation of eugenics is certainly worrying. Eugenics can be defined as the attempt to 'improve' humankind by increasing the reproduction of people with 'desirable' traits and decreasing the reproduction of

[151] I de Miguel Beriain 'Should human germ line editing be allowed? Some suggestions on the basis of the existing regulatory framework' (2019) 33 *Bioethics* 105 at 108.
[152] T McGleenan 'Human gene therapy and slippery slope arguments' (1995) 21 *Journal of Medical Ethics* 350 at 350.
[153] Ibid.
[154] Ibid at 353.
[155] Ibid at 354.
[156] Ibid.
[157] Ibid.
[158] Smith note 64 op cit at 103.
[159] Ibid.
[160] Lanphier et al note 135 op cit at 410.
[161] Ormond et al note 6 op cit.
[162] Ibid.

people with 'undesirable' traits.[163] In this way, eugenics can be positively or negatively implemented, through the selection and retention of traits which are deemed 'positive,' and the deletion of traits which are deemed 'negative,' respectively.[164] Both forms are harmful and instil prejudice in society.[165]

Eugenics was rife in America in the 1920s.[166] The Eugenics Record Office, which was established in 1910, was run by scientists who utilised genetics to promote discrimination.[167] Its research 'spurred forced-sterilization campaigns and barred refugees from entering Ellis Island.'[168] Eugenics was accepted as a science, with disease, disability and 'undesirable traits'[169] being identified for breeding out.[170] The Eugenics Record Office had gained influence over government by the 1920s, resulting in the enactment of the Immigration Act of 1924 and the forced sterilisation of thousands of people.[171] It also influenced Nazi ideologies in Germany.[172] Eugenics had a horrific effect in Germany, causing the Holocaust and forced sterilisations under the rule of Nazi Germany.[173] The misuse of human germline gene editing for eugenics would be a crime against humanity.[174] Opponents of human germline gene editing liken it to 'liberal eugenics' where parents can choose to edit their offspring.[175]

Those who support HHGE argue that

> 'what was wrong with eugenics practices was unrelated to the aspiration of making biological changes that benefit future generations (such as by freeing them of genetic diseases), and rather that the means used to achieve this suppressed liberty, by depriving individuals of reproductive choice.'[176]

The difference between eugenics and HHGE is that the former limited procreative freedom in order to breed 'improved' humans, while the latter promotes procreative freedom

[163] T Ishii 'Germ line genome editing in clinics: the approaches, objectives and global society' (2015) *Briefings in Functional Genomics* 1 at 6.
[164] Ormond et al note 6 op cit at 171.
[165] Ibid.
[166] JA Krisch 'When Racism was a Science' (2014) *New York Times* available at *https://www.nytimes.com/2014/10/14/science/haunted-files-the-eugenics-record-office-recreates-a-dark-time-in-a-laboratorys-past.html*, accessed on 5 Nov 2020.
[167] Ibid.
[168] Ibid.
[169] Ibid.
[170] Ibid.
[171] Ibid.
[172] Ibid.
[173] Ishii note 163 op cit at 6.
[174] Ibid.
[175] Shozi note 123 op cit at 63.
[176] Ibid.

by leaving the choice up to individuals.[177] Further, the arguments against genetic enhancement assume that 'there are no morally justifiable reasons for enhancement applications'[178] of HHGE. One morally justifiable reason for genetic enhancement is the 'selection of desirable genetic traits in future offspring, in a way similar to choosing embryos using the information generated by pre-implantation genetic testing,'[179] such as genetic selection against single-gene disorders.[180]

(iv) 'Playing God' and the sacrality of the human genome

Gene editing is deemed wholly unethical by those who oppose interference in the human gene pool.[181] These objections are often bolstered in the argument that gene editing constitutes 'playing God.'[182] Those who utilise the 'playing God' argument view the human genome as sacred and inextricably linked to human dignity.[183] This view assumes that 'there is something like an inner human nature that is grounded in our genes, that is, in the human genome.'[184] The reliance on this unjustified assumption renders the argument illogical.[185] The gene pool is impacted by many decisions, such as the decision to abort when an embryo is defective, or choosing a specific person to reproduce with.[186]

Even if one were to consider the genome as designed by God, it is still a constantly changing entity.[187] The genetic makeup of a person is affected by mutations and environmental factors such as nutrition.[188] Further, natural selection, which occurs during the course of evolution, results in the alteration of genetic sequences.[189] Gene editing is simply a more efficient and precise manner in which to alter genetic sequences.[190] Thus, Smith et al argue, to accept natural selection and selective breeding, but reject gene editing, is 'a form of naturalistic

[177] D Thaldar, M Botes & B Shozi et al 'Human germline editing: Legal-ethical guidelines for South Africa' (2020) 116 (9/10) *South African Journal of Science* 1 at 4.
[178] Ibid.
[179] Ibid.
[180] Ibid.
[181] Smith et al note 106 op cit at 505.
[182] Ibid at 492.
[183] De Miguel Beriain note 151 op cit at 107.
[184] Ibid.
[185] Smith et al note 106 op cit at 504.
[186] Ibid.
[187] De Miguel Beriain note 151 op cit at 107.
[188] Ibid at 108.
[189] Smith et al note 106 op cit at 492.
[190] Ibid.

fallacy.'[191] The argument that HHGE is 'playing God' is unfounded as it would merely modify a continuously changing genome.[192]

Another logical argument is that the germline modification of a person's genome does not necessarily modify the human genome in terms of the gene pool of the human species.[193] De Miguel Beriain provides the example of replacing a mutated *HTT* gene with a healthy version of the gene.[194] This is a change to the person's genome, but it would not incorporate anything new to the human gene pool.[195]

Arguments surrounding the sacrality of the genome assume that the genome has moral significance and that it is a basis of human identity.[196] I agree with Shozi's response that the idea that the genome in its 'natural' form is a basis of human identity is an exaggeration of the influence that genetics have on the identity of persons.[197] He argues that debates surrounding CRISPR-Cas9 'omit relevant, context-specific factors'[198] for South Africa, such as the scourge of HIV, and suggests that CRISPR-Cas9 research could eventually play an important role in decreasing such disease.[199]

(v) Access

Should HHGE become available for clinical application, access to it may be limited,[200] most likely to those who can afford it, which would increase differences in the incidence of diseases and conditions between those with different socio-economic standings.[201] This raises concerns that genetic disease could turn into 'an artifact of class, geographic location, and culture.'[202] This is especially relevant in South Africa, where there are existing wealth and healthcare access inequalities.[203] These concerns are valid, however, they are not sufficient reason to prohibit the use of such technologies.[204] It would be illogical to prohibit any members of society

[191] Ibid.
[192] De Miguel Beriain note 151 op cit at 108.
[193] Ibid.
[194] Ibid.
[195] Ibid.
[196] Shozi note 123 op cit at 64.
[197] Ibid.
[198] Ibid at 66.
[199] Ibid.
[200] A Dhai, G Gray & M Veller et al 'Governance of gene editing in South Africa: Towards addressing the ethico-legal hiatus' (2020) 116(5/6) *S Afr J Sci* available at *https://doi.org/10.17159/sajs.2020/7933* at 1.
[201] Ormond et al note 6 op cit at 172.
[202] Ibid.
[203] Thaldar et al note 177 op cit at 5.
[204] Smith et al note 106 op cit at 510.

from benefitting from technology simply because others will not be able to access it.[205] Rather, measures should be put in place to ensure wider access.[206] Historically, new technologies are expensive and attainable by the wealthy and, as they age, they become available to a wider range of people.[207] Thaldar et al consider the dictum which calls for 'equality of the vineyard not the graveyard.'[208] This means that HHGE should not be restricted on the grounds of concerns regarding equal access but should rather be allowed and promoted to ensure increasingly wide access.[209]

(vi) The use of embryos in research

Another reason offered for the rejection of HHGE is the use, and resultant loss, of embryos.[210] This argument is based largely on 'religious dogma or intuitive responses,'[211] which hold that embryos should be given respect in the same way as humans are.[212] Smith et al argue that embryos are not ethically significant because they are not sentient and do not have personhood.[213] An embryo cannot have interests, and in this way, 'cannot be harmed (in an ethically meaningful way) by death.'[214]

Some reject this argument based on the potential of embryos to become sentient. However, such arguments cannot be considered as

> '[l]ogically, where entity A, with no interests, has the potential to develop into entity B, with interests, it does not follow that A ought to be treated as if it already possesses those interests. By analogy, it would be inappropriate to accord environmental protection to an acorn simply because it has the potential to develop into an oak tree.'[215]

Opponents of HHGE on the basis of embryo death should logically reject in vitro fertilisation for the same reason.[216] The popularity of IVF as a fertility treatment indicates that there is no major opposition to embryo death in this context.[217]

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[205] Ibid.
[206] Ibid.
[207] Thaldar et al note 177 op cit at 5.
[208] Ibid.
[209] Ibid.
[210] Smith et al note 106 op cit at 492.
[211] Ibid.
[212] Ibid.
[213] Ibid.
[214] Ibid.
[215] Ibid.
[216] Ibid.
[217] Ibid.

While it is clear that the application of CRISPR-Cas9 in HHGE raises many ethical issues, it has been established that these concerns must not impede basic scientific research. The following section analyses the global ethical attitude towards CRISPR-Cas9 in light of the ethical concerns discussed above.

IV THE INTERNATIONAL ETHICS FRAMEWORK

This section is largely based on Brokowski's article entitled *Do CRISPR Germline Ethics Statements Cut It?* which analyses 61 international ethics statements and reports published between 2015 and 2018.[218] The statements, which all consider the ethics surrounding CRISPR-Cas9, vary 'from being direct, pithy, and practical to expansive, indeterminate, nuanced, and philosophical.'[219] This section facilitates an understanding of international ethical attitudes towards CRISPR-Cas9.

