Research participants' views on sharing health-related data in South Africa

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Declaration

I declare that this dissertation represents my own work, except for where due acknowledgement is made, and that it has not been included in a thesis, dissertation or report submitted to this university or any other institution for a degree, diploma or other qualifications.

Signed …… [redacted] **……** **Date** …17 February 2022

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Abstract

Sharing of health-related data is increasingly recognised as a democratic imperative and a marker of responsible science. However, little is known about how research participants perceive data sharing. This study investigated research participants' views on the sharing of health-related data and analysed two different empirical sources of data: (i) the review of twenty empirical papers using framework analysis and (ii) face-to-face accounts of sixteen respondents from focus group discussions from two independent clinical cohorts in South Africa.

The thematic insights were created to provide critical points of ethical comparison between both sources, the papers themselves and the face-to-face accounts given by participants. Three different methods were employed to generate data sources: (i) the matrix method, to review grey literature, official gazette reports, peer-reviewed articles, and scientific textbooks, (ii) framework analysis to review primary sources, and (iii) lastly, data were gathered from two focus group discussions (FGDs) and processed using thematic analysis.

Democratic deliberation assisted in eliciting participants' thoughts on ethical issues and helped solicit participants' opinions on the research questions. Suggestions for additional research on this topic are to develop an understanding of appropriate communities' informational needs to reassure individuals and community members of democratic engagement with systems protecting their constitutional rights. The sharing of health research data was perceived as contributing to greater development and improvement in health care in Africa.

Chapter 1. Introduction

1.1 Past and present context

'yesterday's data are today's information, and tomorrow's knowledge…" (Spiegler, 2000).

Research data support and validate scientific observations. As a means of communicating and extrapolating research findings, sharing empirical data has long been a scholarly practice in mathematics, astronomy, meteorology, biology, physics and the natural and social sciences (National Research Council, 1985; Sieber, 1991). Within the bounds of academia, empirical data tends to culminate in scientific knowledge and practical applications in teaching and learning. Additional elements of information generation include the peer review process, a scholarly standard in certifying the validity and reliability of scientific findings supporting the quality and originality of scientific claims published by academic journals (Allison & Cooper, 1992). The recognition and protection of investments, such as intellectual property, patents, or complying with staff/partner licensing requirements are additional concerns (Marshall, 1990).

While principal investigators (PIs) assume responsibility for data collection, there was a cultural change towards the end of the 1960s that saw some academics thinking about "the notion that scientific data … are, in effect, common property" (Marshall, 1990, p. 954). However, this thinking was largely opposed because of the costs spent for original work, potential lost rewards or missed grant opportunities (e.g., proprietary rights to intellectual property) (Weil & Hollander, 1990). Arguing that "scientific knowledge is publicly available knowledge" demonstrated a shift in democratic society, but this move for open science was disputed for several reasons (Allison & Cooper, 1992, p. 94). Firstly, as a research practice, sharing data was not a valued goal until the 1980s because of the perceived conflict it posed to the integrity of scientific research and potentially tarnish esteemed investigators' careers (Stanley & Stanley, 1988). Secondly, the consequence of open access could have a negative effect on the public (academic) reward systems associated with publications and acknowledged original work; and lastly, there were concerns about the possible infringement on academic freedoms by coercing PIs to release datasets (Ceci, 1988; Rosenberg et al., 2001; Stanley & Stanley, 1988).

Hyman, a social scientist (1972), published in response to a vast underutilisation of empirical data once collected on a large scale (e.g., national survey), and conducted and funded by government and public institutions (with public taxes) (Glenn, 1973). Hyman helps through light on the organisational procedures and principles in research to govern the "*potentialities"* of rich datasets (Rosenberg, 1972). In *'A Banquet for Secondary Analysts'* Hyman suggested that large datasets could be mined from

example the annual “[national] general social surveys” tend to be cumulative in terms of their analytical range and depth: “A statistical abstract rich in substance for non-survey researchers: students, teachers, and scholars, who can learn all kinds of fascinating, otherwise fugitive, facts about America in the 1970s” (Hyman, 1978, p. 546). The wealth of opportunities offered by the ability to share and re-use data is a scientific trait that refines familiar patterns associated with reproducing evidence, research instrumentation, hypothesis testing, knowledge production and better management of research-related resources (Wallis et al., 2013). The degree to which secondary analysis contributes to research benefits (i.e., theoretical knowledge) have some bearings on the standard of procedural mechanisms that govern accessing sources of datasets (Glenn, 1973; Rosenberg, 1972).

Critical about "the dearth of contributions to social scientific literature based on [the lack of] data [curation]" Hyman called attention to the “wealth of largely unanalysed and unpublished information" archived by knowledge institutions (Glenn, 1973, p. 42). The mission was to enhance the understanding of broader societal issues applicable in a variety of sources (i.e., social, cultural, political, or historical contexts). Hyman proposed that secondary analysis meant "the extraction of knowledge on topics other than those which were the focus of the original surveys" (Rosenberg, 1972, p. 1193).

1.2 Information society and knowledge exchange

The literature on sharing data emerged in the 1970s, the cusp of the information society, and references the consequential impact of communication technologies on social transformation, arriving at the brink of the information society. This transformational change in the structure of social systems was "the action of knowledge upon knowledge itself as the main source of productivity" (Webster, 2006, p. 101).

The information society – a cluster of related ideas such as the “network society”, “service society”, “knowledge society”, “post-industrial society” and “globalisation” (Smith, 2010) – is used by theorists, sociologists, scholars and economists to describe a series of social, economic, political and cultural changes (Webster, 2006). The digital revolution was thought to have first sparked in the 1950s and developed to reflect six definitional areas of analytic investigation that captured technological, economic, occupational, spatial, cultural and theoretical knowledge dimensions (Mackay, 2007; Webster, 2006). While a discussion of each criterion is beyond this dissertation’s scope, it suffices to acknowledge that the creation, use, analysis and dissemination of information are a fundamental source of power (Grimshaw, 2017; Hey et al., 2009; Marr, 2015). This is because of the important role

that reliable communications play in globalisation, the knowledge economy, innovation and systems of governance (Webster, 2006). In a democratic society, accessing and utilising informational resources contributes to civil society (Department of Science and Technology, 1996), which propels entrepreneurship, innovation, and scientific discovery (UN Secretary General, 2017). This construct brings to bear the freedom of expression and scientific theoretical knowledge (Department of Science and Technology, 1996).

The integration of technology in economic life resembles patterns in the world of work that have been transformed by the introduction of innovations in information technologies (Lemke et al., 2010; Lundvall & Borrás, 2005). Among wealthy nations, advancements in information technologies and global communications have increased the number of professional, technical and service-skilled occupations across all sectors of society, leading developments in theoretical knowledge to become initiators of innovation (Smith, 2010). Bell (1973) characterised the relationship between theoretical knowledge and innovation by conceiving of

> *"[t]he post-industrial society [as] a knowledge society [wherein] the sources of innovation are increasingly derivative from research and development (and more directly, there is a new relation between science and technology because of the centrality of theoretical [sic] knowledge"* (Bell, 1973 as cited in Webster, 2006, p. 54).

1.3 Trends in sharing data

Representing a broad constituency of institutions, governments and global organisations, interest in sustainable access to empirical health data has underpinned several major global strategies and multilateral innovation systems over the last four decades (National Research Council, 1997; Organisation for Economic Co-operation and Development [OECD], 2004; OECD, 2007; Pisani & AbouZahr, 2010; Rani & Buckley, 2012; United Nations, 2015). 'Innovation systems' broadly refers to public institutions (e.g., universities or statutory research bodies) in partnership with private organisations (e.g., scientific funders or companies) to support economic competition and grow social capacity in science and technology (Lundvall & Borrás, 2005; Manzini, 2012). A national or international view of progress is conceptualised as the "means by which a country seeks to create, acquire, diffuse and put into practice new knowledge that will help that country and its people achieve their individual and collective goals" (Department of Science and Technology, 1996, p. 18).

Many advances in public health care and scientific research are attributed to the inter-institutional transfer of digital public health data across the academic/research/policy nexus (van Staa & Smeeth,

2015; Whiddett et al., 2006). From a health research systems perspective, this intersection is found between the health and research systems of a country (Pang et al., 2003). The systems they use are part of "a network of economic agents, together with the institutions and policies that influence their innovative behaviour and performance" (Manzini, 2012, p. 2). Such systems are like national health policy and research systems (HPRS), which are discussed below.

1.4 Utility and social value of sharing health-related data

"Data are the building blocks of empirical research, whether in the behavioural, social, biological, or physical sciences. To understand fully and extend the work of others, researchers often require access to the data on which that work is based" (National Research Council, 1985, p. 3).

Data, "the physical representation of information in a manner suitable for communication, interpretation or processing by human beings …" (OECD, 2008, p. 119), are instrumental for understanding shared social, economic, political, environmental aspects and scientific reality. Data sharing refers to "the practice of making data from scientific research available for secondary uses" (Institute of Medicine, 2015, p. 24). Its utility is due to the fact that data can be re-used for purposes other than originally intended (Huh, 2019). The utility of secondary analysis provides rich information and completeness to knowledge through linking networks to resources (WHO 2016). This interconnectedness exists between external database sources and concordance with collaborative research, leading to corrections of knowledge gaps applied by secondary analysts (van Staa & Steem, 2015). The development of new methods "in the collection, storage, and use of biological material and health-related data has changed the practice of research from an activity mainly carried out in individual projects to an activity that is organised around research infrastructure such as biobanks and databanks" (van Delden & van der Graaf, 2017, p. 135). This shift in research practice has also led to changes and challenges in research governance.

Rationales supporting such sharing are that it will:

(i) Promote faster analysis of datasets by a community of researchers,
(ii) Promote more efficient use of datasets with cost savings,
(iii) Improve the quality of analysis,
(iv) Maximise social and scientific values,
(v) Minimise risks and harms to individuals and their community.

In our current era of data-intensive scientific discovery, advocates for the advancement of policies mandating that data be managed for wider use present new opportunities for collaborations, administrators, policy-makers and researchers (Hey et al., 2009; Kaye et al., 2009). The magnitude of changes seen in a short period across various fields and influence from external or international entities and other institutional behavioural, social, biological, medical, or physical sciences calls for the global cooperation of open scientific inquiry to address major problems (Heymann et al., 2016).

The promotion of access to information is imperative to the efficacy of all human endeavours and a human right prerequisite for equitable communication and to mediate ethical conflicts following social transformation (Department of Health [DoH], 1997; Department of Science and Technology, 1996). The advent of the internet is marked by the recent history of globalisation following: (i) the intensification and expansion of fiscal activities across trade, science, health, research and development; (ii) the emergence of big information, communication and technologies (ICTs) (Lee, 2015; Phua et al., 2015) and (iii) the experience of zero-sum gains between the collection of research data and open dissemination of scientific output in LMICs (Chan et al., 2011; Maxwell, 2017).

Data sharing is recognised as a growing area of interest to maximise knowledge among global organisations, regulatory agencies, research funders, scientific journals, universities, and researchers (Institute of Medicine, 2013, 2014, 2015; National Academies of Sciences, 2015; Taichman et al., 2016). The transboundary flow of research data must be congruent with existing health policy, leveraging practices that strengthen the translation of research outputs that ultimately improve equity in health (DoH, 2001; Bull, 2016; Hoosen. Coovadia & Irwin. Friedman, 2015). South Africa's history of fragmentation and inequity in health research point to the need for improved quality in health data collection, analysis, data management and dissemination (Abdool Karim et al., 2009; Chopra, Lawn, et al., 2009; Coovadia et al., 2009; World Trade Organization, 2001).

Existing research has not incorporated opinions from research participants in South Africa, nor are data sharing activities well established among South African research constituents (de Vries et al., 2017; Denny et al., 2015; National Academies of Sciences, 2015). Denny and colleagues (2015) found local stakeholders across the public research sector – biomedical, clinical and social science fields – favoured open research but were uncertain about how best to practice data-sharing activities. The extant literature on the perspectives of research participants from LMICs emphasises the need for research to paint a better perspective of research participants to determine what informational provisions would reduce uncertainties about data sharing among prospective participants in a proposed study (Sieber et al., 2015).

1.5 Outline of this study

An integrated approach used three sources of information to identify research participants' views on sharing data. These were (i) deliberative democratic theory to guide the study design and methodological decisions bearing on the analytical treatment for each dataset; (ii) the matrix method used to review literature revealing the depth and range of relevant topics to this study together with thematic and framework analysis empirical insights provided a good record of data triangulation, and (iii) reiterative steps taken in sharing information with and eliciting views from FGDs with research participants. Hopefully, these steps increased the accuracy of data elicited from FGD participants' perceptions of sharing data for research (Srivastava & Hopwood, 2009).

Chapter 2. Literature review

2.1 Potential benefits of sharing data

Sharing data can be advantageous for researchers and the public in multiple ways. A researcher's academic profile can be increased when quality datasets are shared with the broader research community to advance scientific knowledge (Lang, 2011; Pisani et al., 2010; Sieber et al., 2015). Sharing data promotes the scientific ethos of openness by removing barriers to academic freedom and information (de Wolf et al., 2005; Estabrooks & Romyn, 1995; National Research Council, 1985; Sieber, 1991). Here academic freedom refers to "the collective freedom of researchers, including students, to conduct research and to disseminate ideas or findings without religious, political or institutional restrictions; it includes freedom of inquiry and freedom to challenge conventional thought…" (National Health Research Ethics Council, 2015, p. 76). Freedom of academic research is essential for two reasons: firstly, it recognizes the long-term value of serendipity in theoretical knowledge from hypothesis-driven scientific research, and secondly, it fulfils the critical role science plays in democracy (Lundvall & Borrás, 2005; Sieber, 2006).