Of the 61 reports, 55 expressly differentiate basic research from clinical research.[220] The remainder of the reports do not address this issue.[221] This has an impact on the way in which the reports are interpreted — a lack of differentiation may result in vagueness or over-restrictiveness in the case of prohibitions on genetic editing. The majority of the statements, in fact, 54 per cent of them, were of the view that HHGE is not currently acceptable.[222]

Seven of the reports, comprising eleven per cent, hold that while HHGE is not currently accepted, it could potentially be permitted under certain conditions.[223] The US National

[218] C Brokowski 'Do CRISPR Germline Ethics Statements Cut It?' (2018) 1(2) *The CRISPR Journal* 115 at 117–119.
[219] Ibid at 116.
[220] Ibid.
[221] European Group on Ethics in Science and New Technologies 'Statement on gene editing' (2016); European Society of Gene and Cell Therapy 'Editing our future: Facilitating dialogue on the use of gene-editing to modify human embryos' available at *http://www.esgct.eu/Content/Media/ESGCT%20FSGT%20Congress%20and%20Debate%20Press%20Release.pdf*, accessed on 5 Nov 2020; Alliance for Regenerative Medicine 'The alliance for regenerative medicine issues statement in response to reports of first use of genome editing technology in human embryos in the US' (2017); American Society for Investigative Pathology 'Position statement of the American Society for investigative pathology on manipulation of the human genome' (2015); Centre for Genetics and Society 'Open letter calls for prohibition on reproductive human germline modification' (2015); Editas Medicine 'Editas Medicine comments in connection with International Summit on Human Gene Editing' (2015).
[222] Brokowski note 218 op cit at 122.
[223] National Academies of Sciences Engineering and Medicine 'Human genome editing: science, ethics, and governance' (2017); The Danish Council on Ethics 'Statement from the Danish Council on Ethics in genetic modification of future humans: in response to advances in the CRISPR technology' (2016); Hellenic National Bioethics Commission 'Recent developments in human genome modification: genome editing' (2016); G de Wert, G Pennings & A Clarke et al 'HHGE: Recommendations of ESHG and ESHRE' (2018) 26 *European Journal of Human Genetics* 445 at 447; The Hinxton Group 'Statement on genome editing technologies and human germline genetic modification' available at *http://www.hinxtongroup.org/hinxton2015_statement.pdf*, accessed on 12 Nov 2020; The National Academies of Sciences, Engineering, and Medicine 'On Human

Academies of Sciences Engineering and Medicine (NASEM) recommends that clinical application of HHGE should be allowed 'only within a robust and effective regulatory framework,'[224] that includes, among other things, a restriction to the prevention of serious diseases.[225] Basic research is necessary to determine the risks and benefits of HHGE technologies.[226] Only once its risks and benefits are understood, and there is broad societal consensus, should clinical application of CRISPR-Cas9 be permitted.[227]

The Royal Netherlands Academy of Arts and Sciences (KNAW) mirrors the approach of NASEM in its position that once the risks and benefits of HHGE are understood, and there is broad societal consensus, clinical application should be permitted. [228] Thus, KNAW promotes basic scientific research for the advancement of knowledge surrounding gene editing technologies.[229]

The Danish Council on Ethics recommends that germline gene editing should be prohibited 'until the technologies are far more developed and safety tested than the case is today, and there are major technical problems to overcome before this will be the case.'[230] While a majority of the Danish Council were of the view that germline gene editing would be ethically irresponsible,[231] six members differed from this by considering the balancing of risks and benefits and opining that germline gene editing should be allowed in the case of serious disease.[232]

The European Society of Human Genetics (ESHG) and European Society of Human Reproduction and Embryology (ESHRE) recognise that basic research is necessary before the clinical application of CRISPR-Cas9.[233] This would allow for the determination of safety issues and the reduction of risk for future generations.[234] Basic research would allow for the analysis

Genome Editing: International Summit Statement' (2015); Royal Netherlands Academy of Arts and Sciences 'Genome editing: Position paper of the Royal Academy of Arts and Sciences' (2016).
[224] National Academies of Sciences Engineering and Medicine 'Human genome editing: science, ethics, and governance' (2017) 134.
[225] Ibid.
[226] The National Academies of Sciences, Engineering, and Medicine 'On Human Genome Editing: International Summit Statement' (2015) 6.
[227] Ibid at 7.
[228] Royal Netherlands Academy of Arts and Sciences 'Genome editing: Position paper of the Royal Academy of Arts and Sciences' (2016) 3.
[229] Ibid at 1.
[230] The Danish Council on Ethics 'Statement from the Danish Council on Ethics in genetic modification of future humans: in response to advances in the CRISPR technology' (2016) 11.
[231] Ibid.
[232] Ibid at 13.
[233] G de Wert, G Pennings & A Clarke et al 'HHGE: Recommendations of ESHG and ESHRE' (2018) 26 *European Journal of Human Genetics* 445 at 447.
[234] Ibid.

and reduction of off-target effects using preimplantation genetic testing or whole genome sequencing.[235] The ESHG and ESHRE hold that if HHGE basic research demonstrates sufficient safety of HHGE, clinical applications may be ethically justified.[236]

The Hinxton Group holds that 'concerns about human genome editing for clinical reproductive purposes should not halt or hamper application to scientifically defensible basic research.'[237] Safety and efficacy issues must be addressed before the clinical application of HHGE.[238] This must be guided by a 'detailed but flexible roadmap,'[239] which would address the use of human embryos.[240]

An 'openness to further exploration'[241] was expressed in three of the statements.[242] The Dutch Commission on Genetic Modification and the Health Council of the Netherlands recommend that the ban on creating embryos for the purpose of scientific research should be removed, so as to allow the creation of embryos for certain research, including basic research on CRISPR-Cas9 germline genetic editing.[243] The Health Council of the Netherlands argues that the use of CRISPR-Cas9 for disease prevention is not a violation of human dignity. [244]

The Bioethics and Law Observatory of the University of Barcelona (the University of Barcelona) employs a gradual approach to the precautionary principle in the recommendation that gene editing should be permitted in phases.[245] The first phase requires basic research to be permitted.[246] Thereafter research in somatic cells should be permitted and, finally, the third phase involves 'evaluating the possibility of approving germline therapy in certain cases.'[247]

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[235] Ibid.
[236] Ibid.
[237] The Hinxton Group 'Statement on genome editing technologies and human germline genetic modification' available at *http://www.hinxtongroup.org/hinxton2015_statement.pdf*, accessed on 12 Nov 2020 at 3.
[238] Ibid at 6.
[239] Ibid.
[240] Ibid.
[241] Brokowski note 218 op cit at 122.
[242] Commission on Genetic Modification & the Health Council of the Netherlands 'Editing human DNA: Moral and social implications of germline genetic modification' (2017); Bioethics and Law Observatory of the University of Barcelona 'Document on bioethics and gene editing in humans' (2016); The Academy of Medical Sciences 'The Academy of Medical Sciences' response to the Nuffield Council on Bioethics "Genome editing and human reproduction"' (2017).
[243] Commission on Genetic Modification and the Health Council of the Netherlands 'Editing human DNA: Moral and social implications of germline genetic modification' (2017) 8.
[244] Ibid.
[245] Bioethics and Law Observatory of the University of Barcelona 'Document on bioethics and gene editing in humans' (2016) 45.
[246] Ibid.
[247] Ibid.

The United Kingdom (UK) Academy of Medical Sciences supports 'the future development of non-heritable and heritable therapeutics based on genome editing'[248] based on scientific evidence and the values of society determined through public engagement.[249] In light of the potential benefits of HHGE,[250] basic research is fully supported[251] and necessary for the increase of safety and efficiency.[252]

Of the 61 reports analysed by Brokowski, 59 were accessible. Of the 59 reports and statements accessed, only seven mention scientific freedom.[253] Of the seven reports that mention scientific freedom, only four go into any further detail.[254]

The International Bioethics Committee argues that freedom of scientific research is limited by ethics and regulations,[255] but 'should not be inhibited by too many strict regulations.'[256] The Hinxton Group recommend that decisions regarding HHGE must 'aim to strike the best possible balance between free scientific inquiry and social values.'[257] Further, it recommends that limitations

> 'of scientific inquiry should be derived from reasonable concerns about demonstrable risks of harm to persons, societal institutions, or society as a whole. Policymakers should refrain from constraining scientific inquiry unless there is substantial justification for doing so that reaches beyond disagreements based solely on divergent moral convictions.'[258]

[248] The Academy of Medical Sciences 'The Academy of Medical Sciences' response to the Nuffield Council on Bioethics "Genome editing and human reproduction"' (2017) 1.
[249] Ibid.
[250] Ibid at 2.
[251] Ibid at 1.
[252] Ibid at 3.
[253] On a search of 59 of the statements and reports, only seven of the reports yielded relevant results for the search terms 'freedom,' 'free,' and 'inquiry.' These reports are: Institut National de la Sante´ et de la Recherche Médicale 'Ethical issues surrounding CRISPR-Cas9 technology' (2016) 2; International Bioethics Committee 'Report of the IBC on updating its reflection on the human genome and human rights' (2015) 7; H Chneiweiss, F Hirsch & L Montoliu et al 'Fostering responsible research with genome editing technologies: a European perspective' (2017) 26(70) *Transgenic Research* 1 at 5; Knoppers et al note 87 op cit at 5; Federation of European Academies of Medicine 'The application of genome editing in humans' (2017) 6; The Hinxton Group note 237 op cit at 5; Nuffield Council on Bioethics 'Genome editing: An ethical review' (2016) 25.
[254] International Bioethics Committee 'Report of the IBC on updating its reflection on the human genome and human rights' (2015); The Hinxton Group note 237 op cit; Knoppers et al note 87 op cit; Nuffield Council on Bioethics 'Genome editing: An ethical review' (2016).
[255] International Bioethics Committee 'Report of the IBC on updating its reflection on the human genome and human rights' (2015) 10.
[256] Ibid at 7.
[257] The Hinxton Group note 237 op cit at 5.
[258] Ibid at 6.

In the context of gene editing, the application of restrictive regulation must be limited to research, or parts of research, that have been proven to be 'unacceptable,'[259] and such regulation must be 'proportionate to the magnitude of what is morally at stake.'[260]

Knoppers et al refer to scientific freedom in reference to the International Covenant on Economic, Social and Cultural Rights (ICESCR) right to enjoy the benefits of science and its applications.[261] They argue that 'the application of this right would guarantee scientific freedom as a core principle of liberal democracies and instil the obligation for governments to ensure access to new technologies.'[262]

The Nuffield Council on Bioethics states that contemporary arguments highlight scientific freedom in a context 'which makes scientific freedom conditional on doing no harm (rather than actually doing good).'[263] However, the practicality of scientific freedom is not as simple, since the consequences of some technological developments cannot be predicted.[264] In granting scientific freedom, a level of public trust is demonstrated, however, this trust is

> 'balanced between ambition and concern, and is sensitive to events and to narratives that celebrate the achievements of science, on the one hand, or draw attention to its failures, limitations and historical perversions, on the other.'[265]

None of the reports extend on what could be considered limitations on freedom of scientific research, nor engage in an analysis of freedom of scientific research in the context of gene editing. This demonstrates that freedom of scientific research is neglected in HHGE ethics statements and reports.

This section served to develop an understanding of the general international ethical attitudes towards CRISPR-Cas9. As can be seen, most international ethics statements oppose HHGE, while others do not take a position on its permissibility. HHGE is largely rejected, with none of the statements promoting the attitude that it should be permitted currently. However, a more explorative attitude also emerges. Those statements that consider a future which is permissive of HHGE provide that the risks and benefits must first be established, and that broad

[259] Ibid.
[260] Ibid.
[261] Art 15(1)(b), International Covenant on Economic, Social and Cultural Rights, UN General Assembly (16 December 1966) UNTS 993 (ICESCR).
[262] Knoppers et al note 87 op cit at 5.
[263] Nuffield Council on Bioethics 'Genome editing: An ethical review' (2016) 25.
[264] Ibid.
[265] Ibid.

societal consensus is important.[266] HHGE basic research is generally recognised as essential for the analysis of the risks and benefits of CRISPR-Cas9 HHGE. The general attitude towards freedom of scientific research is dismissive, with the majority of the reports failing to mention the freedom at all. Most of the statements which do mention freedom of scientific research fail to engage with the concept or apply it to CRISPR-Cas9.