Access to quality research data is a valuable resource not only because it reduces the financial and time costs accrued in generating big datasets but because it also makes the most use of limited resources (Estabrooks & Romyn, 1995; Glenn, 1973; Pisani et al., 2010; Smith, 1994). Quality datasets are seldom exhausted by primary researchers and can, therefore, encourage the formation of new collaborations as well as promote interdisciplinary research (de Wolf et al., 2005; Estabrooks & Romyn, 1995; National Research Council, 1985; Sieber et al., 2015; Tenopir et al., 2011). Quality datasets can also be used to conduct new secondary analyses while exploring alternative hypotheses (Cheah et al., 2015; Clubb et al., 1985; Sieber et al., 2015). Accessible and quality datasets are often applicable for training purposes, for example: in establishing standards in data management, reporting and learning techniques in data analyses (de Wolf et al., 2005; Delamothe, 1996; Hate et al., 2015; Pisani & AbouZahr, 2010; Sieber et al., 2015; Smith, 1994; Tenopir et al., 2011). Shared data can increase the statistical power of a study by improving meta-analyses that lead to more conclusive scientific evidence (de Wolf et al., 2005; Delamothe, 1996; Sieber et al., 2015). The more extensive use of quality empirical datasets allows for identifying gaps in health research systems, ensuring that better planning for public health identifying priorities is a product of robust science (Estabrooks & Romyn, 1995; Sieber et al., 2015).

Sharing research data also allows independent scrutiny to ensure the verification and refutation of results, thereby improving the overall quality of research and assuring public accountability of researchers' (Cheah et al., 2015; Howe et al., 2018; Sieber, 1991, 2006; Smith, 1994; Tenopir et al., 2011). This can be particularly important for addressing competing conclusions or to resolve concerns over selective, biased, or fabricated findings (de Wolf et al., 2005; National Research Council, 1985; Sieber, 1991; Sieber et al., 2015; Tenopir et al., 2011; Zarin, 2013).

2.2 Moral obligation and human rights

In addition to the economic, social and pedagogical benefits, sharing research data claims to fulfil the moral and ethical obligations of science to research participants and the public at large (1992; Institute of Medicine, 2013; Taichman et al., 2016). Contained within the Universal Declaration of Human Rights is the right for everyone "[…] to share in scientific advancement and its benefits" (United Nations, 1948, p. 8). The International Covenant on Economic, Social and Cultural Rights affirms for everyone the right "to enjoy the benefits of scientific progress and its applications" under Article 15 paragraph 1(b) and states in paragraph 2 that "[…] this right shall include those [steps] necessary for the conservation, the development and the diffusion of science" (United Nations, 1966, p. 5). These steps are understood to refer to regulatory obligations, the actions of which are defined by Shaheed (2012) as follows:

(i) "conservation requires the identification and safeguarding of scientific knowledge, products and tools, including […] databases."
(ii) "development demands an explicit commitment to the development of science and technology for human benefit."
(iii) "diffusion encompasses the dissemination of scientific knowledge and applications both within the scientific community and in society at large" (2012, p. 13).

Vitullo and Wyndham (2013) found that scientists understood the "conservation of science" to mean the ways scientific data and other outputs are retained and used to contribute to conducting scientific inquiry. The "development of science" was thought to be dependent on the open interchange of ideas and scientific knowledge, while the "diffusion of science" refers to the moral obligation that social justice has for scientific research and society (AAAS Science & Human Rights Coalition, 2013). Furthermore, the Universal Declaration on Bioethics and Human Rights Article 15 paragraph 1 claims that the *"benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries"* (The United Nations Educational, Scientific and Cultural Organisation [UNESCO], 2005, p. 78).

With the provision of accessible and quality data, health-related research stakeholders in low-to-middle-income countries (LMICs) have the potential to transcend global health inequalities (Bull, 2016; Cheah et al., 2015; Jao et al., 2015a, 2015b; Lang, 2011). To a large extent, the presence of non-state institutions in international affairs have filled the hollow public health research systems for some of the poorest communities by promoting and sustaining positive health care and service.

2.3 Innovation is about sharing data

Literature published during the late 1980s, 1990s and early 2000s tended to show that the legitimacy of government intervention in health and science policy relied on the scaling up of technology through innovation (OECD, 2004; Lundvall & Borrás, 2005). Innovation policy is instrumental in the context of national organisation and guides infrastructure research (i.e., the industrial complexes, or academic/research/policy nexus) which coordinates national resources utilising human and social development in addition to engaging the knowledge economy (OECD, 2004).

As a prominent theme of sharing health-related research datasets, the ease of access to knowledge and exchange of cultural awareness learnt through interaction helps to cultivate innovation processes that are both industry-minded (market-driven) and democratic in identifying paths to local solutions (DoH, 1997; Jansen et al., 2010; United Nations, 2019). Through collective action and inclusive participation, innovation signifies the importance of public research in policymaking aimed at ensuring that investments (i.e., infrastructure for research) are a sustainable resource for all stakeholders concerned, especially those from LMICs (Afonso-Gallegos et al., 2018; Bull, 2016; United Nations, 2019). Attempts to understand stakeholders' expectations from knowledge institutions regarding health services and public research missions assist in mobilising local communities and the responsiveness of key actors and generate accountability for those actors and authorities involved (Mayosi et al., 2009).

To consider research and innovation policy as a means for development in public health, is to acknowledge that it is foundational for research to make links with systems and institutional mechanisms so that individuals belonging to a scientific community (e.g., clinical, epidemiological, pharmaceutical or biomedical) can work collaboratively, innovatively and productively. Examples of this are cooperative strategies with and between leading universities, companies, funders and global health organisations (OECD, 2004; World Economic Forum, 2016a, 2016b; WHO, 2016a).

2.3.1 Innovation systems

Acknowledged as a forerunner to the field of genomics, the Human Genome Project (HGP) proposed to sequence the entire human genome successfully in a 15-year period from 1990 to 2005. The project was initially established by the United States Department of Energy and the National Institutes of Health (Juengst, 1991; Olson, 1993; Roberts, 1990). The international collaboration comprised more than 20 laboratories across six countries to advance the understanding of human health and disease. In addition to achieving its scientific objectives, the HGP was concluded under budget and two years ahead of projection. The contributions made towards science and biomedical research also made significant impacts on global governance and research policy-making in adapting to the evolving environment of multinational networks. Through international collaboration, the development of new research infrastructure saw the initiation of open access policies to release genetic research data into public repositories (Collins & McKusick, 2001; Olson, 1993; Roberts, 1990). At the same time, it has long been a goal for "both the scientific community and society [to] benefit from any reductions in errors resulting from an open-access policy" (National Research Council, 1985, p. 131).

Research infrastructure, or infrastructure science, refers "to the biological, informational, and methodological tools with which genetics research is carried out" (Olson, 1993, p. 4339). Open access (OA) policy was promulgated in the Bermuda Principles in 1996 (Wellcome Trust, 1997) and later amended in the Fort Lauderdale Agreement in 2003 (Wellcome Trust, 2003). Such policies give investigators access to data online or through public repositories that attempt to accelerate scientific progress (Toronto International Data Release Workshop Authors, 2009). OA policies were believed to "promote the best interests of science and help to maximise the public benefit to be gained from research" by giving scientists access to quality datasets in the application of research on human health (Collins, Morgan & Patrinos, 2003, p. 288).

The Open access policy drew into perspective novel biomedical research, health technology and new disease diagnostics paralleled important ethical, legal and social implications (Juengst, 1991). As an area of investigation, the Ethico-Legal Social Implications (ELSIs) consisted of scientific progress, empirical claims ethics and policy was integral in fostering awareness about the need for better privacy and non-discrimination laws, science policies on health technology assessments, guidelines for biomedical research and public education about the benefits and risks associated with accessible health data present in developing information societies (Collins & McKusick, 2001; Collins et al., 2003).

2.3.2 South Africa's health research enterprise

The South African White Paper on Science and Technology (1996) introduced the notion of a national system of innovation, calling for the integration of science and technology sectors in mutual support of national goals and programmes. In keeping with the rate of global change, democracy and equitable development were envisioned to engender an information society, enabling citizens to participate in a growing knowledge economy (Carmody, 2013). However, given South Africa's history of structural fragmentation and social, political, economic and geographic inequity, the responsiveness of research in addressing public health problems was obstructed by weak research governance structures and the lack of accessible and quality health-related information (DoH, 1997, 2001; Department of Science and Technology, 1996; Senkubuge & Moayosi, 2013).

In its proposal for a democratic health system that would contribute to the development of equitable health, the South African government outlined the Essential National Health Research (ENHR) agenda in 1994. The aim was to direct health-related research and resources to communities in greatest need of health care and public services (DoH, 1997; Lutge et al., 2008). Its philosophy and emphasis on vulnerable groups embodied an ethical framework that sought to foster health equality and social justice through community participation in determining public health priorities (Singh, 2004).

The National Health Research Policy embodied the spirit of ENHR in 2001. The purpose of the policy was to "provide an enabling framework for the conduct of research that improves human health and well-being in South Africa" (DoH, 2001, p. 5). In establishing the national health research system, governance structures integrated democratic mechanisms to include the concerns and views of stakeholders in setting the health research agenda. Priorities were determined through voting on a series of shared values to contribute to equitable health developments reached in a consensus, not a pluralist result (Lutge et al., 2008).

However, despite a beneficial political context, the research enterprise in South Africa had critical failures in the leadership and stewardship of scaling up the national health system (Coovadia et al., 2009). A small group of research stakeholders, mostly externally funded, was seen to dominate the fields of HIV/AIDS and TB by crowding out research on other significant public health problems (DoH, 2001; Lutge et al., 2008; Poreau, 2014; Senkubuge & Moayosi, 2013). As a result, problems in leadership and proper governance delayed the scale-up of the health systems needed for implementation research (Chopra et al., 2009; Coovadia et al., 2009; Senkubuge & Moayosi, 2013). In contrast to South Africa's international trade partner countries, such as the BRICS alliance (Brazil, Russia, India, China and South Africa), the number of full-time researchers per 1 000 employed citizens

was very low, i.e. 1,4, compared, for example, with 8,2 per 1 000 citizens in Russia (Senkubuge & Moayosi, 2013).

2.3.3 Global governance

Global governance is the combination of intentional and patterned human interactions that regulate action worldwide for the common good. It there is now a global discourse of political ethics centring on the values of freedom, democracy, human rights, and social justice (Jennings, 2017). Governance broadly concerns the agreed actions, rules, and means adopted by a society to promote collective action and solutions in pursuit of common goals. Governance takes place whenever people seek to organize themselves to achieve a shared end through agreed rules, procedures, and institutions.

While technology creation and digital instruments simplify the way data are fabricated, captured, manipulated and disseminated, it is not without certain risks of harm to individuals, groups of people, or organisations (Friedewald & Pohoryles, 2013). Academic commentary on knowledge management and evidence generation are consequential for how data-based science supports social transformation and benefits research. Science is perhaps best thought of as being driven by innovation (a social practice) rather than a technical intervention from the state or solely economically motivated (Lundvall & Borrás, 2005). However, in Schiller's view, "the contemporary [networked] environment is expressive of the interests and priorities of corporate capitalism [neoliberalism] as it has developed over time and is an essential component in sustaining the international capitalist economy [including global health research]" (Webster, 2006, p. 135).

Data sharing has increasingly attracted new forms of research with attention to finding novel patterns and variables, interpreting evidence in ways that frame new questions supporting scientific discovery (e.g., hypothesis testing) (Frankel & Reid, 2008). The attention placed on accessible and quality datasets comes to the new forum of research and with it the sum of new scientific methods (machine learning, big data, sophisticated algorithms) and contemporary data management policies to develop a better understanding of local, regional and global public health research through the growth of data-based science. However, arguments favouring open data must require stakeholders to be cognizant of the events that constitute moral, ethical and legal substantive issues when consent is sought and obtained from participants (i.e., human rights, democracy, legal authority). Innovation moves research forward to identify linkages through institutional mechanisms cut across the academia/research/ policy nexus (Hahnel et al., 2018). The White Paper on Science and Technology and White Paper for the transformation of the health system in South Africa followed trends in these fields science and technology, public health, society, democracy and knowledge economy.

As the world demands more flexibility from intergovernmental partnership and industry, failure in innovations and data-sharing are caused by technical limitations and theoretical or ideological assumptions incompatible with the dynamics of innovation (Lundvall & Borrás, 2005). Data-sharing implementation lacks investments in knowledge, production, and as such, requires capacity building and skills competence (Bull, 2016; Hahnel et al., 2018; Kaye et al., 2018). In common with innovation policy, the data-based research enterprise rests on governance as a tool for instrumental mechanisms that link universities and other institutions (e.g., public laboratories or clinical studies) to research stakeholders. However, data-sharing policies have rapidly begun to shape current global health research and global governance through collaboration might mean leaving some less developed countries behind the fourth industrial revolution due to lacking innovation.

Global health and public research governance protect stakeholders' wellbeing by enforcing good practices, resulting in reduced harmful conduct throughout the research process. However, good governance in global health research and human ethics is challenged by the growing scope of problems that empirical data accurately magnifies by combining datasets from multiple sources (UN Global Pulse, 2012). While sharing data contribute to better public health and research benefits, the situation is further complicated by globalisation and the interconnectedness of public institutions, private organisations, and civil groups that require coordination to address global, regional or local problems (Benedict, 2015).

The need for a global governance domain underpins an ethical framework to address gaps in governance processes involved in structuring deliberations about how to maximise the social and economic returns in sustainable public research systems. Innovation conduces co-operative decision-making (strategies) and intergovernmental partnerships that harmonise competition regarding a new societal and economic context brought on by international regulations. An example of this are the Sustainable Development Goals of the United Nations 15-year plan (Fabian & Fabricant, 2014; Kalkman et al., 2019; Kaye et al., 2018; United Nations, 2019).