V THE REGULATORY FRAMEWORKS OF FOREIGN JURISDICTIONS

In this section, I analyse the legal frameworks of twenty foreign jurisdictions.[267] I consider how each jurisdiction regulates genome editing in human embryos with a focus on three possible limitations on freedom of scientific research, namely:

- Whether each jurisdiction permits gene editing in human embryos;
- Whether each jurisdiction permits the creation of embryos for research purposes; and
- Whether each jurisdiction enforces the fourteen-day rule.

(a) Three possible limitations on gene editing in human embryos

The prohibition of gene editing in human embryos is a clear limitation on the right to freedom of scientific research as it prevents scientists from engaging in research in an area of their choosing.[268]

The prohibition of the creation of embryos for research purposes limits scientists to the use of surplus or non-viable embryos. Since non-viable embryos are defective, their use in research may be of little benefit.[269] This is demonstrated by the results of Liang et al's experiments on tripronuclear embryos.[270] Another issue is that most non-viable embryos will only be deemed non-viable or unsuited for implantation after undergoing preimplantation genetic diagnosis (PGD).[271] Before undergoing PGD, fertilised embryos are developed in vitro

[266] This call for broad societal consensus as a requirement for allowing HHGE is problematic in the South African context. This is discussed further in Section VI.
[267] Australia, Canada, China, Finland, Germany, Hungary, India, Israel, Italy, Lithuania, Netherlands, New Zealand, Republic of Korea, Singapore, Slovenia, Spain, Sweden, Switzerland, UK and the United States of America.
[268] T Wilholt 'Scientific Freedom: Its Grounds and Their Limitations' (2010) 41 Studies in History and Philosophy of Science 174 at 4.
[269] Dianne Nicol 'The Regulation of Human Germline Genome Modification in Australia' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 543–67 at 558.
[270] Ibid; Liang et al note 33 op cit.
[271] Nicol note 269 op cit at 557.

for three to six days, at which stage they will comprise of 100 to 150 cells.[272] This is an issue in research as the more developed an embryo is before the research begins, the more likely the occurrence of mosaicism is.[273]

The use of surplus IVF embryos is also insufficient for gene editing research utilising human embryos.[274] In order for IVF embryos to be deemed as surplus, the gamete donors will either have achieved pregnancy, or no longer wish to use the embryos to achieve pregnancy.[275] This entails that only frozen embryos will be surplus embryos.[276] This is problematic as

> '[w]hile it is possible to freeze zygotes and embryos at early cleavage stages, current best practice is for embryos to be frozen at much later cleavage stages, or at the blastocyst stage, making them unsuitable for the types of genome modification research currently being undertaken.'[277]

Once surplus IVF embryos reach researchers, they are already six to eight days old.[278] Again, this increases the likelihood of mosaicism.[279] Further, it shortens the gap in which research may be conducted before the embryos are fourteen days old.[280]

Van Beers et al argue that even if gene editing in human embryos is permitted, a prohibition on the creation of embryos is 'a de facto prohibition on research in the field of human germline editing, since the creation of research embryos is indispensable for the most important types of research in this field.'[281] Van Beers et al argue that the prohibition on creation of embryos for research is 'the main legal obstacle for research involving human germline editing.'[282] Thus, the prohibition on the creation of embryos for research is a limitation on freedom of research.[283]

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[272] Genetic Alliance UK 'Preimplantation Genetic Diagnosis: How Does It Work?' (2016) available at *https://geneticalliance.org.uk/information/service-and-testing/preimplantation-genetic-diagnosis-how-does-it-work/*, accessed on 12 Nov 2020; Family Fertility 'Preimplantation Genetic Diagnosis' available at *https://familyfertility.com/services/preimplantation-genetic-testing/preimplantation-genetic-diagnosis-pgd*, accessed on 12 Nov 2020; Igenomix 'What is PGD Testing and How Does it Work?' (2019) available at *https://www.igenomix.com/blog/fertility-challenges/what-is-pgd-testing-and-how-does-it-work/*, accessed on 12 Nov 2020.
[273] Commission on Genetic Modification & the Health Council of the Netherlands note 243 op cit at 32.
[274] Ibid at 6.
[275] Nicol note 269 op cit at 558.
[276] Ibid.
[277] Ibid.
[278] Commission on Genetic Modification & the Health Council of the Netherlands note 243 op cit at 32.
[279] Ibid.
[280] Ibid.
[281] Britta van Beers, Charlotte de Kluiver & Rick Maas 'The Regulation of Human Germline Genome Modification in the Netherlands' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 309–34 at 326.
[282] Ibid at 324.
[283] A Boggio, BM Knoppers & J Almqvist 'The Human Right to Science and the Regulation of Human Germline Engineering' (2019) 2(3) *The CRISPR Journal* 134 at 137.

The fourteen-day rule originated from the UK *Report of The Committee of Inquiry into Human Fertilisation and Embryology* (hereinafter referred to by its popular name, the Warnock Report).[284] The Committee convened to investigate the ethical issues surrounding emerging technologies in embryo research and infertility treatment.[285] The Committee decided that the human embryo must be legally protected in some manner.[286]

In order to decide on issues surrounding embryo research, the Committee considered the early stages of embryonic development.[287] While the Committee recognised that there is no specific stage in embryonic development which makes the embryo more worthy of protection than any previous stage, a 'precise decision must be taken, in order to allay public anxiety.'[288] Around the fifteenth day of embryonic development, the primitive streak appears.[289] The primitive streak is a 'heaping-up of cells at one end of the embryonic disc,'[290] and is the first distinguishable feature in embryonic development.[291]

The Committee considered different arguments on a possible time limit for embryo research.[292] One suggestion was that embryo research should be limited to 22 days after fertilisation, as this is when the neural tube (the precursor to the central nervous system) is almost fully formed.[293] Another suggestion was a twenty-day limit as this is when the neural tube begins to develop.[294] For this reason, the Committee came to an agreement on the fourteen-day rule, which was a compromise between the various different views.[295]

When the Warnock Report was published, embryos could only be maintained in vitro for a few days.[296] In 2016, Shahbazi[297] and Deglincerti[298] and their respective teams successfully developed human embryos in vitro for thirteen days. Both teams had to cease the development

[284] Department of Health & Social Security 'Report of the Committee of Inquiry into Human Fertilisation and Embryology' (1984).
[285] Ibid at 1.
[286] Ibid at 58.
[287] Ibid.
[288] Ibid at 65.
[289] Ibid at 59.
[290] Ibid.
[291] Ibid.
[292] Ibid at 65.
[293] Ibid.
[294] Ibid.
[295] Ibid at 66.
[296] S Chan 'How and Why to Replace the 14-Day Rule' (2018) *Current Stem Cell Reports* 1 at 2.
[297] MN Shahbazi, A Jedrusik & S Vuoristo et al 'Self-organisation of the human embryo in the absence of maternal tissues' (2016) 18(6) *Nature Cell Biology* 700.
[298] A Deglincerti, GF Croft & LN Pietila et al 'Self-organization of the in vitro attached human embryo' (2016) 533 *Nature* 251.

of the embryos at the fourteenth day due to the fourteen-day rule.[299] The ability to maintain embryos in vitro for fourteen days does not justify an extension of the rule[300] — as argued by Chan, 'the mere fact that something is possible does not mean we ought to do it, or that it is morally permissible.'[301] However, an extension of the rule could allow for the advancement of scientific knowledge, and these benefits 'weigh in favour of allowing research, providing a reason at least to reconsider whether a revision of the current rule might be justified.'[302]

An extension of the fourteen-day rule could benefit HHGE basic research in that it would allow scientists to better understand the effects of edits in later stages of development.[303] This would allow CRISPR-Cas9 to 'transition from "bench to bedside" safely and responsibly.'[304] Kofler & Kraschel argue that the fourteen-day rule might be a limitation on the 'development of clinical applications of CRISPR germline editing since it precludes assessments of efficacy, off-target effects, or other issues at later stages of embryonic development.'[305]

(b) Jurisdiction comparison

I chose the jurisdictions contained in this section as they were included in comparative studies on the regulation of HHGE.[306] The information included in these studies was verified through online searches. Where primary sources such as state laws could not be accessed as a result of a language or access barrier, I rely on secondary sources. I represent the information in the form of a table (Figure 1). The table consists of four columns — one for the states and one for each of the possible limitations I have identified. Reliance on a secondary source is noted with an asterisk. Following Figure 1, I discuss the results of the comparison.

[299] Ibid; Shahbazi et al note 297 op cit at 703.
[300] G Cavaliere 'A 14-day limit for bioethics: the debate over human embryo research' (2017) 18(38) *BMC Medical Ethics* 1 at 6; Chan note 296 op cit at 2.
[301] Chan note 296 op cit at 2.
[302] Ibid at 5.
[303] JB Appleby & AL Bredenoord 'Should the 14-day rule for embryo research become the 28-day rule?' (2018) *EMBO Molecular Medicine* 1 at 3.
[304] Ibid at 4.
[305] N Kofler & KL Kraschel 'Treatment of heritable diseases using CRISPR: Hopes, fears, and reality' (2018) 42 *Seminars in Perinatology* 515 at 520.
[306] Ishii note 163 op cit; R Yotova 'The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law' (2017); Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020).

Figure 1: Table of the regulation of HHGE research in terms of three possible limitations on freedom of scientific research

STATE	GENE EDITING IN HUMAN EMBRYOS	CREATION OF EMBRYOS FOR RESEARCH	14-DAY RULE
Australia	Uncertain[307]	Prohibited[308]	Enforced[309]
Canada	Uncertain[310]	Prohibited[311]	Enforced[312]
China*	Permitted[313]	Prohibited[314]	Enforced[315]
Finland	Permitted[316]	Prohibited[317]	Enforced[318]
Hungary	Prohibited[319]	Prohibited[320]	Irrelevant
Germany	Permitted[321]	Prohibited[322]	Indirectly enforced[323]*
India*	Permitted[324]	Prohibited[325]	Enforced[326]

[307] S 15, Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 172 of 2006.
[308] S 14, ibid.
[309] Ibid.
[310] S 5(1)(f), Assisted Human Reproduction Act 2004.
[311] S 5(1)(b) & S60(a), ibid.
[312] S 60(a), ibid.
[313] Lingqiao Song & Rosario Isasi 'The Regulation of Human Germline Genome Modification in the People's Republic of China' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 469–99 at 488.
[314] Ibid.
[315] Ibid; Ministry of Science and Technology & Ministry of Health 'Ethical Guidelines for Human Embryonic Stem Cell Research' (2003); Bu note 2 op cit at 127.
[316] S 15, Medical Research Act 488 of 1999.
[317] S 13, ibid.
[318] S 11 & s13, ibid.
[319] S 168, Act C of 2012 on the Criminal Code.
[320] S 172(1), ibid.
[321] S 5(4), Embryo Protection Act 1990.
[322] S 1(1), ibid.
[323] Embryos are granted the right to life fourteen days after fertilization (Timo Faltus 'The Regulation of Human Germline Genome Modification in Germany' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 241–65 at 242.)
[324] 8.2.8, Indian Council of Medical Research & Department of Biotechnology 'National Guidelines for Stem Cell Research' (2017).
[325] 8.2.8.1, ibid.
[326] 8.2.8.2, ibid.

Israel	Permitted[327]	Permitted[328]	Enforced[329]*
Italy	Prohibited[330]	Prohibited[331]	Irrelevant
Lithuania	Prohibited[332]	Prohibited[333]	Irrelevant
Netherlands	Permitted[334]*	Prohibited[335]	Enforced[336]
New Zealand	Permitted[337]	Prohibited[338]*	Enforced[339]
Republic of Korea	Permitted[340]	Prohibited[341]	N/A
Singapore*	Permitted[342]	Permitted[343]	Enforced[344]
Slovenia	Prohibited[345]	Prohibited[346]	Irrelevant

[327] Art 3, Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law 5759/1999.
[328] S 16, Ovum Donation Law 5770 of 2010.
[329] Vardit Ravitsky & Gali Ben-Or 'The Regulation of Human Germline Genome Modification in Israel' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 568–81 at 573.
[330] Art 13(1), Rules on Medically Assisted Procreation Act 40 of 2004.
[331] Art 13(3)(a), ibid.
[332] Art 3(2), Law on Ethics of Biomedical Research 2000 no VIII-1679.
[333] Art 3(2), ibid.
[334] Commission on Genetic Modification & the Health Council of the Netherlands note 243 op cit at 43; Van Beers et al note 281 op cit at 325.
[335] Art 24(a), Act Containing Rules Relating to the Use of Gamete and Embryos 2002.
[336] Ar 24, ibid.
[337] S 8(1) & schedule 1(8), Human Assisted Reproductive Technology Act 92 of 2004.
[338] The National Ethics Committee on Assisted Human Reproduction 'Guidelines for Research on Gametes and Non-viable Embryos' (2005); Grace KA Williams *Embryo Research in Legal Limbo: A Critique of the Legal Framework for Embryo Research in New Zealand* (Bachelor of Laws (Honours) dissertation, University of Otago - Te Whare Wānanga o Otāgo, 2018) 10.
[339] S 9(4), Human Assisted Reproductive Technology Act note 337 op cit.
[340] Art 47(1), Bioethics and Safety Act 2005.
[341] Art 47, ibid.
[342] Calvin WL Ho 'The Regulation of Human Germline Genome Modification in Singapore' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 516–40.
[343] Bioethics Advisory Committee 'Ethics Guidelines for Human Biomedical Research' (2015) 45.
[344] Ibid at 46.
[345] Art 114(4), Criminal Code of the Republic Of Slovenia (2008).
[346] Art 114(2), ibid.

Spain	Prohibited[347]	Prohibited[348]	Enforced[349]
Sweden	Uncertain[350]	Permitted[351]*	Enforced[352]
Switzerland	Prohibited[353]	Prohibited[354]	Irrelevant
UK	Permitted[355]	Permitted[356]	Enforced[357]
USA	Restricted[358]	Restricted[359]	Indirectly enforced[360]*

[347] Art 2(1), Law on Biomedical Research 14/2006.
[348] Art 5(8), ibid.
[349] Art 15(b), ibid.
[350] Ch2, s3, Genetic Integrity Act 351 of 2006.
[351] A Elstner, A Damaschun & A Kurtz et al 'The changing landscape of European and international regulation on embryonic stem cell research' (2009) 2 *Stem Cell Research* 101 at 106; Santa Slokenberga & Heidi Carmen Howard 'The Regulation of Human Germline Genome Modification in Sweden' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 281–308 at 307.
[352] Ch 5, s 3, Genetic Integrity Act note 350 op cit.
[353] Art 119(2)(a), Constitution of the Swiss Federation, 1999.
[354] Art 119(2)(e), ibid.
[355] S 41, Human Fertilisation and Embryology Act 1990.
[356] S 3 & schedule 2, s3(1), ibid.
[357] S 3(3)(a) & s 3(4), ibid.
[358] S 508 & s 745, Further Consolidated Appropriations Act 2020.
[359] S 508(1), ibid; Kerry Lynn Macintosh 'The Regulation of Human Germline Genome Modification in the United States' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 103–28 at 122.
[360] Kerry Lynn Macintosh 'The Regulation of Human Germline Genome Modification in the United States' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 103–28 at 123.

(c) Results

Half of the analysed jurisdictions expressly permit gene editing in human embryos.[361] For example, the UK permits gene editing in human embryos pursuant to a licence.[362] The first licence for gene editing research on embryos was granted in 2016.[363] It is a criminal offence to engage in gene editing in human embryos research without a licence.[364] Only six of the jurisdictions expressly prohibit gene editing in human embryos.[365] The USA restricts the use of public funds for basic research on embryos.[366] The positions of Australia, Canada and Sweden are uncertain due to the wording of their provisions on HHGE research.

Australia clearly prohibits HHGE in section 15 of its Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act as the 'intent of this provision is to prohibit germline genetic manipulations intended to be passed on to future generations.'[367] Nicol argues that

> 'this prohibition could also apply in the research context, where the intention for the genetic manipulation to be passed on to future generations is absent, but the intention to modify the genome in a way that could be inherited is present.'[368]

As a genetically edited embryo which is not intended to be used for reproduction still has heritable changes, which are 'able to be passed to future generations,'[369] it seems that research is prohibited. However, this is not yet clarified.[370]

Canada's Assisted Human Reproduction Act completely prohibits HHGE in section 5(1)(f), where it states that no person may 'alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants.'[371] There is confusion as to whether the AHRA prohibition extends to gene editing in human embryos

[361] China, Finland, Germany, India, Israel, Netherlands, New Zealand, Republic of Korea, Singapore and the UK.
[362] James Lawford Davies 'The Regulation of Human Germline Genome Modification in the United Kingdom' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 217–40 at 219.
[363] The Parliamentary Office of Science and Technology 'Human Germline Genome Editing' available at *https://post.parliament.uk/research-briefings/post-pn-0611/,* accessed on 5 Nov 2020; Davies note 362 op cit at 222.
[364] S 41, Human Fertilisation and Embryology Act note 355 op cit.
[365] Hungary, Italy, Lithuania, Slovenia, Spain and Switzerland.
[366] S 508 & s 745, Further Consolidated Appropriations Act note 358 op cit.
[367] Nicol note 269 op cit at 554.
[368] Ibid.
[369] Ibid at 555.
[370] Ibid at 556.
[371] S 5(1)(f), Assisted Human Reproduction Act note 309 op cit.

as the Act prima facie prohibits both clinical and research applications.[372] While Health Canada states that section 5(1)(f) 'prevents people from using genetic technologies to alter the DNA of embryos before transferring them to a uterus,'[373] no research has been undertaken in Canada.[374] This has been attributed to the criminal prohibitions and their lack of clarity on the permissibility of gene editing in human embryos.[375]

Sweden's Genetic Integrity Act appears to prohibit gene editing in human embryos in its provision that '[e]xperiments for the purposes of research or treatment that entail genetic changes that can be inherited in humans may not be carried out.'[376] However, Slokenberga and Howard argue that as it was enacted to liberalise research, the Genetic Integrity Act permits gene editing in human embryos,[377] as long as the embryos are destroyed after the fourteenth day.[378]

Italy's Rules on Medically Assisted Procreation Act only permit embryo research which is 'for the protection of health and development of the embryo itself,'[379] and if there are no alternatives to the research.[380] This clearly prohibits basic gene editing in human embryos and, as Poli argues, HHGE technology 'can further certain values enjoying a constitutional status under the Italian legal system, such as the promotion of scientific progress and the protection of health,'[381] both of which are core values in Italy.[382]

[372] Erika Kleiderman 'The Regulation of Human Germline Genome Modification in Canada' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 83–102 at 91.
[373] Health Canada 'Prohibitions related to scientific research and clinical applications' (2020) available at *https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction/prohibitions-scientific-research-clinical-applications.html*, accessed on 5 Nov 2020.
[374] Kleiderman note 372 op cit at 92.
[375] Ibid.
[376] Ch 2, s 3, Genetic Integrity Act note 350 op cit.
[377] Santa Slokenberga & Heidi Carmen Howard 'The Regulation of Human Germline Genome Modification in Sweden' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 281–308 at 299.
[378] Ibid at 307; ch5, s3, Genetic Integrity Act note 350 op cit.
[379] Art 13(2), Rules on Medically Assisted Procreation Act note 330 op cit.
[380] Ibid.
[381] Ludovica Poli 'The Regulation of Human Germline Genome Modification in Italy' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 335–57 at 338.
[382] Ibid.

Switzerland's framework is one of the most restrictive in Europe,[383] and is consistent with the Oviedo Convention, which was ratified in 2008.[384] Switzerland has ratified the ICESCR,[385] however, Swiss national legislators may derogate from international law instruments.[386] The limitations placed on research in the Swiss constitution thus have precedence over the ICESCR.[387] The Swiss constitution prohibits 'interference with the genetic material of human reproductive cells and embryos.'[388] All HHGE is criminally prohibited whether or not implantation is intended[389] and, thus, gene editing in human embryos is completely prohibited.[390]

The creation of embryos for research is prohibited in the majority of the jurisdictions. Israel, Singapore, Sweden[391] and the UK permit this practice.

In Israel, embryos may be created, used for research and then disposed at liberty.[392] The Ovum Donation Law allows women to donate their ova for many purposes, including for use in research.[393] A maximum of twenty per cent of the donated ova, or two ova, whichever is the least, may be withdrawn for research purposes.[394] Jewish culture considers the human embryo to be 'mere water'[395] until the fortieth day after fertilisation, when it becomes a 'formed embryo.'[396]

Singapore permits the creation of embryos for research provided there is 'strong scientific merit in and potential medical benefit from such research.'[397] Women are permitted to donate gametes specifically for the purpose of research.[398]

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[383] Alessandro Blasimme, Dorothée Caminiti & Effy Vayena 'The Regulation of Human Germline Genome Modification in Switzerland' in Andrea Boggio, Cesare PR Romano & Jessica Almqvist (eds) *Human Germline Genome Modification and the Right to Science* (2020) 409–37 at 409.
[384] Ibid at 412.
[385] Ibid at 411.
[386] Ibid at 412.
[387] Ibid.
[388] Art 119(2)(a), Constitution of the Swiss Federation, 1999.
[389] Ibid; Art 35, Federal Act on Medically Assisted Reproduction 810:11; Blasimme et al note 383 op cit at 409.
[390] Ibid at 429.
[391]A Elstner, A Damaschun & A Kurtz et al 'The changing landscape of European and international regulation on embryonic stem cell research' (2009) 2 *Stem Cell Research* 101 at 106; Slokenberga & Howard note 377 op cit at 307.
[392] Ravitsky & Ben-Or note 329 op cit at 573.
[393] S 16, Ovum Donation Law note 328 op cit.
[394] S 16(c), ibid.
[395] Ravitsky & Ben-Or note 329 op cit at 573.
[396] Ibid.
[397] Bioethics Advisory Committee note 343 op cit at 45.
[398] Ibid at 46.