2.4 Civil democracy

Finding solutions to public health problems turns to "digital health" infrastructure and platforms to drive innovations that are inclusive of the better conservation of quality, reliable and sustainable practice and responsible conduct (Center for Strategic International Studies, 2019).

As a means of yielding research resources, sound policy in the interest of sharing data must align "the central political function" of public health (Gutmann & Thompson, 2004, p. 22). For instance, study

programmes applied to scientific progress that parallels global and national sustainable innovation (United Nations, 2019). The interconnection and interrelatedness of global health networks provide opportunities to enhance policy coherence between institutions and stakeholders in several critical ways (Hoosen Coovadia & Irwin Friedman, 2015). For instance, official datasets related to epidemiological records of a community, or population household health surveys, all perform an essential function in the information systems of a democratic society that serves government, markets and the public with reliable (coded information) about the economic, demographic and environmental situation (OECD, 2008).

As a normative principle, confidentiality imposes "the responsibility to protect information entrusted to researchers for research purposes from unauthorized access, use, disclosure, modification, loss or theft" (National Health Research Ethics Council, 2015, p. 77). However, secondary investigators might not demonstrate honour in the same sense of duty (or due respect) when specific datasets are released to public repositories and broadly used for additional or alternative purposes (Kaye et al., 2009; Robling et al., 2004). The degree to which privacy in research avoids breached confidentiality is partially dependent on legislative and other formal regulatory measures governing the subsequent use of research data (Bersoff, 1992; OECD, 2008).

Yet, legislation on public access to information and the protection of personal information does not specifically deal with sharing health-related data obtained from research participants (Marais et al., 2017; National Health Research Ethics Council, 2015; Nordling, 2019).

Rothstein notes that contemporary ethico-legal requirements are "bimodal: [in that] if the information is 'identifiable,' then all the legal protections are applicable; [but] if the information is 'not identifiable,' then there are no protections whatsoever" (2010, p. 3). A similar 'bimodal' statute exists in South Africa, under Chapter 2, Section 6 of the Protection of Personal Information Act (No. 4 of 2013). It states that the Act "does not apply to the processing of personal information" under paragraph 1(b) "that has been de-identified to the extent that it cannot be re-identified again." De-identification means to remove any information that:

(i) identifies the individual data subject
(ii) can be used or manipulated by a reasonably foreseeable method to identify the data subject; or
(iii) can be linked by a reasonably foreseeable method to other information that identifies the data subject (Chapter 1, Section 1 Act No. 4 of 2013).

Furthermore, Part 2, Chapter 4 of the Promotion of Access to Information Act (No. 2 of 2000) stipulates the mandatory protection of confidential information, be it commercial or scientific in nature, to regulate access to categories of datasets (Sections 36, 37 and 43, or Part 3 Chapter 2 Sections 64(1)(b), 65(1)(b), and 69(2)). The regulatory duty of an information officer (i.e., a responsible curator of personal information) is obligated to refuse requests for access to public or private datasets in terms of conditions listed below:

(i) "scientific or technical ['innovative'] information" (Section 36, paragraph 1(b)).
(ii) "information that was supplied in confidence by a third party" and who is a natural person (Section 37, paragraph 1(b)).
(iii) "information about research being or to be carried out by or on behalf of a third party" [the public, or private body] (Section 43, paragraphs 1 & 2).

Grounds for refusal of access to records include consideration of whether disclosure would prejudice, impair or otherwise cause harm to the commercial or financial interests of that third party, public body or private body. Additionally, if it "would constitute an action for breach of a duty of confidence owed to a third party [and to a public body or private body] in terms of an agreement" with a person (Sections 37(1)(a), or 65(1)(a)).

Rothstein discusses ethico-legal fractures that trouble privacy protections in the USA over data de-identification and further processing. He notes that research regulations on health data usage lack an operational distinction "between health care providers and researchers, especially when the providers and researchers work for the same institution and patient-based clinical records and specimens are used in the research" (Rothstein, 2010, p. 7). However, the problem of confidentiality and sharing data implicates the autonomy and trust of individuals. Therefore, because research governance may not disclose outputs about study participants, resulting in harms to individuals, groups or communities caused by de-identification (Chassang, 2017; de Wolf et al., 2006a; Sieber, 2006), the development of regulations that respond to rapid notifications of further processing have been implemented with *greater transparency* (Carter, Laurie, & Dixon-Woods, 2015; Chassang, 2017; Dixon-Woods & Ashcroft, 2008; Toronto International Data Release Workshop Authors, 2009; Walport & Brest, 2011).

Six principles relevant to democratic forms of exchanging data are outlined below:

(i) Datasets that are of a high standard and possess practical utility should be conserved and made available on an impartial basis by regulatory agencies to honour citizens' entitlement to public information.

(ii) To retain public trust, regulatory processes must ensure research is conducted according to relevant professional and ethical considerations regarding the scientific methods and analytical procedures employed to gather, process, store and communicate results (van Delden & van der Graaf, 2017).

(iii) Furthermore, individual data obtained by research for scientific analysis requires that records be kept confidential and used almost exclusively for scientific purposes.

(iv) The governance, regulations and measures under which the research systems operate should be made public and ensure that individuals are appropriately aware of their rights and responsibilities as study participants.

(v) Coordination among scientific institutions and networks of professionals within a country is crucial in optimising health policy and research that impact all levels of public health.

(vi) Regional and global collaboration promotes sustainability and efficient translational research and knowledge exchange, which in turn contributes to the improvement of governance systems and structures in other countries.

The sharing of data may "[…] view democracy as an institution for pooling widely distributed information about problems and policies of public interest by engaging the participation of epistemically diverse knowers" (Anderson, 2006, p. 8). By sustaining access to independent sources, scientific knowledge promotes democracy because of the desire for open, transparent and representative political decision-making (Lundvall & Borrás, 2005). This may imply that data-sharing "[…] increases reliance [and accountability] on research evaluation, and monitoring mechanisms, as well as incentives for human resource and technology development" (González-Block et al., 2015, p. 317).

For equitable access to health services, national information systems require official data management to monitor population inequalities and inequities in healthcare. The way data are captured should be designed to evaluate the health of different groups of society, especially vulnerable groups that face barriers due to geographical, economic, social and cultural factors (González-Block et al., 2015). Data sharing mechanisms focus on both the technical and ethical, or the procedural and the substantive, aspects of research systems and scientific innovation policy. Improvements in public health outcomes are attributed more to the diffusion of knowledge and information technology than changes in the level of national income (González-Block et al., 2015). Expressive modes of democratic action understand that public involvement creates forms of deliberations that populate forms of reason-based decision-making (Bohman & Rehg, 1997). This

approach emphasises an inclusive framework to cover broad societal interests (Parker, 2007), for example, the human rights enacted by the United Nations and the Constitution of the Republic of South Africa. Sharing data is increasingly instrumental for information societies and "refers to the ability to access and utilise information resources, to give expression to theoretical concepts and their innovative application" (Department of Science and Technology, 1996, p. 63). In an open and democratic society, expressions that promote human dignity, equality and freedom incorporate moral factors relevant to scientific instrumentalism and the commitment of research stakeholders to public health (The Republic of South Africa, 1996).

2.4.1 Regulatory context

Described as a field of scientific investigation by the WHO, national health policy and research systems (HPRS) examine "how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and ultimately our health and well-being" (WHO, 2017, p. 12). In South Africa, national HPRS functions are conducted by three different public institutions that interact across the academic/research/policy nexus namely: the Departments of Health, Science and Technology and Higher Education and Training (Senkubuge & Moayosi, 2013). Under the National Health Act (No. 61 of 2003), the operations of each department are coordinated by the National Health Research Committee (NHRC), which is mandated to develop and manage related activities (Senkubuge & Moayosi, 2013).

The NHRC is directed to identify and advise the Minister on health-related research priorities. According to Section 70, paragraph 2 of the National Health Act (No. 61 of 2003), there are five core factors that must be given consideration in the determination of health-related research priorities. These are listed as follows:

(i) *"The burden of disease;*

(ii) *The cost-effectiveness of interventions aimed at reducing the burden of disease;*

(iii) *The availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;*

(iv) *The health needs of vulnerable groups such as woman, older persons, children and people with disabilities; and*

(v) *The health needs of communities".*

Relevant to this dissertation is *"the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities"* (p. 45). This is facilitated and realised through the national health information system (NHIS).

The NHIS facilitates the creation and evaluation of resources and their dissemination to stakeholders throughout the national academic health complexes (DoH, 1997, 2001; Senkubuge & Moayosi, 2013). To ensure that HPRS are an integrated and comprehensive component of the NHRC, it is the Minister of Health's responsibility to:

> *prescribe categories or kinds of data for submission and collection and the manner and format in which and by whom the data must be compiled or collated and must be submitted to the national department[s]* (South Africa, 2003, p. 77).

The state, acting in the interest of public health, enacts legislation that routinely captures and categorises population health data from individual participants' or patients' records, from which clinical information must be routinely extracted, stored and categorised. Collection, storage and re-use of patients' electronic health records (EHRs) found from health establishments (i.e., hospitals, clinics, trials) and in the form of processing participants' and patients' data are permitted for study, teaching or research purposes.

Provisions of essential resources towards the academic health complexes are crucial for national education and training, stimulating new knowledge, developing and assessing health technologies and protocols that monitor and improve public health services. However, little to no coordination has taken place regarding data-sharing practices in LMIC state (de Vries et al., 2017; Munung et al., 2016), and the regulation of broad informed consent procedures in South Africa, until recently (Nordling, 2019; Staunton et al., 2019).

2.4.2 Research participant-centricity

The interconnectedness of health policy and research systems offers an opportunity to develop new critical scientific applications through technologies and better knowledge exchange (OECD, 2015). At the instrumental level of global health research, data sharing can find public involvement leverage research resources gained through the interconnectedness of stakeholders, linking practitioners to institutions and scientific or political interventions together in the interest of communities (Bull, 2016). However, simply having access to health-related datasets magnifies a multitude of undesirable outcomes (Kass, Paul & Siegel, 2015). The complexity of globalisation transcends territory, distance and borders since there is no single global centre (Yeoh, 2015). This means that public health concerns

require more international cooperation than was previously possible, through governments acting together inclusively and transnationally (Benedict, 2015). The connection between people, institutions and governments leads towards developing interdependencies with others having shared agendas, common economies and pluralistic cultures (National Academies of Sciences, 2017).

That “there is now a global discourse of political ethics centring on the values of freedom, democracy, human rights, and social justice” is well established (Jennings, 2017, p. 183). It reflects changes in the relationship between civil society and democratic institutionalism, or between “the governing and the governed” (Yeoh, 2015, p. 791). The governance of public health sciences can no longer be considered in isolation from the global community and is now better thought of as transcending national states to incorporate the private sector and civil society to deal with major public health problems (United Nations, 2019). Therefore, research governance demands transparency and fair representation for an inclusive view of particular stakeholders (Kaye et al., 2018).

Attitudes to health-related research are changing towards a more active involvement of research participants and their potential democratic role in decision-making (Hamakawa et al., 2020). Research “participant-centricity begins with governance, ensuring that all key stakeholders — including the participants who are the data contributors and ultimate beneficiaries — have a seat at the table” (McGuire et al., 2019, p. 14). Participant-centric research aims to ensure that research stakeholders’ voices are heard and included in meaningful ways to enhance decision-making when seeking an ethical resolution (Murtagh et al., 2018).

Participant centricity is conceived of as “tools, programs, and projects that empower participants to engage in the research process” (Anderson et al., 2012, p. 25). The benefits from new technological initiatives are designed innovatively to help participants be “more actively involved in the research process” (Hamakawa et al., 2020, p. 2). Such developments give participants the option to have control or make decisions over their participation and engage in a reciprocal relationship with researchers throughout the research process (McGuire et al., 2019). With participants placed at the centre of the decision-making process, the alignment of participants’ expectations (e.g., perceptions on social norms and cultural values) can influence public confidence in research (Hamakawa et al., 2020). Therefore, social and political scientists play a pivotal role in conducting critical research regarding national goals and choices about development policies and strategies, transform South African society (Department of Science and Technology, 1996).

2.5 Risks and Benefits of sharing data

The literature on international ethical guidelines for health-related research involving people has highlighted several developments including (i) a heightened emphasis on the importance of translational research[2], (ii) a felt need to clarify what can be constituted as fair research in low-resource settings, (iii) more emphasis on community engagement in research, (iv) a change in the global perspective on the awareness that the exclusion of potentially vulnerable groups contributes to a lack of good evidence base, and (v) the increase of data in research (Council for International Organisations of Medical Sciences [CIOMS], 2016). The latter indicator regards increased data in research and the changes to traditional methods "in the collection, storage, and use of biological material and health-related data has changed the practice of research from an activity mainly carried out in individual projects to an activity that is organised around research infrastructure such as biobanks and databanks" (van Delden & van der Graaf, 2017, p. 135).

That data sharing has benefits is manifestly clear and widely accepted by research stakeholders for accelerating scientific progress (Walport & Brest, 2011). This is achieved by pooling data and permitting access to quality data for secondary analysis with data already collected and used for another study (Howe et al., 2018). It is expected to foster new hypotheses (e.g., problem-based learning, or theoretical knowledge) and advance science and clinical knowledge-generating better information on the safety and effectiveness of interventions for patients (Institute of Medicine, 2015; OECD, 2015; Zarin, 2013). However, research participants in health research face a variety of research interventions and study procedures, some of which may include risk of harm.

The risks posed on participants in health research must be substantiated on ethical grounds, such as having social and scientific value, to genuine demonstrate respect for participants and the members of their community. The prospects of the potential individual benefits must far outweigh the risks posed by research interventions and study procedures before they are deemed acceptable results. Risks are believed acceptable only if outweighed by the potential individual benefits that participants stand to gain from research. The risks posed to participants may arise in two general instances during research: (i) participants experiencing "physical, psychological, social or other harm" and (ii) the magnitude and significance of the harm, this might imply "that discomfort, inconvenience or burdens are harms of a very small magnitude that are almost certain to occur" (CIOMS, 2016, p. 10).

[2] Translational research is research aimed at translating results in basic research into results that directly benefit humans. The term is used in science and technology, especially in biology and medical science.

Potential individual benefits are outcomes that generate scientific or political knowledge necessary to protect and promote the health of future research participants and patients. Furthermore, research stakeholders must maximize the potential individual benefits of additional studies by making data available for future research. It is the task of all research stakeholders (especially the research ethics community) to ensure that the risks of all research interventions, procedures in a study are deemed acceptable.

The risks and benefits of data sharing require the careful balancing of competing considerations. They are associated with the concerns, risks, burdens, and challenges as well potential individual benefits for various stakeholders. When sharing data, researchers must respect the privacy and consent of study participants.

Researchers want a fair opportunity to publish their analyses and receive credit for carrying out studies and collecting data. Other researchers want to analyse data that would otherwise not be published in a timely manner and to replicate the findings of a published paper. Sponsors want to protect their intellectual property and commercially confidential information and allow a quiet period to review marketing applications. All stakeholders want to reduce the risk of invalid analyses of shared data" p.92.

2.5.1 Ethical imperatives and economic necessity

Ethical justifications for conducting research with people must yield great social and scientific value, namely the prospect of generating knowledge and means necessary to protect and promote public health (CIOMS, 2016).

There are compelling reasons to share the data of health-related research. Responsible sharing for biomedical data can substantially serve in the public interest by strengthening health sciences that are foundational for safe clinical care and public health practice. This type of benefit-sharing also fosters sound regulatory decisions, generates research hypotheses, and increases the scientific knowledge gained from study participants' contributions, the study itself and the resources of biomedical science funders (CIOMS, 2016).

Procedurally, the rationale of data sharing aims "to ensure that datasets collected at considerable expense using public and charitable research funds are used in a manner that achieves the greatest possible benefit to health and society" (Carr & Littler, 2015, p. 315). Distinctions were made between "research purposes" and "commercial gain". In Aitken's review of past research participants wanted assurances that public benefits would be prioritised over profit […] also, that individuals' privacy would be prioritised over profit" (Aitken, de St. Jorre, Pagliari, Jepson, & Cunningham-Burley, 2016, p. 13).

Participants felt it was appropriate that private sector organisations finance access to public sector data (Aitken et al., 2016). For research to improve public health, the literature maintains that the repeated re-use of scientific data reduces the research burden exerted upon participants, limiting the number of individuals or communities recruited in a study and the associated costs. By making the most use of finite resources, from public or charitable finances, data sharing recognises that there is an ethical imperative for researchers to serve the interests of the public (Ceci, 1988; Kaye et al., 2009; Pisani & AbouZahr, 2010; Sieber et al., 2015; Tenopir et al., 2011). Public confidence in the research community can be enhanced when the research enterprise makes the best use of participants' contributions to public health, with available research resources, as well as showing both social and scientific value (Bull, Cheah, et al., 2015).

Data sharing highlights three broad areas of ethical importance. First, is the promotion of the scientific and social value of research yielded from human participants in an endeavour to improve global public health (Sieber et al., 2015). Second, it honours the altruism of individual research participants' contribution in knowledge with a show of respect for research participants' rights and concerns over the welfare of the host community where research has been undertaken (Zarin, 2013). Third, ethics focuses on the public accountability of health-related research that upholds the social and scientific obligations of research required to demonstrate public health benefits for public health and from research (CIOMS, 2016). All three principles tie into one another and form the basis of public trust in the conduct of scientific investigation.

As a motivator for sharing data research stakeholders who "…rely on the results of research for activities and decisions that impact individual and public health, welfare, and the use of limited resources" (CIOMS, 2016, p. 1). Undertaking research among researchers, sponsors, research ethics committees and health authorities "…[has] a moral obligation to ensure that all research is carried out in ways that uphold human rights, and respect, protect, and are fair to study participants and the communities in which the research is conducted" (CIOMS, 2016, p. 1)

Commentary on research with human data data reported by IOM and ICMJE (Institutes of Medicine, 2013, 2015; Taichman et al., 2016) include:

(i) The prevention of selective publication and bias reporting of research outcomes
(ii) To prevent the unnecessary duplication of research efforts and costs of future studies
(iii) The reduction of undue exposure of additional participants to experimentation
(iv) Enable the identification of incomplete reports by independent analyses
(v) Enhance transparency in the conduct and reporting of clinical trials

Research designs must offer a means of developing information not otherwise obtainable, in part supporting policy on data-sharing. The risks to research participants must be deemed to be acceptable in relation to the proposed benefits to participants and to society, as determined by the ethics review process.

2.5.1.1 Scientific and social value of sharing

"In particular, there must be sufficient social value to justify risks to participants in studies that lack the prospect of potential individual benefits to them" (CIOMS, 2016 p.2).

Empirical research must begin by ensuring that the study poses a socially valuable research question and employs sound scientific methods for addressing this question. Social value refers to the importance of the information that a study is likely to produce. This principle aims to "…ensure that a study has sufficient social value to justify its associated risks, costs and burdens" (CIOMS, 2016, p. 2).

Scientific value is an ethical principle that refers to "the ability of a study to produce reliable, valid information capable of realizing the stated objectives of the research […] because a diverse range of stakeholders rely on information that research generates to make decisions that have important consequences for individual and public health" (CIOMS, 2016, p. 2).

The inherent scientific value of a study might not be fully realised until its datasets are shared and analysed by different investigators using different methods to answer a different question or reproduce similar data to verify outputs of a research problem (Lowrance, 2003; Parker et al., 2009; Tangcharoensathien et al., 2010). It is believed that by extending empirical data from beyond any single study, "*the research community accelerates the pace of discovery and enhances the efficiency of the research enterprise*" (Walport & Brest, 2011, p. 537). Sharing health-related data is of scientific value to a study because secondary analyses allow the fullest possible understanding of public health problems to be revealed, based on the best available empirical data and evidence (WHO, 2016). This ensures that a study produces reliable, valid information to inform decision-makers.

Given rapid developments in technology and global information, society increasingly relies on accessible and quality empirical data in everyday practice (Hanson et al., 2011). Sharing empirical data fosters the responsiveness of researchers with communities by ensuring that data are open in serving the needs and interests of the public (Institute of Medicine, 2015; McGuire, Hamilton, Lunstroth, McCullough, & Goldman, 2008; Whiddett et al., 2006). For instance, sound regulatory decisions regarding the safety and efficacy of public health services and research can improve the social value of knowledge gleaned from shared data (Bull, Cheah, et al., 2015; Lang, 2011; Pisani et al., 2010).

2.5.1.2 Respect for participants and research transparency

All research with humans must covey genuine respect for individual participants' human rights and concerns about the welfare of members of their community. Respect and concern are manifested by requirements for informed consent, ensuring risks are minimized and are also reasonable by virtue of the importance of the research. "Research must be sensitive to issues of justice and fairness. This concern is manifest in choosing whose health needs are investigated; how risks, burdens, and anticipated benefits of individual studies are distributed; and who will have access to any resulting knowledge and interventions" (CIOMS, 2016, p. 2).

Data sharing can reflect respect for individuals' participation in research by acknowledging their scientific and social contribution to public health knowledge and applying findings responsive to their local context (Kaye et al., 2018). Knowledge tends to be seen as a public good and data can be used beyond the original study's scope (Institute of Medicine, 2015; Parker et al., 2009; Pisani & AbouZahr, 2010). A metadata review of health datasets, for instance, can produce results reducing "risks to future volunteers from undisclosed harms identified in previous [health-related] studies" (CIOMS, 2016, p. 78).

However, since SIPD represents changes in research practice, 'respect for participation' is governed by ethical principles responsible for maintaining transparency between investigators and participants, which are generally organised in regulations (Howe et al., 2018). In honouring participants' interests, autonomy, and confidentiality, data-sharing requires ethical frameworks that include institutional components to ensure the protection and integrity of study datasets where their future use is unspecified at the time of data collection (Kalkman et al., 2019). This respect is transferable to forms of public accountability, wherein proper governance ensures the security and longevity of individuals' privacy and preserves the dignity of host study communities, whilst producing quality outputs (Bull, Roberts, et al., 2015).

2.5.1.3 Public accountability for sharing research data

Public accountability for health-related research is an ethical principle that seeks to promote the social and scientific value of research. According to the Council for International Organisations of Medical Sciences this is most successfully achieved by sharing information and data about past and ongoing research through credible scientific journals and policy (CIOMS, 2016). The ethics of research publication recognises the obligation that authors and stakeholders (i.e., researchers, sponsors, research ethics committees, funders, editors and publishers) must comply with ethical reporting on

research results (CIOMS, 2016). It is respectful for those involved and the surrounding community for researchers to communicate the results of their work to the lay public (CIOMS, 2016). It is, therefore, in the interest of all to improve the fundamental effectiveness of public health "to prevent and cure disease, where possible, and alleviate pain and suffering" (CIOMS, 2016, p. 91). While sharing data still presents risks, burdens, and challenges, there are also benefits for various stakeholders. Data sharing must respect the privacy and consent of study participants. The risks here might be mitigated "by controlling with whom the data are shared and under what conditions, without compromising the scientific usefulness of the shared data" (CIOMS, 2016, p. 92). Good governance should employ data use agreements to ensure that secondary users observe original informed consent. Accessible and high-quality empirical data mean that solutions to public policy issues can, in theory, be addressed more rapidly and with greater transparency than previously permitted because of data infrastructure and storage protocols (Clubb et al., 1985; National Research Council, 1985; Pisani et al., 2010). In addition to promoting the responsiveness of health-related research, sharing data recognises the obligation of enhancing public accountability (CIOMS, 2016). Disseminating research findings and other forms of public information about additional data sharing activities help raise public awareness about the role that data sharing plays in promoting democratised health research (Kalkman et al., 2019).

2.5.2 Measures to minimize harm

Measures to minimize the risks of harm to individuals from sharing participants' data require the careful balancing of stakeholders competing considerations regarding the scientific and social value of research and fair subject selection with undue burdens, and challenges to those working in resource poor setting (Jao et al., 2015b).

According to CIOMS' ethical guidelines on public accountability for health-related research

> "the risks of data sharing may be mitigated by controlling with whom the data are shared and under what conditions, without compromising the scientific usefulness of the shared data. Organisations should employ data sharing use agreements, observe additional privacy protections beyond de-identification and data security, as apt, and appoint an independent panel that includes public members to review data requests. These safeguards must not unduly impede access to data" (CIOMS, 2016, p. 92).

"the true value of data can only be unlocked if there are laws and policies in place that foster the legal and ethical sharing of genomic data" (Staunton et al., 2019, p. 468).

2.5.2 Potential harms of sharing data

“When researchers use the online environment and digital tools to obtain data for health-related research they should use privacy-protective measures to protect individuals from the possibility that their personal information is directly revealed or otherwise inferred when datasets are published, shared, combined or linked” (CIOMS, 2016, p. 1)P.83.

The risks associated with sharing data are multiple and not limited to the harms of not sharing or withholding data, leading to unnecessary complications subsequently resulting in harms from an avoidable consequence such as anxiety or possible stigma or discrimination.

Such harms may deter individuals or communities from participating in future clinical trials as a direct result of failing to respect participants' interests. Data shared from vulnerable communities may create situations where confidential health data becomes exploited for use of commercial products (EMA, 2014; Hate et al., 2015; Bull, Cheah, et al., 2015). Much of the debate remains focused on issues related to informed consent and disclosure of confidential records. Policies supporting data sharing recognise that ethical issues can arise when sharing occurs and that appropriate responses are necessary. For example, clinical trials prospectively now conform to the registration of data-sharing plans recommended by the Institute of Medicine (IOM) and the International Committee of Medical Journal Editors (ICMJE) (Drazen 2015; Institute of Medicine, 2014; Taichman et al., 2016).

The literature discusses investigators, policymakers, and other stakeholders' concerns about releasing datasets into the public domain and reiterates arguments about the incongruent purpose between science health policies and public interest (Aitken et al., 2016; Sanderson et al., 2017). Past research framed the scope of deliberations on sharing data as a series of dichotomies balancing the potential social and scientific benefits gained from sharing health-related data in contrast to the risk of harm to individuals and communities.

The potential risk of harm from greater access to and use of individual participant data(sets) (IPD) may cause public disquiet if not appropriately governed (Carter, Laurie, & Dixon-Woods, 2015). Potential harms include:

(i) The invasion of privacy
(ii) The breaches of confidentiality
(iii) The threat of interference

Although sharing data adds value to public health and science, some fear that the integrity of the research enterprise is more susceptible to inappropriate access and misuse of individual datasets (Delamothe, 1996; Lemke et al., 2010; Parry & Mauthner, 2004). Multiple stakeholders contributing to and disseminating data in health sciences may complicate finding answers to the questions regarding who is responsible and accountable for failures if curation mechanisms are lacking (Fischer & Zigmond, 2010; Friedewald & Pohoryles, 2013; Merson et al., 2015), especially when end users are untraceable after the further use of datasets (Denny et al., 2015). Each of the above harms is discussed briefly below.

2.5.2.1 Invasion of privacy

The Organisation for Economic Co-operation and Development (OECD) defines privacy to mean:

> *"the status accorded to data which has been agreed upon between the person or organisation furnishing the data and the organisation receiving it and which describes the degree of protection which will be provided" (OECD, 2008, p. 422)*.