The UK permits the creation of embryos, as well as the use of surplus IVF embryos, for research pursuant to a licence.[399] Embryos may be created for research which has the purpose of:

> '(a) increasing knowledge about serious disease or other serious medical conditions,
>
> (b) developing treatments for serious disease or other serious medical conditions,
>
> (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
>
> (d) promoting advances in the treatment of infertility,
>
> (e) increasing knowledge about the causes of miscarriage,
>
> (f) developing more effective techniques of contraception,
>
> (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
>
> (h) increasing knowledge about the development of embryos.'[400]

Further, an application for a licence to create embryos for research 'must explain why it is necessary, not merely desirable, to use human embryos, as opposed to another source of material.'[401]

All of the jurisdictions which permit basic research enforce the fourteen-day rule. Interestingly, despite Israel's treatment of embryos as 'mere water,' it enforces the fourteen-day rule.[402]

Of the twenty jurisdictions analysed, only eight constitutionally protect scientific freedom in some manner.[403] Five of the eight jurisdictions which constitutionally protect scientific freedom[404] also completely prohibit HHGE basic research.[405] Of the three

[399] S 3 & schedule 2, s3(1), Human Fertilisation and Embryology Act note 355 op cit.
[400] Schedule 2, s3A(2), ibid.
[401] Davies note 362 op cit at 227.
[402] Ravitsky & Ben-Or note 329 op cit at 573.
[403] S 16, Constitution of Finland, 1999; Art X, Constitution of Hungary, 2011; Art 5, Constitution of Germany, 1949; Art 33, Constitution of the Republic of Italy, 1947; Art 42, Constitution of Lithuania, 1992; Art 23, Constitution of Sweden, 1974; S 20, Constitution of Spain, 1978; Art 59, Constitution of the Republic of Slovenia, 1991.
[404] Hungary, Italy, Lithuania, Spain and Slovenia.
[405] S 168, Act C of 2012 note 319 op cit; Art 13(1), Rules on Medically Assisted Procreation Act note 330 op cit; Art 3(2), Law on Ethics of Biomedical Research note 332 op cit; Art 2(1), Law on Biomedical Research 14/2006; Art 114(4), Criminal Code of the Republic Of Slovenia note 345 op cit.

jurisdictions that expressly permit,[406] or are argued to permit,[407] HHGE basic research, only one permits the creation of embryos for research,[408] and all three enforce the fourteen-day rule in embryo research.[409] I argue that this pattern demonstrates that freedom of scientific research, even when protected constitutionally, is not sufficiently considered in the drafting of legislation and policy.

I argue that the of the legal frameworks analysed, those of Israel, Singapore and the UK[410] are the least restrictive on freedom of scientific research in the context of HHGE basic research. They not only permit HHGE basic research, but also the creation of embryos for research purposes. However, even these jurisdictions enforce the fourteen-day rule, thus possibly limiting freedom of scientific research in that manner.

The enforcement of the fourteen-day rule in all of the jurisdictions, and the prohibition of the creation of embryos for research purposes in the majority of the jurisdictions illustrates that the general pattern is that the regulation of HHGE is restrictive. The enactment of these limitations on HHGE research may constitute infringement of freedom of scientific research. The prevalence of these legal limitations on research reveals a need for the consideration of freedom of scientific research in the drafting of legislation pertaining to scientific research in general, and HHGE research in particular. The uncertainty caused by ambiguity in legislation in certain jurisdictions[411] demonstrates the need for clearly drafted legislation and guidelines.

VI THE SOUTH AFRICAN FRAMEWORK

South Africa has not enacted laws specifically regulating HHGE.[412] However, the National Health Act 61 of 2003 (NHA) and its regulations, as well as health research ethics committee guidelines, are applicable.[413] The NHA does not expressly permit or prohibit HHGE, making

[406] S 15, Medical Research Act note 316 op cit; S 5(4), Embryo Protection Act note 321 op cit.
[407] Ch 2, s 3, Genetic Integrity Act note 350 op cit; Slokenberga & Howard note 377 op cit at 299.
[408] A Elstner, A Damaschun & A Kurtz et al 'The changing landscape of European and international regulation on embryonic stem cell research' (2009) 2 *Stem Cell Research* 101 at 106; Slokenberga & Howard note 377 op cit at 307.
[409] S 11 & s 13, Medical Research Act note 316 op cit; Ch 5, s 3, Genetic Integrity Act note 350 op cit; S 3(3)(a) & s 3(4), Human Fertilisation and Embryology Act note 355 op cit.
[410] Arguably, Sweden is among the least restrictive of the analysed jurisdictions, but this is dependent on the clarification of ch 2, s 3 of the Genetic Integrity Act note 350 op cit; Slokenberga & Howard note 377 op cit at 299.
[411] Australia, Canada and Sweden.
[412] Academy of Science of South Africa (ASSAf) 'Human genetics and genomics in South Africa: Ethical, legal and social implications' (2018) available at *http://dx.doi.org/10.17159/assaf.2018/0033*, accessed on 15 Nov 2020 at 20.
[413] Thaldar et al note 177 op cit at 4.

for a somewhat uncertain framework.[414] Section 57(1) of the NHA prohibits the manipulation of genetic material of gametes, zygotes or embryos 'for the purpose of the reproductive cloning of a human being.'[415] This is an ambiguous prohibition as NHA does not clarify whether section 57 applies to all gene editing or only human reproductive cloning.[416] Section 57(6) fails to clarify the position — 'reproductive cloning of a human being' includes 'the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose.'[417] This does not clarify whether the manipulation of genetic material is only prohibited for the purpose of nuclear transfer or embryo splitting, or if gene editing would classify as 'manipulation of genetic material'[418] for the purposes of this section. The contravention of this vague section is a criminal offence, with provision for a fine and/or imprisonment of up to five years.[419]

It could be argued that while HHGE is not human cloning, it is the 'manipulation of genetic material' in terms of section 57(6) and is criminally prohibited in South Africa.[420] However, Thaldar et al argue that on an interpretation of section 57, HHGE 'should *not* be included within the ambit of the definition of "reproductive cloning of a human being."' In accordance with interpretation in South African courts, Thaldar et al argue that on a plain reading of section 57, its purpose 'is to specifically outlaw human reproductive cloning.'[421] Section 56(7) defines reproductive cloning as 'the manipulation of genetic material in order to achieve the reproduction of a human being and *includes nuclear transfer or embryo splitting for such purpose*.'[422] [emphasis added] The use of the word 'includes' indicates that the subsequent words define the scope of the provision or concept being defined.[423] Thus, human cloning in terms of section 57 only relates to nuclear transfer and embryo splitting, not HHGE.[424] Thaldar et al argue further that provisions which provide criminal penalties are afforded the 'narrowest possible interpretation.'[425] Thus, for the purposes of section 57, human

[414] Ishii note 163 op cit at 2; Shozi note 123 op cit at 63.
[415] S 57(1), National Health Act 61 of 2003 (NHA).
[416] Shozi note 123 op cit at 63.
[417] S 57(6), NHA.
[418] S 57(6), NHA.
[419] S 57(5), NHA.
[420] Thaldar et al note 177 op cit at 3.
[421] Ibid.
[422] S 57(6), NHA.
[423] Thaldar et al note 177 op cit at 3.
[424] Ibid.
[425] Ibid referring to *Rossouw v Sachs* 1964 2 SA 551 (A).

cloning would not be interpreted to include HHGE.[426] However, the applicability of section 57 to HHGE remains unclear.[427]

The NHA permits researchers to utilise embryos on the conditions that

- the researcher acquires written permission from the Minister of Health to conduct the research;
- the embryos are no more than fourteen days old;
- the researcher documents their research; and
- the donor consents to the utilisation of their embryos for research.[428]

Gene editing in human embryos likely falls within the ambit of the Regulations Relating to the Use of Human Biological Material[429] as the they regulate 'genetic health research.'[430] HHGE research is certainly genetic, and falls within the scope of the definition of health research in the NHA:

> '"[H]ealth research" includes any research which contributes to knowledge of–
>
> (a) the biological, clinical, psychological or social processes in human beings;
>
> (b) improved methods for the provision of health services;
>
> (c) human pathology;
>
> (d) the causes of disease;
>
> (e) the effects of the environment on the human body;
>
> (f) the development or new application of pharmaceuticals, medicines and
>
> (g) the development of new applications of health technology.'[431]

Gene editing in human embryos clearly contributes to knowledge of a number of the above themes. Since the Regulations Relating to the Use of Human Biological Material apply to HHGE research, researchers must acquire approval from a registered health research ethics committee.[432] Researchers are required to maintain registers which record their research,[433] and

[426] Ibid.
[427] Ibid.
[428] S 57(4), NHA.
[429] Thaldar et al note 177 op cit at 2.
[430] Reg 2(a), Regulations Relating to the Use of Human Biological Material in GN 177 GG 35099 of 2 March 2012.
[431] S 1, NHA.
[432] Reg 3(2), Regulations Relating to the Use of Human Biological Material note 430 op cit.
[433] Reg 12(1), ibid.

must submit these registers to the Minister of Health annually.[434] Researchers must keep their records in a manner which ensures confidentiality.[435] The Regulations Relating to the Use of Human Biological include gametes and embryos in the definition of human biological material.[436] Human biological material may be 'removed or withdrawn'[437] for the purpose of health research.[438] However, as embryos are not removed or withdrawn from a person for research, but rather created through in vitro fertilisation, this provision logically does not apply to embryos.

The Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes define artificial fertilisation as 'introduction by other than natural means of a male gamete or gametes *into the internal reproductive organs of a female person* for the purpose of human reproduction.'[439] [emphasis added] The definition of artificial fertilisation includes artificial insemination, which is defined as 'in vitro fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection.'[440] The use of gametes is limited to medical and dental purposes, which includes 'the artificial fertilisation of another person.'[441] These Regulations thus limit in vitro fertilisation and the use of gametes to reproductive purposes — excluding the withdrawal of gametes for research purposes as well as the fertilisation of embryos for research purposes.

The Regulations Relating to Artificial Fertilisation of Persons define artificial fertilisation as

> 'the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction and includes artificial insemination, in vitro fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection.'[442]

A gamete donor is defined as a 'living person from whose body a gamete or gametes are removed or withdrawn, for the purpose of artificial fertilisation.'[443] Gametes may only be

[434] Reg 12(2), ibid.
[435] Reg 13, ibid.
[436] Reg 1, Regulations Relating to the Use of Human Biological Material note 430 op cit.
[437] Reg 5, ibid.
[438] Reg 5(b), Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes in GN 180 GG 35099 of 2 March 2012.
[439] Reg 1, ibid.
[440] Reg 1, ibid.
[441] Reg 3(1)(c), ibid.
[442] Reg 1, Regulations Relating to Artificial Fertilisation of Persons in GN 175 GG 35099 of 2 March 2012.
[443] Reg 1, ibid.

removed for artificial fertilisation.[444] The use of in vitro fertilisation is limited to the purpose of embryo transfer.[445] Thus, the withdrawal of gametes, or the fertilisation of embryos for research purposes, are not permitted. Stored embryos must be destroyed once the person for whom they were fertilised conceives or consents in writing that the embryos may be used for the artificial fertilisation of another person, or for a purpose other than embryo transfer.[446] Thus, excess IVF embryos may be used for research purposes with consent.