Privacy is thought of as the privileged access to and use of personal information by an individual or group. This includes the agreed distribution and restriction of personal information and persons' identification (Jain et al., 2016). Although best practice routinely anonymises participant datasets, sharing data contends with traditional measures taken by investigators in ensuring that individual participations are kept confidential (Asai et al., 2002; Ceci, 1988; Clubb et al., 1985; Delamothe, 1996; Lowrance, 2003). The interconnectedness of all information and data sources on the internet enables investigators to link studies to datasets across a finite number of data repositories in innovative ways was not possible until the 1990s (Kaye et al., 2009; Marr, 2015; McGuire & Beskow, 2010; McGuire, et al., 2008; McGuire et al., 2011; Trinidad et al., 2010). Advancements in communication technologies threaten individuals' rights to privacy because they facilitate the collection, storage, management, analysis and manipulation of personal data for investigators and non-research stakeholders if not managed responsibly (Friedewald & Pohoryles, 2013; Lang, 2011). By matching, datasets investigators can use new methodologies to comprehensively conduct data meta-analyses in novel ways (de Wolf et al., 2005, 2006a; UN Secretary General, 2017; WHO, 2016). While these data interlinkages offer increased statistical power, so too does the likelihood of detecting individuals' identities or the location of where the study was conducted and hosted community by triangulating granular details (de Wolf et al., 2006b; Estabrooks & Romyn, 1995; Lowrance, 2003; Sieber et al., 2015).

As cited by the CIOMS “the more difficult it becomes to anonymize data, the more important it will be to retain the ability to remove personal data from a dataset” (CIOMS, 2016, p. 44). However, the mutually reinforcing cycles of the right to privacy and technology as an extension of social practices continue to influence our understanding of privacy regarding technological developments (Friedewald & Pohoryles, 2013).

2.5.2.2 Breach of confidentiality

Breach of confidentiality can:

> *“result in [the] disclosure of data which harms the individual. This is an attack on privacy because it is an intrusion into a person’s self-determination on the way his or her personal data are used* (OECD, 2008, p. 422).

As a normative principle, confidentiality imposes “the responsibility to protect information entrusted to researchers for research purposes from unauthorized access, use, disclosure, modification, loss or theft” (National Health Research Ethics Council, 2015, p. 77). Although it is ethically important to ensure that sharing data does not undermine participants’ privacy nor the interests of the community in which they reside (UNESCO, 2007), the ubiquity and propensity of vast inter-connected databanks make it possible to identify individual participants even without identifiable information . As mentioned earlier, making people knowable through granular details about them intrudes into people's lives and privacy and fail research governance and data steward insurance of participant confidentiality (UN Secretary General, 2017; UN General Assembly, 2014).

It is important in research ethics to ensure that sharing data does not undermine participants’ privacy nor the interests of the community in which they reside (UNESCO, 2007). The ubiquity and propensity of vast inter-connected databanks or souces make it possible to identify a person even without identifiable information. As mentioned earlier, making people knowable through granular details about them intrudes into people's lives and privacy and fails insurance of participant confidentiality (UN Secretary General, 2017; UN General Assembly, 2014).

However, secondary investigators might not demonstrate honour in the same sense of duty (or due respect) when specific datasets are released to public repositories and broadly used for additional or alternative purposes (Kaye et al., 2009; Robling et al., 2004). The degree to which privacy in research avoids breached confidentiality is partially dependent on legislative and other formal regulatory measures governing the subsequent use of research data (Bersoff, 1992; OECD, 2008). Yet, legislation on public access to information and the protection of personal information does not specifically deal

with sharing health-related data obtained from research participants (Marais et al., 2017; National Health Research Ethics Council, 2015; Nordling, 2019). “the true value of data can only be unlocked if there are laws and policies in place that foster the legal and ethical sharing of genomic data” (Staunton et al., 2019, p. 468).

2.2.2.3 Interference in privacy

Arbitrary interference with the protection of individuals, or family, a home or community, infringes on human dignity, human rights and fundamental freedoms (United Nations, 1948; UNESCO, 2005). Interference disrespects participants’ autonomy.

The systematic manipulation of datasets, amassed from populations, pose a threat to national security in the form of being commercially and politically motivated (Clubb et al., 1985; Hate et al., 2015; Howe et al., 2018; Lemke et al., 2010; National Academies of Sciences, 2017). This is the idea of obfuscating the views of social and political events to deliberately influence public opinion. A case in point would be Cambridge Analytica and big data obtained from Facebook users and other social media sources without users’ knowledge or consent (Confessore, 2018). The misuse of citizens’ data constitutes an intrusion into personal privacy in generating distortions of media politics (Cochrane South Africa, 2017). The protection of public health relates to national and international security (National Academies of Sciences, 2017). Good governance has been shown to improve scientific knowledge, evidence, methodology, and good practice regarding data management and international collaboration.

The ethics of SIPD require adequate information communication to inform participants, but only if adequate regulations are responsive to and protective of public stakeholders’ rights while also promoting public benefits and scientific interests, without interference (Gostin, 2015; World Medical Association, 2015). However, data collected by investigators may impart identifiable information about research participants, such as the geolocation and socio-economic health context through study metadata. This could increase vulnerability to exploitation, stigma and interfere with individuals’ rights to freedoms and wellbeing (Bull, 2016; Bull, Cheah, et al., 2015; Denny et al., 2015; Hate et al., 2015; Howe et al., 2018; Parker et al., 2009; Sieber et al., 2015).

The trust and respect between participants and investigators rest fundamentally on the accountability for SIPD and public and global governance standards related to creating primary data and controlling its future usage (Kaye et al., 2009).

Arbitrary interference could violate the protection of a study's host community or otherwise lead to the unethical disclosure of IPD, resulting in privacy rights violations (Anane-Sarpong, Wangmo, Sankoh, et al., 2018; Jao et al., 2015a, 2015b). This raises debate among investigators, policymakers and other stakeholders about whether de-identification measures for sharing data ensure both privacy protection and scientific utility (de Wolf et al., 2005, 2006a; Rothstein, 2010). The credibility of investigators' publications and claims on intellectual property rights might be damaged through contradictory secondary analyses (Bersoff, 1992; Delamothe, 1996; Estabrooks & Romyn, 1995; National Research Council, 1985; Smith, 1994; Weil & Hollander, 1990). Commentators caution that events arising from poor data handling could result in scandals, diminish public trust in further research engagement and consent to sharing data (Cheah et al., 2015; Merson et al., 2015; Rani & Buckley, 2012; Sieber et al., 2015; Vickers, 2006).

2.5.3 Broad informed consent and respect for autonomy

Broad informed consent in essence is consent for governance. Adequate governance systems substitute for the loss of an individual's control over their data. Broad informed consent encompasses the range of future uses in research for which consent is given. Broad informed consent places certain limitations on future use of data. Broad consent should specify:

(i) the purpose of the databank,
(ii) the conditions and duration of storage,
(iii) the rules of access to the databank,
(iv) the ways in which the donor can contact the databank custodian and remain informed about future use;
(v) the foreseeable uses of the data, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies,
(vi) the intended goal of such use, whether only for basic or applied research, or also for commercial purposes; and
(vii) the possibility of unsolicited findings and how they will be dealt with. The REC must ensure that the proposed collections, the storage protocol, and the consent procedures meet these specifications.

These governance systems should specify—among other items—to which legal entity the material is entrusted, how authorization from the donor is obtained, and what procedure determines whether unsolicited findings should be disclosed. Proper governance systems are also important because

complete anonymization is becoming increasingly difficult owing to increases in cross-matching large data sets" (van Delden & van der Graaf, 2017, p. 136).

As the role of informed consent broadens from the single study data use, reaching out to external deposit and data storage for further research purposes, so do governance systems and data stewardship in the twenty-first century. Research governance should specify: the purpose of the databank; the conditions and duration of storage; the rules of access to the databank, the ways in which the donor can contact the databank custodian and remain informed about future use; the foreseeable uses of the data, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies; who will manage access to the data; the foreseeable uses of the data, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies; the intended goal of such use, whether only for basic or applied research, or also for commercial purposes; and the possibility of unsolicited findings and how they will be dealt with

Chapter 3. Theoretical framework

This dissertation's theoretical and methodological tenets framed the research question within a qualitative study design that took as its premise a deliberative democratic approach. Gutmann and Thompson (2004) define deliberative democracy (DD) is a 'form of government in which free and equal citizens (and their representatives), justify decisions in a process in which they give one another reason that are mutually acceptable and generally accessible, intending to reach conclusions that are binding in the present on all citizens but open to challenge in the future" (p. 7). DD is based on the belief that the people themselves should inform decisions affecting their lives or representatives rather than external government (Parker, 2007).

Normative democratic theory aims to find substantive (moral based) and procedural (democratic, institutional) resolutions to conflict over competing interests in a pluralistic society that "forces decision-makers to take into account the interests, rights and opinions of most people in society" (Christiano, 2006, p. 2). The outcome supports citizens' freedom of speech, access to information, and public policy regarding national debates, constitutionalism and institutional mechanisms (Bohman & Rehg, 1997). However, in expanding globalised health research, the "ethical-political self-understanding of citizens of a particular democratic life is missing in the inclusive community of world citizens" (Habermas, 2001 as cited in Chambers, 2003, p. 314).

Deliberation "as a social process is distinguished from other kinds of communication in that deliberators are amenable to changing their judgements, preferences, and views during the course of their interactions, which involve persuasion rather than coercion, manipulation, or deception" (Bohman, 1996 as cited by Parker 2007, p. 186). Successful deliberations are conducted in an open public forum and facilitate transparency and accessibility throughout the process. Deliberative approaches to democracy see the boundaries between the public and the private as being constructed by social practice that is open to further democratic enquiry and amendable to pluralistic social conventions (Parker, 2007).

3.1. Democratic Deliberation

Democratic deliberation (DD) theory is pertinent to ethics analysis of public health policies and research systems regarding scientific regulations and research governance (Parker, 2007). DD theory and methodology emphasise the significant role that stakeholders (i.e., citizens) have in understanding normative action through the inclusive democratic process of decision making (Presidential Commission for the Study of Bioethical Issues [PCSBI], 2016). Empirical studies focus on public

dialogue that investigates the accountability of institutions, groups, or governments and regard such ideals of constitutionalism as units of analysis to identify empirical ethical (also moral) claims (Parker, 2007).

Dryzek and colleagues (2019) refer to DD as "the science of [seeking] evidence on the capacities of citizens as they engage democratic dialogue, not as they respond as isolated individuals to survey questions" (p. 1145). Democratic outcomes are reached either through the aggregation of views (i.e., consensus and voting) or the transformation of preferences naturally concluding or resulting in new opinions and possibly deeper understanding (Bohman & Rehg, 1997; Parker, 2007). The latter is advocated because of participants' interest in or pursuit of "beneficial educative effects" (Bohman & Rehg, 1997, p. xiii). It also adds depth and richness to empirical insights derived from citizens' reasoning about common opinions shared publicly to appreciate and respectfully engage in debates over competing or additional civil interests (Bohman & Rehg, 1997).

The "expected outcomes of public deliberation include the identification of shared public values, which in a pluralist society should underpin public policy, and acceptable trade-offs among competing public goods and interests that determine the preferable type of society" (Molster et al., 2011, p. 212). Parker (2007) and Rothwell et al. (2016) recommended four qualities for investigators to follow when facilitating research deliberations. They are to:

(i) Weight the accounts to balance the range of views.
(ii) Ensure accounts are comprehensive in their scope and practical implications.
(iii) Ensure topics are acknowledged as being of importance to respondents' interests and values.
(iv) Ensure that respondents' expressed views are open to revision on the grounds of persuasive counterarguments.

A central component of DD research is the assumption that deliberations can change deliberators' minds and transform, or inform their opinions about the subject under examination (Chambers, 2003). This suggests that in modified FGDs, the ability to inform, interact and assess respondents' views are reportedly more productive with the inclusion of educative materials prior to conducting FGDs than without supporting materials to orientate participants (Rothwell et al., 2016). There are many ways to convey meaning and understanding in addressing the research problem through an educational presentation and the addition of an expert witness (Rothwell et al., 2016). Because of the openness to sharing information, feedback from participants is incorporated in the course of the study, allowing

study groups to become sensitised to the issues at hand (O'Doherty & Burgess, 2009; Rothwell et al., 2016) (See also Limitations in Chapter 6 below).

3.2 Deliberative scope

The scope of the deliberations refers to the preliminary information necessary to elucidate FGD respondents' engagement with the research topic and related concepts. This attempt "reflects the very real political and social power that consultations can have related to the legitimation of social policies" (O'Doherty & Burgess, 2009, p. 205). Past literature relates data-sharing in two deliberative approaches. First, procedural statements about the instrumental nature of health data-driven science; second, substantive claims about the axiology (value) of different stakeholders' views and vested interests towards research benefits. The structure and literature review of the present work's scope are presented in the next chapter.

Deliberative scope aims to supply participants with enough relevant information to optimise the deliberative aspect of face-to-face group discussions. This follows from the simple observation that better-informed participants convey their areas of interest better overall in peer-group studies, especially in open platforms addressing groups of individuals affected by common issues (PCSBI, 2016). These conditions make it possible for decision-making to result in civil actions that more broadly represent the interests, customs, cultures and expectations of community members, thus reaching outcomes more legitimately when issues are articulated publicly and respected by others working in addressing a collective goal towards problem-solving (Parker, 2007; PCSBI, 2016; Rothwell et al., 2016).

Past research on perceptions of sharing health-related data report on the trade-offs between mandates releasing IPD, which utilises the efficacy of health science on the one hand, and the constitutional rights and freedoms implicated through the democratisation of access to information on the other (Dixon-Wood, 2015). These balances are reported in the Results section of the present study.