The Regulations Relating to Research with Human Participants will also apply to such research.[447] In terms of these regulations, researchers are bound by the Department of Health's ethics guidelines[448] and must have approval from a registered health research ethics committee.[449] Research must 'be responsive to health needs or priorities of the population, participating community or proposed participants.'[450] Further, the research must 'have a valid scientific methodology and be likely to provide answers for the specific research questions that are posed,'[451] and must incorporate 'a favourable risk-benefit analysis.'[452] Researchers are required to consult with the representatives of the community participating in the research,[453] as well as the relevant institutions or government authorities.[454]

The National Department of Health's guidelines, *Ethics in Health Research: Principles, Processes and Structures*, contain brief, general discussions of genetic research and genomic research,[455] but genetic editing is not specifically included.[456] The possible benefits and risks involved in genetic research are mentioned, however, the guidelines do not take a position on the permissibility of gene editing in human embryos.[457]

The Health Professions Council of South Africa (HPCSA) ethics guidelines, *General Ethical Guidelines for Biotechnology Research in South Africa*, purport that as genetic

[444] Reg 3(1), ibid.
[445] Reg 10(2)(a), ibid.
[446] Reg 10(2)(c)*(iii)*, ibid.
[447] Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014.
[448] Reg 2(a), ibid.
[449] Reg 2(g), ibid.
[450] Reg 2(b), ibid.
[451] Reg 2(c), ibid.
[452] Reg 2(d), ibid.
[453] Reg 3(b), ibid.
[454] Reg 3(c), ibid.
[455] 3.3.8 & 3.3.9, National Department of Health 'Ethics in Health Research: Principles, Processes and Structures' (2015) available at *https://www.ul.ac.za/research/application/downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf*, accessed on 29 September 2020.
[456] Thaldar et al note 177 op cit at 2.
[457] 3.3.8 & 3.3.9, National Department of Health note 455 op cit.

modifications are heritable, '[r]esearch relating to germ line gene therapy is therefore not acceptable.'[458] There is no justification provided for this prohibition.[459] The HPCSA guidelines expressly prohibit the 'intentional alteration of the genome of a human cell in a manner that makes the alteration heritable by descendants of the human whose cell was altered.'[460] Thaldar et al argue that this provision of the HPCSA guidelines seems to prohibit all forms of gene editing in human embryos, based only on the reason that such research results in heritable changes, and that heritability 'is not necessarily a negative factor, or sufficient reason for a ban.'[461]

The Medical Research Council of South Africa's (MRC) *Reproductive Biology and Genetic Research* guidelines (the MRC guidelines) echo the NHA's fourteen-day rule, arguing that the 'pre-embryo should be treated with the utmost respect because it is a genetically unique, viable human entity.'[462] The MRC guidelines refer to 'pre-embryo manipulation and research,'[463] which is permissible as long as the embryos were not produced solely for the research.

The MRC guidelines discourage the creation of excess IVF embryos for research purposes.[464] This demonstrates that 'an individual's interest in procreating is allocated a value far exceeding society's collective interest in scientific progress.'[465] The MRC guidelines are research-limiting without rational or justified moral reasons for such limitation.[466]

The MRC guidelines state that 'gene modification of the human germline should not yet be attempted until such time that it is clearly sanctioned in South Africa.'[467] Thaldar et al argue that '[t]his statement is comprehensively vague: Who must sanction human germline editing before it should be attempted, and when will such sanction be sufficiently clear?'[468]

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[458] 13.3.2, Health Professionals Council of South Africa (HPCSA) 'Booklet 14: General Ethical Guidelines for Biotechnology Research in South Africa' in Guidelines for Good Practice in the Health Care Professions (2008) available at *https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf,* accessed on 30 September 2020.
[459] Thaldar et al note 177 op cit at 2.
[460] 13.5.2, HPCSA note 458 op cit.
[461] Thaldar et al note 177 op cit at 2.
[462] 2.2, Medical Research Council of South Africa 'Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research' (2016).
[463] 2.17, ibid.
[464] 2.2, ibid.
[465] DW Jordaan 'Science versus anti-science: the law on pre-embryo experimentation' (2007) 124(3) *SALJ* 618 at 625 [the author has since changed his surname to Thaldar].
[466] Ibid.
[467] 3.2.3.1, Medical Research Council of South Africa note 462 op cit.
[468] Thaldar et al note 177 op cit at 2.

Neither the HPCSA nor MRC guidelines provide justifications for their positions on HHGE research.[469] Thaldar et al suggest that '[a]t best, considerations of safety and efficacy are good reasons for a temporary ban on clinical application, but not on research.'[470] Such a position would allow for research to be undertaken to determine and improve safety and efficacy.[471]

VI THE ROAD FORWARD FOR SOUTH AFRICA

South Africa's position on HHGE is unclear,[472] however, HHGE basic research is permitted.[473] The country prohibits the creation of embryos for research purposes[474] and enforces the fourteen-day rule.[475] This is consistent with the frameworks of nine of the jurisdictions included in the jurisdiction comparison.[476] This demonstrates that while South Africa's HHGE framework is not highly restrictive (relative to the twenty foreign jurisdictions), it could be more permissive in terms of the creation of embryos for research and the fourteen-day rule. There is a need for the enactment of legislation specific to the research of CRISPR-Cas9 and HHGE clinical applications, especially if South Africa is to benefit from the advancements of such technologies.

The safety and efficacy concerns posed by CRISPR-Cas9 can be addressed through further HHGE basic research. Since South Africa has an interest in pursuing the clinical application of CRISPR-Cas9, it also has an interest in promoting and funding the basic research necessary to achieve this. Thus, South Africa cannot afford to take an overly cautious approach to regulating HHGE.[477]

The argument based on the issue of informed consent — that a parent choosing to genetically edit their future child does so without the child's consent — is not applicable in the South African context. South Africa permits artificial insemination,[478] the genetic selection of

[469] Ibid.
[470] Ibid.
[471] Ibid.
[472] S57(1), NHA; Ishii note 163 op cit at 2; Shozi note 123 op cit at 63.
[473] S57, NHA.
[474] Reg 3(1)(c), Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes note 438 op cit.
[475] S57(4)(b), NHA.
[476] Australia, Canada, China, Finland, Germany, India, Netherlands, New Zealand and the Republic of Korea.
[477] Shozi note 123 op cit at 63.
[478] Regulations Relating to Artificial Fertilisation of Persons note 442 op cit.

gametes and embryos,[479] IVF[480] and the use of donor embryos,[481] which are all processes employed without the consent of the prospective child.[482] Thus, the use of the argument of informed consent of the prospective child would be inconsistent with the current position.

The rejection of HHGE based on the use of embryos in research is not relevant in the South African context. Thaldar argues that

> 'as our law currently stands, a pre-embryo does not qualify as a legal subject or as a bearer of the right to human dignity. To claim that any entity other than a human person can possess human dignity is to degrade human dignity.'[483]

Thaldar refers to *Clarke v Hurst*, where a distinction was made between biological life and human life. Biological life is 'evidenced by the continued functioning of the patient's bodily organs such as his heart, lungs, liver, kidneys and the like, including his digestive and respiratory systems.'[484] Human life, on the other hand, is in reference to the 'cognitive or intellectual life.'[485] The embryo may be considered biological life, since it is made up of living and developing cells. However, it is not human life, since it lacks consciousness and sentience.[486]

Thaldar further references *Christian Lawyers Association of South Africa v Minister of Health*, in which it was held that in terms of constitutionally protected rights, personhood begins at birth.[487] Thus, the embryo is afforded no protection in constitutional law, and arguments surrounding the use of embryos in research should not sway South African decision-making.

As concluded in Section IV, the ethics statements and reports analysed are generally dismissive towards freedom of scientific research. Of the seven statements that do mention freedom of scientific research, only four do so in a manner which is more than mere lip service. This is an attitude that South Africa must avoid — the constitutional protection of the right to freedom of scientific research necessitates its analysis in ethics statements on HHGE. In order

[479] Thaldar et al note 177 op cit at 5.
[480] Regulations Relating to Artificial Fertilisation of Persons note 442 op cit.
[481] Ibid.
[482] Smith note 64 op cit at 101.
[483] Jordaan note 465 op cit at 631.
[484] *Clarke v Hurst NO* 1992 (4) SA 630 (D) at 644.
[485] Ibid at 645.
[486] Jordaan note 465 op cit at 628.
[487] *Christian Lawyers Association of South Africa v Minister of Health* 1998 (4) SA 1113 (T) at 1121.

for a statement or report to recommend the permissibility or impermissibility of applications of HHGE, it must consider all relevant factors, among which are human rights.

South Africa must base its legal and ethical regulation of HHGE on the values of the Constitution.[488] Thaldar et al argue that 'South Africa needs to be bolder (than other countries need to be) in seeking healthcare solutions.'[489] This is because diseases such as HIV and TB are rampant here, and have an impact on the quality of life and the protection of dignity; and South Africa constitutionally protects the right to freedom of scientific research.[490] South Africa's existing health inequalities may be exacerbated by the prohibition of gene editing research.[491] The country already has a 'robust formal legal regulatory environment' for HHGE research, and can thus be confidently bold in its regulation.[492]

Thaldar et al recommend the following principles for the regulation of HHGE in South Africa:

> 'Principle 1: Human germline editing should be regulated, not banned
>
> Principle 2: Use the well-established standard of safety and efficacy
>
> Principle 3: Non-therapeutic uses of germline gene editing may be permissible
>
> Principle 4: Respect parents' reproductive autonomy[493]
>
> Principle 5: Promote the achievement of equality of access'[494]

The first, third and fifth principles are applicable to this study and will be discussed in more detail.[495] The first principle, which is the most relevant to this study, is applicable to research.[496] The principle is that HHGE research should not be prohibited since it has 'potential to improve the lives of the people of South Africa.'[497] Instead, it must be regulated.[498] Given that such research will be overseen by health research ethics committees, Thaldar et al

[488] Ibid at 3.
[489] Ibid.
[490] Ibid.
[491] Dhai et al note 200 op cit at 2.
[492] Thaldar et al note 177 op cit at 3.
[493] Ibid at 4.
[494] Ibid at 5.
[495] The second principle calls for the utilisation of the standard of safety and efficacy in the decision to make clinical applications of HHGE accessible to the public. This is only relevant to this study in that it is the permissibility of basic research and the promotion of the right to scientific research which allow for the development of a safety and efficacy standard. The fourth principle is solely relevant to clinical application and is thus outside of the scope of this study. However, due to its basis in the fulfilment and protection of constitutional rights, it is in alignment with the approach of this study.
[496] Thaldar et al note 177 op cit at 4.
[497] Ibid.
[498] Ibid.

recommend that health research ethics committees 'apply the same substantive criteria as with any other proposed health research that involves human participants who provide human biological material.'[499] However, an added consideration is the heritable nature of HHGE — 'consideration should be given to the potential long-term implications of the proposed research.'[500] The possible long-term risks should be included in the risk-benefit analysis, informed consent procedures and in community engagement.[501]

In light of the right to freedom of scientific research, this principle is consistent with the results and recommendations of this study. The addition of this consideration by research ethics committees would not unjustifiably limit the right to freedom of scientific research. This consideration is an important factor to consider when determining the ethics and safety of HHGE research. Further, its inclusion in consent procedures and community engagement is imperative to obtaining informed consent and thereby protects the rights to dignity and privacy. As discussed in Chapter Four, informed consent is a justified limitation on the right to freedom of scientific research. Thus, Thaldar et al's first recommendation is supported by this study.

The third principle argues for the permissibility of non-therapeutic applications of HHGE.[502] This is in contrast to the view that such application is 'genetic enhancement,' and is 'reminiscent of the state-sponsored eugenics programmes of early 20th-century Britain, America and Nazi Germany.'[503] Thus, non-therapeutic application is largely viewed as unethical.[504] The differences between eugenics and genetic enhancement, which were discussed above, bring into question whether these arguments are applicable in South Africa.[505] Further, Thaldar et al argue that there is no apparent reason for the blanket prohibition of non-therapeutic applications.[506] This is applicable to this study in that it forms a basis for a recommendation that any regulation of HHGE research should allow for research relating to the editing of any genes — even those unrelated to health research. Thus, research on non-therapeutic applications in human embryos should be permitted.

The fifth principle calls for the promotion of equal access to HHGE technologies in South Africa.[507] The concern of equal access, which was discussed in section III, is especially relevant

[499] Ibid.
[500] Ibid.
[501] Ibid.
[502] Ibid.
[503] Ibid.
[504] Ibid.
[505] Ibid.
[506] Ibid.
[507] Ibid at 5.

in the South African context.[508] One argument is that as technologies age, they become more affordable.[509] This does result in the delayed attainment of such technologies by the less wealthy, but this is not a justified reason to restrict innovation. The solution to access issues

> 'cannot be to suppress the technology, as that would mean levelling down to the "equality of the graveyard"; rather, if the state seeks to promote the achievement of equality in the context of human germline editing it must do so by levelling up to the "equality of the vineyard."'[510]

Thus, technologies must be promoted and made 'as widely available as possible.'[511]

This principle is not only relevant to the regulation of clinical applications of HHGE, but also to HHGE basic research. The more research that occurs using CRISPR-Cas9 technologies, the more sophisticated and popular the technologies become. This contributes to a decrease in the costs of the technology. Thus, research is an important step in the achievement of equal access. In the context of the right to freedom of scientific research, Thaldar et al's recommended principles are consistent with this study.

Dhai et al make recommendations based on the conclusions of the First South African Conference on Gene Editing. One of these conclusions was that 'Africa is definitely a home for human gene editing' — the rejection of gene editing research in Africa would exacerbate existing inequalities.[512] While Dhai et al do not include a standard or norm similar to Thaldar et al's first principle, this principle is supported by Dhai et al's norms and standards, which are recommended for inclusion in the gene editing legal framework.[513] This demonstrates that Dhai et al support human gene editing subject to regulation. The norms and standards include that 'there ought to be equitable access to these technologies.'[514] This standard is more exacting than Thaldar et al's fifth principle in that it requires more than *promotion* of equal access; and does not a qualifier regarding its achievement. This standard is consistent with Thaldar et al's fifth principle, and this study, in so far as it promotes equal access to gene editing technology. Further, it is consistent in that it recognises the inequality in access to healthcare.[515] Dhai et al recommend '[v]igorous communication… at several levels including with the public.'[516] This

[508] Ibid.
[509] Ibid.
[510] Ibid.
[511] Ibid.
[512] Dhai et al note 200 op cit at 1.
[513] Ibid.
[514] Ibid.
[515] Ibid.
[516] Ibid.

appears to recommend public engagement, similar to the recommendation of the Academy of Science of South Africa.[517] In addition to the above, Dhai et al's standards and norms include:

- 'There is a need for transparency in scientific and governance processes.

  …

- Patient centricity, autonomy, the public and common good are essential considerations.
- Safety is paramount with protections extending to future generations.
- Research must be conducted responsibly with integrity being pivotal.'[518]

It is appropriate, at this point, to note that Dhai et al and Thaldar et al do not include in their recommendations the requirement of broad societal consensus. A number of the ethics statements and reports, all emanating from America and Europe, considered in this chapter call for 'broad societal consensus' as a condition of the permissibility of clinical applications of CRISPR-Cas9.[519] In a South African context, this call for societal consensus is problematic. In terms of a rights limitation analysis, the court is not to decide whether the limitation is justified by agreement of public opinion, but whether it is justified in terms of the Constitution.[520] While public opinion may be a relevant consideration, 'it is no substitute for the duty vested in the Courts to interpret the Constitution and to uphold its provisions without fear or favour.'[521] Further, a decision on constitutionality 'cannot be referred to a referendum, in which a majority view would prevail over the wishes of any minority.'[522] The Bill of Rights intends to protect minority rights,[523] and making decisions on the constitutionality of these rights based on the public opinion would be to grant constitutional power to the majority. The requirement of broad societal consensus before permitting the clinical application of CRISPR-Cas9 thus gives the public the power to decide on whether or not, and how to, limit the right to freedom of scientific

[517] ASSAf note at 412 op cit at 38 R1(a).
[518] Dhai et al note 200 op cit at 2.
[519] T Friedmann, EC Jonlin & NMP King et al 'ASGCT and JSGT Joint Position Statement on Human Genomic Editing' (2015) 23 (8) *Molecular Therapy* 1282; Royal Netherlands Academy of Arts and Sciences note 228 op cit at 3 ; The National Academies of Sciences, Engineering, and Medicine 'On Human Genome Editing: International Summit Statement' (2015) 7; Institut National de la Sante´ et de la Recherche Médicale 'Ethical issues surrounding CRISPR-Cas9 technology' (2016) 8; CIRM Scientific and Medical Accountability Standards Working Group 'Draft Recommendations for the CIRM Scientific and Medical Accountability Standards Working Group (SWG) Workshop on Human Gene Editing' (2016); European Academies Science Advisory Council 'Genome editing: scientific opportunities, public interest and policy options in the European Union' (2017) 3.
[520] *S v Makwanyane* (CCT3/94) [1995] ZACC 3; 1995 (3) SA 391 (CC) para 87.
[521] Ibid para 88.
[522] Ibid.
[523] Ibid.

freedom.[524] Thus, the requirement is not applicable nor appropriate in the South African context.

Not only is the requirement of broad societal consensus inappropriate in South Africa, but it is also problematic on a global scale. This is because arriving at 'consensus about a delicate subject such as germline modification is an impossible task in a heterogeneous society and certainly across an international community.'[525] It raises questions about who decides when consensus has been met, and who decides what will happen once this occurs.[526] Thus, the requirement is not practical for application to decisions about HHGE, especially in the South African context. South Africa cannot allow Eurocentric thinking to continue to dominate South African science,[527] and thus should not adopt this requirement without considering its impact on human rights and technology development.

South Africa's constitutional commitment to freedom of scientific research entails that the country must 'respect, protect, promote and fulfil'[528] the right. Respect necessitates an active role in ensuring that the right to freedom of scientific research is not infringed by restrictive legislation and guidelines pertaining to HHGE.[529] In order to protect the right to freedom of scientific research, South Africa must 'take positive steps to prevent [the] right from being infringed by both State and private actors.'[530] The state duty to promote freedom of scientific research entails that steps must be taken to 'create the necessary culture and social conditions in which the full enjoyment of human rights is possible.'[531] In order to fulfil the right to freedom of scientific research, South Africa must implement measures which allow the right to be fully enjoyed.[532] There are justified reasons to limit the right to freedom of scientific research in an HHGE context. For example, as discussed in Chapter Four, informed consent is a justified limitation on the right. This is because informed consent protects important rights and interests, such as privacy and dignity. Thus, a justified reason for limiting freedom of

[524] Arguably, it also gives the public power to limit the rights to reproductive healthcare, the right to make decisions regarding reproduction and the right to dignity, but this is beyond the scope of this study.
[525] Netherlands Commission on Genetic Modification & the Health Council of the Netherlands 'Editing Human DNA: Moral and social implications of germline genetic modification' (2017) 68.
[526] Ibid at 69.
[527] L Nordling 'How decolonization could reshape South African science' (2018) 554 *Nature* 159.
[528] S 7(2), Constitution.
[529] Panel of Constitutional Experts and Technical Committee 4 'Memorandum to Members of the Constitutional Committee Sub-Committee' (1996) available at *https://justice.gov.za/legislation/constitution/history/LEGAL/CP008036.PDF*, accessed on 8 Dec 2020 at 1.
[530] Ibid.
[531] Ibid.
[532] Ibid.

scientific research is one which protects other constitutional rights in terms of the limitation analysis.[533]

VII CONCLUSION

This chapter provided the scientific context of CRISPR-Cas9 in order to engage with the ethical issues emanating from its application. CRISPR-Cas9 shows great potential for healthcare, but the safety and efficacy issues observed must be addressed, and ethical issues must be carefully considered. In order to do this, basic research on HHGE must be permitted, and its regulation must be liberal enough to make it practicable. Thus, the creation of embryos for research should be permitted. The fourteen-day rule needs to be revisited, and possibly extended to ensure that CRISPR-Cas9 is observed in later embryonic development before it is applied in a clinical context. South Africa's regulation of HHGE is consistent with the broad international position in its prohibition of the creation of embryos for research and its implementation of the fourteen-day rule. However, due to the impact of disease on the South African population, and the constitutional protection of the right to freedom of scientific research, the country has an interest in permitting HHGE basic research with an aim at clinical application. South Africa must not let Eurocentric thinking heed this progress.

[533] S 36, Constitution.

CHAPTER SIX:

CONCLUSION AND RECOMMENDATIONS

This study has shed light on the right to freedom of scientific research, which is underappreciated in debate, and which the South African courts have not been required to interpret. The right is constitutionally protected under the umbrella of the right to freedom of expression in South Africa,[1] Fiji,[2] Kenya[3] and Zimbabwe,[4] and in conjunction with freedom of opinion in other jurisdictions.[5] Even separately from expression and opinion, the right to freedom of scientific research is constitutionally protected in many jurisdictions.[6] In light of its constitutional protection, it is recommended that the right to freedom of scientific research is allocated its fair weight in bioethical discourse, especially in the South African context.

In Chapter Three I identified the purposes of the right to freedom of expression and applied them to the right to freedom of scientific research, concluding that these rights intend to safeguard mutual goods and achieve mutual purposes. Freedom of scientific research is a core component of achieving the public goods of individual self-fulfilment and the search for truth, which are protected by freedom of expression. Understanding the purposes of the right to freedom of scientific research assisted in the justification analysis in Chapter Four.