The main benefit of DD research is its utility in empirical ethical research. DD method possesses valuable potential to conduct qualitative research that emphasises collective learning of goals through mutual understanding. Participants are provided with the conceptual tools required for understanding, reasoning and articulating their opinions on an unfamiliar or complex topic (Rothwell et al., 2016). By describing some of the issues between the ethical importance of individual autonomy over health research outputs and the instrumental societal benefits gained from sharing participants'

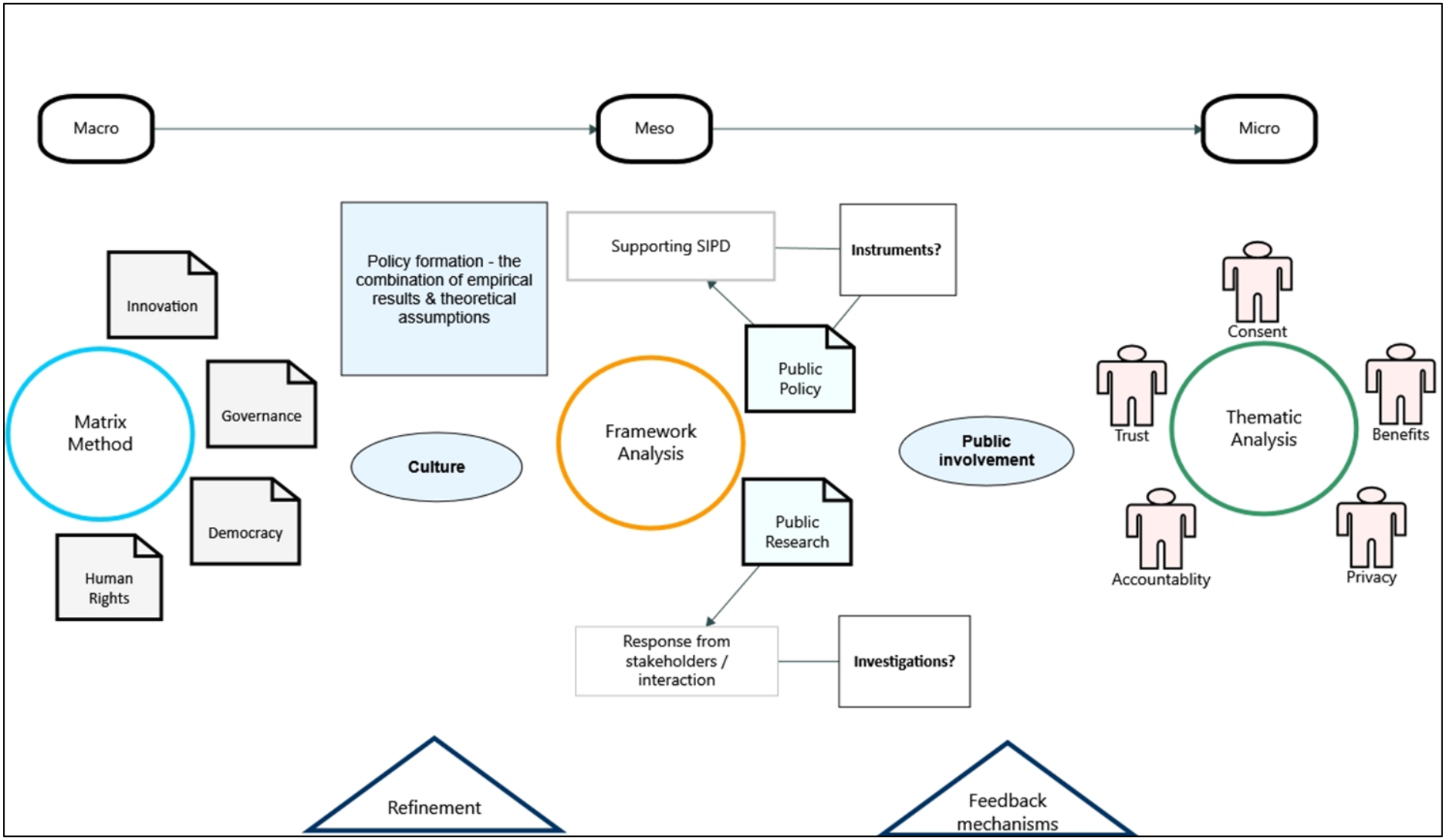
health data, it is hoped that participants will be better informed about such issues and therefore contribute more meaningfully to the focus group.

Substantive accounts weigh ethical considerations in procedural trade-offs between the private and the public. Expressiveness to views and attitudes are moral, or cultural, towards comparative instrumentalism for progress. Epistemic democratic deliberation methodology is a theory and analytic framework to solicit decision making from participants' judgements on the different challenges between the importance of individual autonomy over health research outputs and the societal benefits from sharing data (Jao et al., 2015a). Deliberation is characteristic of public discussion and debate, which makes people reflect on their own opinions, beliefs and values. Parker argues "that public discussion should be central to the identification and analysis of bioethical issues" (2007, p. 185). Furthermore, democratic deliberation enables people to "… justify [their] decisions in a process in which they give one another reasons that are mutually acceptable and generally accessible, with the aim of reaching conclusions that are binding in the present on all [participants] but open to challenge in the future" (Gutmann & Thompson, as cited in Perote-Peña & Piggins, 2015, p. 94).

A particular concern, given the relative novelty of data sharing, concerns an explicit ethical issue regarding the validity of informed consent procedures namely; negative experiences manifested by therapeutic uncertainty as an encumbrance to research with individuals and communities absent of heuristic consent processes (Bull, 2016; Flory & Emanuel, 2004; Nishimura et al., 2013; Prescott, Counsell, Gillespie, Grant, & Russell, 1999; Tam et al., 2015). Reviews on interventions developed to enhance informed consent for research participants have tended to focus on the content, structure and display of information rather, than the process of enabling participants to learn something for themselves as decision makers consenting to research participation (Bull, 2016; Flory & Emanuel, 2004; Nishimura et al., 2013; Prescott et al., 1999; Presidential Commission for the Study of Bioethical Issues, 2016; Tam et al., 2015). Moreover, there is relatively little empirical evidence on the analysis of health-related informed consent approaches in African literature compared to literature from the global north (Munung et al., 2016).

Informed consent, epistemically interpreted as a democratic instrument for predicating the capacity of individuals to make an informed choice to participate in health-related research, would be on the basis of 'their' heuristic interaction in both instrumentalist and expressive approaches to producing knowledge and warrants an empirical ethical investigation (Carter & Little, 2007; Parker, 2007; Rothwell, Anderson, & Botkin, 2016).

Figure 1: Thematic framework matrices of conceptual and empirical source



Chapter 4. Methodology

4.1 Aims and objectives

This qualitative study set out to achieve three objectives:

(i) to elicit attitudes about data sharing from a sample of persons with experience of participation in health research
(ii) to analyse the attitudes elicited thematically
(iii) to compare these findings with published data from other stakeholders as expressed in published reports on sharing health research data

4.2 Research questions

The main concerns of the study were to identify answers to the following questions:

(i) What are research participants' views on sharing health-related data?
(ii) How do these views compare with those of other research stakeholders?

4.3 Study methods

To identify and understand what ethical issues have already been discussed by past research in the context of sharing health-related data a collective literature review was initially undertaken. The term 'collective review' does not refer to a particular study approach; instead, it describes a 'snowballing technique' used in searching scientific literature (Garrard, 2011). Snowballing aims to use relevant sources based on knowledge of the research topic and look for references as they emerge from materials. A list of ten academic journals/databases covering a variety of literature published from 1972 to 2020 (listed alphabetically: EBSCOhost, Google Scholar, National Library of Medicine, PubMed Central, Sabinet, Sage, Science Direct, Taylor & Francis, Wiley Online and WorldCat) was initially gathered using NVivo 12 (software) and guided for health research literature (Garrard, 2011). Different types of articles yielded a broad range of sources. They included grey materials, secondary literature and primary sources.

Articles for this collective review were selected on the basis of two considerations: Firstly, literature that gave an account of procedural developments in health research concerning responsible governance for sharing research data (innovation) and safety to individuals. Secondly, attention on

substantiating research stakeholders' claims studied primary sources to compare those accounts with the participants' views elicited by this study.

Both categories followed a broad thematic approach to identify the literature important to concepts and paradigms underpinning health research data sharing, innovation, governance, and deliberative ethics. Understanding the themes of trends from various and diverse sources was necessary for preparing research participants with comprehensive accounts of how the research topic might impact the role of individual participation in health research**.** The assembly of the materials produced two syntheses (i) the matrix method, (ii) and framework analysis (charting). Ritchie and Spencer describe charting as a technique for synthesizing and interpreting qualitative data by sifting, charting and sorting material according to key issues and themes (Ritchie & Spencer, 2002). Descriptions of each of the reviews are described below.

Although the search strategy lacked structure, for instance by not using the common language of Mesh (medical subject heading) to control for specific vocabulary terms, the purpose of chosen materials was thematic. The review process used a cluster of search terms to identify literature using the snowballing technique. Keywords related to human ethics/ bioethics/ human research ethics and included variations such as 'sharing data,' 'sharing health-related data,' 'sharing health-related research data' and 'sharing individual participants' datasets'.

4.3.1 Literature review

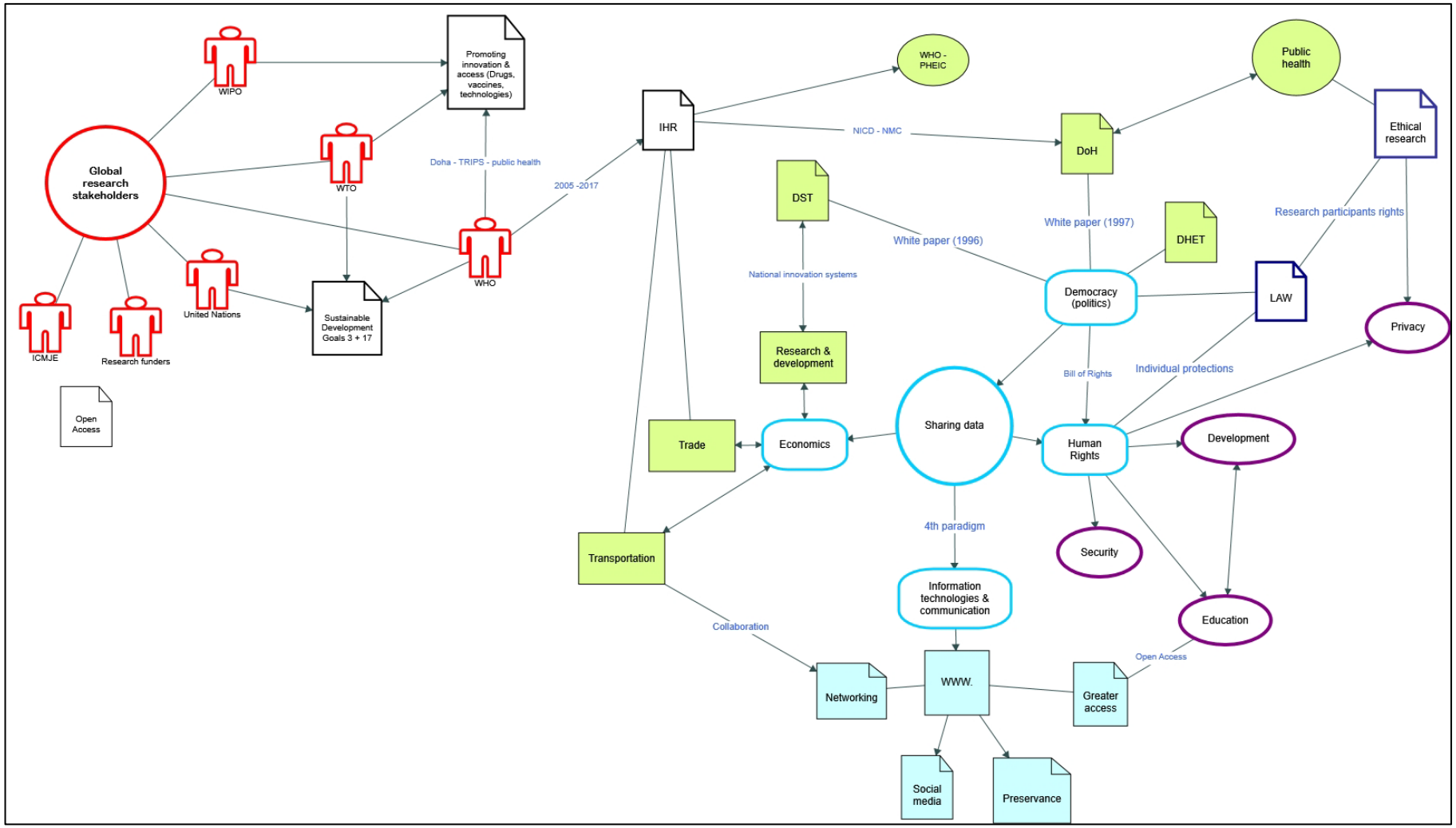
Grey literature is literature produced by organizations outside of the traditional means of commercial publishing or distribution channels (*Grey literature*; Torrico, 2022). According to Mortazavi, such literature "has not undergone the formal peer-review process used by academic journals" (as cited in Torrico, 2022, para. 8) (Torrico, 2022). Common types of grey literature include institutional reports and guidelines, working papers, government documents, white papers and evaluations (*Grey literature*).

At the grey and secondary level of literature, materials were identified conceptually, allowing a wide approach to the scope of the literature presented by the map of grey literature (Figure 2). This collection represents South African legislation, national white papers, health policies and research systems, local and global regulations, world agencies, strategic agendas, and universal declarations of human rights. The purpose was to indicate key concepts underpinning the study area, using available sources to show important insights necessary to produce a rapid account of 'global stakeholders' and 'sharing data' mechanisms.