Chapter Four considered the requirement of informed consent in terms of the Protection of Personal Information Act 4 of 2013 (POPIA) as a limitation on the right to freedom of scientific research. It then considered proposed legal developments regarding consent as a limitation on the right. The purposes of informed consent and of the right to freedom of scientific research, as identified in Chapter Three, were utilised in the justification analysis of informed consent as a limitation on the right to freedom of scientific research. The current South African legal framework on consent was analysed in order to identify limitations on the

[1] S 16(1)(d) of the Constitution of the Republic of South Africa, 1996.
[2] S 17(1)(d) of the Constitution of the Republic of Fiji, 2013.
[3] Art 33(1)(c) of the Constitution of Kenya, 2010.
[4] S 61(1)(b) of the Constitution of Zimbabwe Amendment (No. 20) Act 2013.
[5] Art 47 of the Constitution of Qatar, 2003; Art 23 of the Constitution of Bahrain, 2002; Art 36 of the Constitution of Kuwait, 1962 (reinst 1992); Art of the Constitution of Jordan, 1952; Art 25 of the Constitution of Morocco, 2011.
[6] Art 5 of the Constitution of Brazil, 1988; Art 58 of the Constitution of Albania, 1998; Art 66 of the Constitution of Egypt, 2014; Art X of the Constitution of Hungary, 2011; Art 113 of the Constitution of Latvia, 1922 (reinst 1991); Art 43 of the Constitution of Slovakia 1992; Art 73 of the Constitution of Poland, 1997; Art 38 of the Constitution of South Sudan, 2011; Art 47 of the Constitution of Qatar, 2003; Art 33 of the Constitution of Tunisia, 2014; Art 27 of the Constitution of Yemen, 1991.

right to freedom of scientific research.[7] The specific consent requirement of POPIA was identified as a limitation on the right, as it is more restrictive than the position before POPIA's enactment, which accepted broad and tiered consent.[8] The provisions of POPIA were examined in the justification analysis and it was concluded that informed consent in terms of POPIA is a justified limitation on the right to freedom of scientific research in that it protects the rights to privacy and dignity.

Proposed policy developments, in terms of the ASSAf Report, were analysed for possible limitations on freedom of scientific research through consent requirements. The Report's recommendations are strongly based on Ubuntu. A hypothetical law, the X law, based on the recommendations and deliberations of the ASSAf Report was constructed for utilisation in the justification analysis. The promotion of Ubuntu was determined to be the purpose of the X law. The analysis reached the conclusion that community consent is an unjustified limitation on the right to freedom of scientific research since there are less restrictive manners in which to promote Ubuntu in research.

Chapter Five focused on heritable human gene editing (HHGE), providing a detailed explanation of HHGE and CRISPR-Cas9. The safety and efficacy issues observed in CRISPR-Cas9 research must be addressed before clinical application is permitted.[9] In order to achieve

[7] S 71, National Health Act 61 of 2003 (NHA); Reg 5, Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014; Health Professions Council of South Africa (HPCSA) 'Booklet 13: General ethical guidelines for health researchers' in Guidelines for Good Practice in the Health Care Professions (2008) available at *https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf*, accessed on 30 September 2020; HPCSA 'Booklet 14: General Ethical Guidelines for Biotechnology Research in South Africa' in Guidelines for Good Practice in the Health Care Professions (2008) available at *https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf*, accessed on 30 September 2020; National Department of Health 'Ethics in Health Research: Principles, Processes and Structures' (2015) available at *https://www.ul.ac.za/research/application/downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf*, accessed on 29 September 2020; Material Transfer Agreement for Human Biological Materials in GN 719 GG 41781 of 20 July 2018;

[8] Reg 5, Regulations Relating to Research with Human Participants in GN 719 GG 38000 of 19 September 2014; S 71, National Health Act 61 of 2003 (NHA); Footnote forthcoming (DW Thaldar & BA Townsend 'Exempting health research from the consent provisions of the South African Protection of Personal Information Act' (2020)) provisional page 12.

[9] BM Knoppers, MT Nguyen & F Noohi et al 'Human Genome Editing Ethical and Policy Considerations Policy Brief' (2018) at 4; Q Bu 'Reassess the law and ethics of heritable genome editing interventions: Lessons for China and the world' (2019) 34(2) *Issues in Law & Medicine* 115 at 117; H Ma, N Marti-Gutierrez & S Park 'Correction of a pathogenic gene mutation in human embryos' (2017) 548 *Nature* 413 at 414; KE Ormond, DP Mortlock & DT Scholes et al 'ASHG Position Statement: Human Germline Genome Editing' (2017) 101 *The American Journal of Human Genetics* 167 at 168; E Lanphier, F Urnov & SE Haecker et al 'Don't edit the human germ line' (2015) 519 *Nature* 410 at 411; KR Smith, S Chan & J Harris 'Human Germline Genetic Modification: Scientific and Bioethical Perspectives' (2012) 43 *Archives of Medical Research* 491 at 502; K Smith 'Time to start intervening in the human germline? A utilitarian perspective' (2020) 34 *Bioethics* 90 at 99.

this, basic research must be promoted.[10] Thus, in order to benefit from CRISPR-Cas9 human germline gene editing, freedom of scientific research must be respected and promoted to ensure that valuable basic research is conducted.

Various ethical arguments were analysed. While ethical concerns are important, they should not unjustifiably hamper scientific research. It was concluded that the arguments based on the issue of informed consent and the use of embryos in research are not applicable in the South African context. South African law does not constitutionally protect embryos.[11] It is important for ethical issues to be considered in light of the constitution and human rights.

The study analysed the legal frameworks of twenty foreign jurisdictions.[12] The purpose of the analysis was to determine whether the framework of each jurisdiction included provisions which: Permit HHGE basic research, permit the creation of embryos for research, and enforce the fourteen-day rule. The results revealed that half of the jurisdictions permit HHGE basic research.[13] Only four of the jurisdictions permit the creation of embryos for research,[14] and all of them enforce the fourteen-day rule.[15] The constitutional protection of the right to freedom of scientific research in each jurisdiction was considered in contrast to their frameworks. Five of the eight jurisdictions which constitutionally protect scientific freedom[16] also prohibit HHGE basic research.[17] This demonstrates that the right to freedom of scientific research is insufficiently considered in the drafting of legislation in these jurisdictions.

South Africa's framework is consistent with the frameworks of nine of the jurisdictions included in the jurisdiction comparison:[18] HHGE basic research is permitted,[19] the creation of

[10] KE Ormond, DP Mortlock & DT Scholes et al 'ASHG Position Statement: Human Germline Genome Editing' (2017) 101 *The American Journal of Human Genetics* 167 at 172.
[11] *Clarke v Hurst NO* 1992 (4) SA 630 (D); *Christian Lawyers Association of South Africa v Minister of Health* 1998 (4) SA 1113 (T); DW Jordaan 'Science versus anti-science: the law on pre-embryo experimentation' (2007) 124(3) *SALJ* 618 at 631 [the author has since changed his surname to Thaldar].
[12] Australia, Canada, China, Finland, Germany, Hungary, India, Israel, Italy, Lithuania, Netherlands, New Zealand, Republic of Korea, Singapore, Slovenia, Spain, Sweden, Switzerland, UK and the United States of America.
[13] China, Finland, Germany, India, Israel, Netherlands, New Zealand, Republic of Korea, Singapore and the UK.
[14] Israel, Singapore, Sweden and the UK.
[15] Italy, Lithuania and Slovenia completely prohibit embryo research, and Hungary and Switzerland prohibit HHGE research — thus the fourteen-day rule is non-applicable in the context of these jurisdictions.
[16] Hungary, Italy, Lithuania, Spain and Slovenia.
[17] S168, Act C of 2012 on the Criminal Code; Art 13(1), Rules on Medically Assisted Procreation Act 40 of 2004; Art 3(2), Law on Ethics of Biomedical Research 2000 no VIII-1679; Art 2(1), Law on Biomedical Research 14/2006; Art 114(4), Criminal Code of the Republic Of Slovenia (2008).
[18] Australia, Canada, China, Finland, Germany, India, Netherlands, New Zealand and the Republic of Korea.
[19] S 57, NHA.

embryos for research is prohibited,[20] and the fourteen-day rule is enforced.[21] In Chapter Five, bans on the creation of embryos for research and the enforcement of the fourteen-day rule were identified as possible limitations on the right to freedom of scientific research. Thus, South Africa could be more permissive in terms of the creation of embryos for research and the fourteen-day rule. In light of the interests of South Africa in obtaining solutions to healthcare issues,[22] and the constitutional protection of the right to freedom of scientific research, the prohibition on the creation of embryos for research should be removed. The creation of embryos for research should be permitted and regulated. The fourteen-day rule must also be revisited. As discussed above, the fourteen-day rule arose as a compromise by the British Committee of Inquiry into Human Fertilisation and Embryology. South Africa cannot allow Eurocentric thinking to continue to dominate South African science.[23] The country faces unique issues and has an interest in pursuing contextually appropriate solutions to these problems.[24] Thus, the fourteen-day rule must be reconsidered in the South African context, with consideration of its impact on the right to freedom of scientific research.

South Africa has a constitutional duty to take steps to respect, protect, promote and fulfil the right to freedom of scientific research. The fulfilment of this right has the potential to advance healthcare and provide innovative solutions to South Africa's unique health issues. The right to freedom of scientific research serves to promote and protect the public goods of individual self-fulfilment and the search for truth. It is an essential component of informed debate surrounding HHGE and research and must not be marginalised. If South Africa is to make advances in HHGE and healthcare, legislators, policymakers and academics must give due cognisance to the right to freedom of scientific research.

[20] Reg 3(1)(c), Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes in GN 180 GG35099 of 2 March 2012.
[21] S 57(4)(b), NHA.
[22] D Thaldar, M Botes & B Shozi et al 'Human germline editing: Legal-ethical guidelines for South Africa' (2020) 116 (9/10) *South African Journal of Science* 1 at 3.
[23] L Nordling 'How decolonization could reshape South African science' (2018) 554 *Nature* 159.
[24] Ibid.

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UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

Dr Donrich Willem Thaldar (59413)
School Of Law
Howard College

Dear Dr Donrich Willem Thaldar,

Protocol reference number: 00004704
Project title: To innovate in the field of legal and ethical regulation of gene editing and precision medicine in South Africa

Exemption from Ethics Review

In response to your application received on 19 November 2019, 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,

[redacted]

Mr Simphiwe Peaceful Phungula
Academic Leader Research
School Of Law

HSSREC applicationTo innovate in the field of legal and ethical regulation of gene editing and precision medicine in South Africa , Thaldar, Donrich Willem (59413)

NB: Please click on **Edit** on the top right of the screen to view the full information and make changes to the application. If there is no edit button visible to you, you may be unable to edit the application as it is may be with someone else at the moment. However, you can view the application by clicking on Ethics Applications on the left menu. If there are many applications displayed, you can filter for the application you are looking for.
If you require more help, you can find Ethics User Guides here, OR you can contact the Ethics Office here OR using the Ethics Office contact details here.

Type of ethics review: HSSREC application

Research Project Full Title: To innovate in the field of legal and ethical regulation of gene editing and precision medicine in South Africa

Student Investigator(s):

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