Secondary sources comprise of papers or other documents that summarize, condense or interpret the original results first reported by investigators in peer-reviewed journals (i.e., primary sources) (Garrard, 2011). Examples of secondary literature represent information that provides a broad overview of a field with rich details and information but is less technical and lacks methodology design (Chaves, 2016). The types of literature used for this study included: editorial pieces in academic journals, scientific textbooks, chapters in reference books and a small number of systematic reviews. These papers were not identified using the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA). Instead, sources were snowballed and selected thematically. The collection of literature was refined in an iterative process that initially coded topics and was based on prior research in the same area of interest, as reflected in Table 10 (Codes on research and systems). At the search level of a review of primary sources, research findings derived from empirical papers in peer-reviewed journals were used to understand how the research topic has already been studied. A scoping review attempts to "address broader topics where many different study designs might be applicable" in understanding an emerging research problem (Arksey & O'Malley, 2005, p. 20). Rather than conducting a systematic review to answer a relatively narrow range of research, this study allowed the research topic to be treated conceptually through reinterpretation of themes throughout the writing of this report (Arksey & O'Malley, 2005).

The assembly of all literature served as "a useful way of mapping fields of study where it is difficult to visualize the range of material" (Arksey & O'Malley, 2005, p. 21). The review here does not justify a systematic review (Garrard, 2017), nor does it determine a quality assessment on the body of literature because of addressing the open and unrestricted purpose of the review itself (Arksey & O'Malley, 2005). Here "the scoping process requires analytical reinterpretation of the literature" (Levac et al., 2010, p. 1). The breadth and depth of the information extracted from additional literature followed the thematical review itself.

Figure 2: Map of grey literature



4.3.1 Matrix review

There were 704 literary sources identified from ten databases. Titles and abstracts from 328 articles were examined and sources not addressing the research topic were excluded. After an initial full reading for relevance, 150 papers were imported into NVivo 12 (qualitative analysis software), excluding 178 papers (Garrard, 2011). A second full reading arranged sources in chronological order to track emerging ideas with annotations on the research topic dated between 1972 and 2020. The reviewed grey and secondary literature consider (i) the global agenda of global stakeholders, (ii) health-related data plans that are actionable through international legislation and collaboration, and (iii) networks built between institutions and individual stakeholders.

The map attempts to capture two levels of proceduralism originating from 'Global stakeholders' and expands to include 'National institutions' in scoping international and South African instruments (or mechanisms), as shown above in Figure 2. Proceduralism refers to the principal process or 'procedure' in which decisions should be rendered (Gutmann & Thompson, 2004). The scoping map of grey literature links specific agendas (i.e., strategies) to broader political, scientific, and international affairs on global health, innovation, and governance. An example of multinational involvement is the 2001 Doha Declaration and its resolutions on the ethical problems raised by intellectual property rights that exempted stakeholders from deploying life-saving medicines because of laws protecting such property (González-Block et al., 2015; Sonderholm, 2010; World Trade Organization, 2001).

As previously mentioned, the International Health Regulations 2005-2017 demonstrate external measures that aim to safeguard trade and transportation sectors against economic damages through international pandemics (World Health Organization, 2016a). Specific policies under WHO's PHEIC regulation mandate health data collection, storage, use and distribution (WHO, 2019) - a measure that acts on South Africa's HPSR and calls for preparation by national biomedical and scientific institutions (DoH, 2017).

South Africa's White Papers on public health and technology sciences recognise "…that innovation in the design of South Africa's social and economic institutions, and in its system of governance" (DoH, 2001, p. 2) [and] "…the importance of knowledge, information and evidence health research must be linked and integrated into planning, policies, programmes and implementation" (DoH, 2001, p. 3). The map offers an ecological (or macro) view of a complex area as to review data-sharing, scoping interactions and direction across the academic/research/policy nexus remains poorly understood by research stakeholders in many LMICs (Anane-Sarpong, Wangmo, Sankoh, et al., 2018; Anane-Sarpong,

Wangmo, Ward, et al., 2018; Bull, Cheah, et al., 2015; Bull, Roberts, et al., 2015; Cheah et al., 2015; Denny et al., 2015; Hate et al., 2015; Jao et al., 2015a, 2015b; Merson et al., 2015).

Importantly, South African grey material on the research enterprise in South Africa identified appropriate legislation delineating the protection of personal data concerning the Constitutional Right of Bill (Table 2: Focus group presentations). Other grey information from broader sources such as secondary literature is represented in Figure 2.

They developed study questions (i.e., research items) intended to facilitate the focus group discussions and analyse research stakeholders' views.

(i) The scope of items achieved two outcomes: Identifying 'probing' (explorative) items and questions intended to facilitate the focus group discussions (Goldman & Schmalz, 2004; Klopper, Lubbe, & Rugbeer, 2007),

(ii) and a comparison of thematised findings from both published work and the subsequent qualitative FGD data (Garrard, 2011; NVivo 12, 2017).

Secondary texts and grey material were reviewed using the matrix method to select sources and arrange the information related to trends in global health research towards knowledge management and evidence generation, as shown by policies and systems that are consequential for how data-based science support social transformation [participant centric] and public health. However, the arguments in favour of open data require stakeholders to remain cognizant of the events that constitute moral, ethical and legal issues when further processing IPD. This type of analysis involved deducing interest relevant to the deliberative scope (e.g., The Bill of Rights, legislation on access to information [Act No. 2] and protection of personal data [Act No. 4]). Framework analysis enables the different data sources to generate both within-group patterns and cross-group syntheses of participants' perceptions.

4.3.3 Primary sources

The present work reviewed twenty studies published between 2002 to 2018 containing reports on views of 1719 stakeholders from eleven countries, showing a predominance of research in upper-to-high-income countries (UHICs), namely, the United States of America (six studies), the United Kingdom and New Zealand (two studies each); and one paper each from Canada and Japan. Seven studies were conducted with stakeholders from LMICs over two continents, Africa (South Africa, Kenya, Ghana, Tanzania) and Asia (India, Thailand and Vietnam). Kenya produced two papers (Jao et al., 2015a, 2015b). There were eight papers from LMICs and twelve from UHICs.

Primary sources included research on perspectives on data-sharing from a wide range of different research stakeholders, namely, (i) lay research participants (see table 5), (ii) administrative research stakeholders (see table 6), (iii) research investigators and (iv) officials and stakeholders of governing authorities (as shown in table 7). The empirical material was reviewed to evaluate the degree to which studies incorporated preparatory information concerning the ethical, legal and social implications associated with sharing health data for research purposes. This review allowed study material to be used in developing the group topic guide schedule (Appendix D: Topic guide schedule) and provide an empirical base against which to compare the current research findings. An overview of past research appears in the next section (Chapter 5.2. Results from empirical research).

The sources investigated four general areas of study: (i) genomic studies, (ii) non-biological datasets, (iii) public health research and (iv) electronic health records (EHR), as presented in table 4 (Types of datasets reviewed). The methods employed involved qualitative and quantitative research with one mixed method approach by Haga and O'Daniel (2011). The cross-tabulated data in table 8 (methods and instruments) shows that focus groups and interviews were the most frequently used methods (i.e., 12 focus groups and 9 interviews) employed by 2 studies on EHRs, in contrast to questionnaire or survey designs.

Most research was conducted with small samples of less than *n*100, with thirteen studies ranging from *n*9 to *n*79, likely owing to the nature of qualitative research. Of the five quantitative papers, sample sizes ranged between *n*100 and *n*365. The diversity and selection of research stakeholders fell into four broad categories comprised of lay research stakeholders (i.e., citizens and participants) and other research stakeholders such as professionals, investigators and governmental officials. The selection of participants and the corresponding study are listed in the tables below.

4.3.3 Focus groups

In the present study, focus groups (FGDs) were employed to elicit informed perspectives on sharing data from people with experience of participating in health-related research in South Africa. FGDs are a method employed to produce empirical data gathered from individuals' in discussion with other individuals and considerations across different views and values (Carman et al., 2016). The deliberative discussion process begins by providing prospective FGD respondents with informative materials to increase their background knowledge central to the deliberative topic – 'South African research participants' views on sharing health-related research data'. The deliberate preparatory steps included: (i) allowing time for the distribution of new information to reach potential respondents and

(ii) ensuring the presented information is relevant and balanced in the deliberative topic's scope (Rothwell, Anderson, & Botkin, 2016).

Qualitative data were collected from two face-to-face FGDs with sixteen respondents sampled from two separate cohort groups. Responses to sharing health-related data were preceded by an opening presentation designed to introduce respondents to information pertinent to data sharing (Appendix C: Sharing information presentation). Two focus groups of seven and nine respondents were conducted between 6th November and 3rd – 5th December 2018. The FGDs were guided by a standardised topic schedule. Notably, the information shared via the presentations differed slightly between the groups, but the research items and questions were applied uniformly, as shown below (Appendix D: Topic guide schedule).

4.4 Study setting

The author's earlier co-authored publications on the ethics of sharing research data sought specifically to capture particular elements regarding research participants' views on data sharing (Bull, Cheah, et al., 2015; Denny et al., 2015). Two prominent South African scientific institutions supported this study and assisted in inviting possible research participants from two different health research cohorts. Contact personnel from each institution interacted directly with prospective respondents, distributing information about the present study prior to due consent and arranged a shuttle to transport respondents. The FGDs were conducted on the premises of each study site, and access to meeting rooms was permitted. Boardrooms provided both privacy and technical equipment required to present study information. Site A was situated in a rural community, while site B was based near a peri-urban township.

4.5 Participant selection

Prospective respondents were recruited from two established health research cohorts, with the assistance of contact personnel from each scientific institution. Access to each study site was sought from and granted by gatekeepers before approaching suitable participants. Purposive sampling was used to include people who had experience of participating in health-related research, were 18 years of age or older and were willing to contribute to this project. In addition to showing interest signed informed consent was obtained. By selecting individuals from ongoing cohorts, it was hoped that respondents' *a priori* knowledge and awareness of research would lead to rich insights and thick descriptions of data sharing. It simply assumed that non-research participant would likely be less aware of the relationship between data collection and data storage, analysis and dissemination.

Prospective respondents received information about the purpose of the present study prior to and on the scheduled day of the group discussions. The leaflet provided an account of the research topic, explaining the qualitative means of gaining data used with focus group studies. Additional information outlined the rights and responsibilities associated with respondents participating in a group (see Appendix A) and the agreements and terms of giving informed consent (Appendix B) before starting the FGD sessions. The FGDs were of typical sizes (ranging from four to twelve individuals) with an average duration of 120 minutes (Rothwell et al., 2016; Tong et al., 2007). A total of sixteen respondents (see Table 1) consented to attend both components of the FGDs, which consisted of two parts: (i) the informational presentation on sharing data (see Appendix C) and later, (ii) the group discussion sessions that focused on responding to the presentation.

A brief demographic questionnaire including demographic information, i.e.; age, gender, race (or ethnicity), nationality, education, employment status and current involvement, or prior health research experience was administered (see Table 1 and also Chapter 5.4 Focus group deliberations). There were more women than men from site A, but more men than women in site B. All FGD respondents were South African citizens and reportedly unemployed. Of the 16 respondents, four completed high school, while only one person attended a tertiary institution. All respondents reportedly had experiences participating in only a single cohort study conducted at each Site. Respondents reported no other experiences of participating in a study. Respondents from site A had approximately one year of active research, whereas site B's longitudinal study recruited research members at different times. Seven respondents had one year of participation, while two respondents had three to four years of experience with study site B.

4.6 Research team

Two female translators fluent in IsiZulu and English accompanied the author to assist during the presented information and data collection stages. Both translators were psychology postgraduates familiar with qualitative research and independent of one another. Although neither of the translators had any prior knowledge of the respondents individually, both translators provided unique contributions beyond that of the general focus group format. For instance, the first translator was employed at the first institution (site A), had knowledge about the cohort study, and provided insights into respondents' research context. The second translator was not familiar the second research centre site B.

4.7 Ethical issues

Sharing research data presents a unique set of requirements for many researchers and participants from a variety of disciplines. Also, tensions over democracy crisis between scientific, governmental intervention and social expectations. Ethics committees (RECs), independent review boards (IRBs) and other regulatory bodies.

The difficulty associated with releasing, re-using, and exchanging data is its threat to individuals and the public. It refers to the external abstraction of trade-offs that exist between personal interest and freedom from arbitrary interference, albeit lawful, but nonetheless perceived unreasonable. Health-related data infrastructure (e.g., public databanks repositories) requires research stakeholders to knowingly pass trade-offs from different cultural settings, "types of values and interests, degrees of privacy versus facilitation of research, and individual control of samples versus consideration of community risks and benefits" (O'Doherty & Burgess, 2009, p. 203). The ethical issues concerning sharing data without proper governance, or social licence are explained in ways that research regulations or mandates are executed.

The ethical approach to social research in an African context follows Wassenaar and Mamotte's (2012) adaption of Emanuel, Wendler, Killen and Grady ethical framework (2004) for social science. Their treatment of Emanuel et al.'s work proposes eight ethical principles for health-related research conducted in LMICs. These are outlined briefly below with specific reference to the present study.

(i) *Collaborative partnership* in health-related research aims to build the capacity of research stakeholders to become full partners throughout the research endeavour. While sharing data are highly utilised within and across collaborations, the issue with exporting data transnationally when multiple jurisdictions are required to ensure adequate protection of personal, or public data.

(ii) *Social value* pertains to research that should ideally improve public health and research benefits, contributing knowledge for the overall benefit of society. Additional factors include conducting research that is responsive to a broader social, political and cultural context. This study thus aims to document the opinions of those most closely engaged in research – actual health research participants.

(iii) For research to have *scientific value,* a study must generate reliable and valid data that achieves its objectives in answering the research questions using well-described and verified research methods and analytic techniques. An aspiration that may never be entirely developed because of the potential risks of harms to individuals and the public.

(iv) *Fair selection* of study participants includes determinations about the eligibility of groups or individuals. Participants should be enrolled who are relevant to the study questions. In this case, respondents with prior experience of health research were approached and enrolled, as this suited the key research questions.

There were clear inclusion and exclusion criteria:

Inclusion Criteria

- Adult research participants must have been involved in an existing health research study
- Willing to consent for the present study

Exclusion Criteria

- Aged less than 18
- No consent given
- No prior experience as a health research participant

(v) *A favourable risk-benefit ratio* aims to balance the potential risks of harm and benefits for study participants. The research investigates health and social problems to improve the wellbeing of the society at large but inevitably increases participants' chances of being negatively affected when participating in research. In principle, research risks should be minimised "by using procedures which are consistent with sound research design and which do not unnecessarily expose [participants] to risk" (CIOMS, 2002, as cited in Emanuel, 2008, p. 129).

(vi) *Independent ethics review* of scientific research protocols improves the overall quality of the study design and upholds the integrity of the research. After review and approval by the School postgraduate committee, this study was approved by the UKZN Humanities and Social Sciences Research Ethics Committee reference number HSS/1222/013.

(vii) Investigators must convey their scientific intentions in research with prospective participants or a group or community and obtain valid *informed and voluntary consent*. The decision on whether to participate in research or not must be predicated on the voluntary choice of individuals with full knowledge of the study protocol, sampling requirements and expectations of individuals responsibility. Five general elements of valid informed consent involve:

(a) the provision of relevant study information to prospective participants,

(b) which allows appropriate comprehension of the study objectives.

(c) Participants should have the capacity to consent

(c) Study participants must be made aware of their rights as volunteers in research by informed consent, such as the freedom to withdraw from the study at any point in time and without penalty.

(d) Finally, participants should be provided with clear information about the nature of research and study methodology, including data collection, storage, analysis and further reuse. All participants in this study gave signed informed consent (See Appendix B).

(viii) Emanuel and colleagues recommend *ongoing respect for participants and host communities* that dignify and empower their public health and science contributions. This principle aims to demonstrate respect throughout the study, during data collection and after the study has concluded.

Focus groups typically pose a higher than normal risk to confidentiality. This is because the responsibility for maintaining confidentiality relies on other participants' shared responsibility in respecting each other's anonymity. For this reason, FGD respondents were cautioned to avoid divulging information of a private nature and encouraged to respect the views and privacy of each others' opinions.

Table 1: Respondent demographic data

Sample FGDs	**Study site A**	**Study site B**
Sample size	*n*7	*n*9
Age		
Range of years:	19 – 50	21 - 55
Median:	29	33
Average:	33	35
Gender		
Female	5	4
Male	2	5
Race	African	African
Nationality	South Africans	South Africans
Education		
Grade 1 – 7	1	1
Grade 8 – 11	3	6
Matric	2	2
Tertiary	1	
Current occupation	Unemployed	Unemployed
Duration of participation in years		
One year	All	7
Additional years		1 (3 years) 1 (4 years)
Involvement in other studies	None	None

4.8 Participant data collection

The group discussions were recorded to capture respondents' dialogue. Respondents consented to the use of two microphones during the introductory presentation and the deliberative sessions (see Appendix B: Informed consent form). This gave the author and translator the advantage of having a backed-up copy and the option to choose the better-quality sounding recording. The recordings from both FGDs were translated into English and transcribed by the second translator using MS Word documents. The author listened to recordings to check the accuracy of each transcript. Any queries were settled between the author and the translator.

The audio files produced during the presentations were not translated nor transcribed. Instead, the author listened to the separate presentations and look to recall the non-verbal interactions and exchanges between the author and the translators. Also, the translators were engaged throughout the FGD sessions and assisted immensely with following isiZulu dialogue.

Data collection followed the PowerPoint presentation session. The research purpose, the aim of the slide show, and research topics and concepts were introduced (Appendix C: Sharing information presentation). The research presentation drew from grey and secondary material reviewed by the matrix method. However, two modifications were made to the presentation session at site B, firstly the content to cover the topic presented in more detail (on the projection screen) because it was felt the information in site A was insufficient to trigger productive deliberation. This change saw the presentation session extended from 30 minutes at site A to a 2-hour session with respondents from site B. Secondly, respondents from site B were requested to return in two days to conduct an improved deliberative component of the FGD. The respondents were compensated with transportation by this alteration.

The presentations included subject matter from grey and secondary materials (Table 2: Focus group presentation). The respondents from site B received a more in-depth view of the Constitution and Bill of Rights concepts (The Republic of South Africa, 1996). The additions include:

- The Bill of Rights
- Freedom & security of the person (bodily & psychological integrity)
- The right to privacy
- Freedom of expression
- The right to have access to health care services
- Access to information

Both the Promotion of Access to Information Act (No.2 of 2000) and Protection of Personal Information Act (No.4 of 2013) emphasised the two-way channel of receiving information from state and related institutions; while also communicating the public interest to these structures through policy-making. Legislation mandating that personal health datasets must be archived for further empirical processing store recordings only of national significance under the National Archives of South Africa Act (No.43 of 1996) and the Promotion of Access to Information Act (No.2 of 2000). Mentions included the National Health Act (No. 61 of 2003), which addressed the following three responsibilities:

- The obligation to keep records
- Allow access to health records
- Use records for the purposes of study, teaching or research

A final alteration to the presentation included information on public accountability for research. Qualitative research often offers an organic iterative process in refining the clarity data collection processes can be considered good practice (Srivastava & Hopwood, 2009) when argued that research participants are better informed and more prepared to engage the issues that underly the construct of empirical social, public research. Furthermore, characteristics of deliberative research (Chapter 3.1 democratic deliberation) include amendable "ways to make participants more comfortable and promote their confidence in expressing their views" (O'Doherty & Burgess, 2009, p. 206). The deliberative oriented study planned to enable respondents to have better discussions about the implications of sharing data (Molster et al., 2011). Two underlying implicit outcomes of DD research and decision-making involved: "the beneficial educative effects it has on citizens" (Bohman & Rehg, 1997, p. xiii) and the goal of "producing reasonable [and] well-informed opinions in which participants are willing to revise preferences in light of discussion" (Chambers, 2003, p. 309). Data analysis is described in the following section.

Table 2: Focus group presentations

Information presented at both Sites A & B
These claims contained definitions of: • social and scientific value • data and health-related research • how IPD are shared for further research (Diagram 1). Three potential benefits of sharing data were discussed, namely: • that sharing data improves scientific research • the responsiveness of public health increases • the social value of public health research is promoted Similarly, three potential disadvantages of sharing data covered: • the lack of sharing data procedures prevents developments of science • the underutilisation of sharing data impedes the responsiveness of public health (i.e., in health care, delivery and services) • the social consequences of violations in privacy and vulnerable confidentiality The role of informed consent described three components of valid informed consent discussed: • why it is an ethical standard in health research with humans • information provision • giving voluntary consent The Bill of Rights on research participants protections: (a) to security in and control over their body (c) not to be subjected to medical or scientific experiments without their informed consent
Additional information presented for site B
The obligation of the State to respect, protect, promote and fulfil all human rights with Dignity, Equality and Freedom. Claims about the importance of respondents' views involve: • Constitutional rights • The promotion of access to information • The public accountability of health-related researchers • The protection of personal information and health data The Bill of Rights was expanded to include: • Freedom and security of the persons • Privacy • Freedom of Expression • Health care and health-related services

Access to information claim that “Everyone has the right of access to:
(a) any information held by the state
(b) any information that is held by another person and that is required for the exercise or protection of human rights

Legislation mandates the obligation to record health-related data from patients by health establishments, namely:
- National Archives of South Africa Act No. 43 of 1996
- The Promotion of Access to Information Act No. 2 2000
- The National Health Act No. 61 of 2003

Access to and sharing of health records by health practitioners are permitted when:
- To disclose records acts in the interest of the patient
- For the purposes of study, teaching or research
- Authorisation of health records obtaining no identifiable information is not necessary

The rights of health-related data include:
- The right of citizens IPD to be further processed
- Being informed of data collection, storage and analysis of IPD
- Requests of the correction, destruction or deletion of IPD To opt out or object the collection or analysis of IPD

4.9 Data analysis

Qualitative research aims to produce an in-depth understanding of human behaviour, attitudes, experiences and social expectations (Tong et al., 2012). According to Tong and colleagues, “the synthesis findings from multiple qualitative studies provide a range and depth of meanings, experiences, and perspectives of participants across health-care contexts" (2012, p. 1). In a systematic method, this study thematically analysed claims made from twenty empirical papers with framework analysis and accounts of views on sharing data given by sixteen respondents produced during two focus groups using thematic analysis. These are described separately below.

4.9.1 Framework analysis

Developed by Ritchie and Spencer (1994), framework analysis has its background in applied policy research and qualitative methods (Ritchie & Spencer, 2002). A core ability of the framework analysis is for research objectives to be established under, or linked to, specific informational parameters. For instance, previous research provided an initial overview of topics and codes developed with *a priori* research on sharing data seen in table 11 (Codebook: General nodes). Ritchie and Spencer explain that

“this requires an explicit research methodology which can be viewed, discussed and operated by individuals within the team” to meet the conditions specified by the policy or criteria set by the research design (1994, p. 308).

The framework played an important role in structuring the deliberative scope, which comprised of 21 items in five distinct sections of the topic guide (Appendix D: Topic guide schedule). They related to broad areas of questioning about (i) general awareness of data-sharing, (ii) possible benefits, (iii) potential disadvantages or harms, (iv) individual attitudes to sharing health data and (v) thoughts and suggestions in relation to research governance. These items' were expanded and applied in a deductive approach to analysing codes that used themes drawn from the twenty past studies table 13 (see Table 13: Themes - framework analysis of primary sources). Insights on data-sharing in different contexts create thematic points of ethical comparison found between the papers themselves and against the group of research respondents reported below (see Chapter 5: Results).

4.9.2 Thematic analysis

Thematic analysis is a systematic method of finding meaning across an entire data set and achieves insights into collective and shared reflections of the social context under examination (Javadi & Zarea, 2016). The merit of thematic analysis is its ability to code qualitative data that can be linked to broader theoretical issues (Braun & Clarke, 2012). The analytical treatment of data coding followed the related top-down approach to FA’s analysis of *a priori* ideas and topics, where items developed in the topic guide examined findings generated on FGD respondents’ attitudes (see Table 14: Thematic analysis and focus group data part 1 & part 2).

Chapter 5. Results

This chapter describes the results of this study based on two thematic analyses. First, focus group respondents answered the question '*what is research participants' views on sharing health-related data?*' Second, the findings attempt to describe '*how participants' views on sharing health-related data compare with those of other stakeholders'*

5.1 Results from focus groups with research participants

5.1.1 Awareness

The FGDs with experienced research respondents elicited their knowledge and experiences of participating in health research and the use of participant data. Whilst none of the respondents were aware of study datasets made accessible for unique and unrelated research, most had a grasp about informed consent, as it pertained to their own participation in health-related research. Respondents from both study sites cited informed consent protocols concerning the destruction of individual participant biological samples. They said that they were informed of who the PIs were, what responsibilities participants assume in joining the study, and the purpose of the study. However, none of the respondents were explicitly aware of data sharing as a research outcome, in their own experiences of participation.

Several respondents from site A were aware that information on individual participants was accessible to other investigators via the National Clinical Trials Registry (NCTR). Here, respondents divulged their own experiences of being enrolled in their current cohort. A respondent from site A shared that:

"[investigators] checked on the computer [to see] if [a respondent had] ever participated in any other study besides the one [they had] started" (FGD A, R3).

It was felt that the purpose was to identify any known risks or limitations to individuals as well as the success of the research study overall. For instance, investigators needed to ensure that the adverse effects on participants' health were minimised during the trial (site A, R5). Further awareness of sharing health data came in the form of appreciation for how investigators were able to share clinical observational data (clinical notes) with health practitioners and pharmacists in clinics, ensuring delivery of appropriate treatment to participants or patients.

While respondents from site B echoed many similarities regarding informed consent and related protocols concerning biosamples (i.e., blood drawn from study participants), none had any prior

knowledge of where participant research datasets might be stored nor whether IPD were subject to reuse after the study ended.

5.1.2 Attitudes

Prevailing attitudes towards sharing data were conditional on factors dealing with the acceptability of further data analysis and the potential benefits and disadvantages of individual participants' positive contributions in research. Also, the sense of community and cooperation towards public health research seemed to influence lay stakeholders' attitudes.

It appeared that FGD respondents felt that research was a community practice and that by sharing data, participants' contributions would be used to help others. In this way, sharing data was viewed as *"important [for the community] to know that [such a] service [was] here,"* in hoping *"it encourages the community […] to teach them"* about being healthy (FGD A, R2). As a public benefit, it was suggested that data sharing had the potential to gain support from the government to augment public health efforts in serving the community. For most respondents, data meant it was scientific and studied to produce evidence, sometimes used by other sectors to guide decision-making and public health planning.

In the FGDs, participants explored what they thought distinguished health-related research data from other types of individual datasets collected in different health contexts (i.e., between EHRs and biomedical data) and how they felt regarding SIPD. Respondents suggested that they would have more confidence in sharing data with a researcher than a health practitioner. The discussion supported the idea of researchers providing a participant-centric platform upon which public knowledge can expand to stimulate a better understanding of possible solutions to health problems. One male respondent thought:

> *"it is better to talk to someone who will communicate with you and give you feedback and tell you the root cause of the problem and how to deal with it should it return, rather than a doctor who will just give you a pill and send you home"* (FGD B, R4).

In general, respondents believed that sharing research data was necessary and useful for society. The acknowledgement of sharing with a broader and international community of investigators could be beneficial for other people in other ways. This spirit of altruism was universal between the FGDs and was said that *"sharing data is a good thing for the generations that follow"* (FGD A, R3).

Both FGDs agreed that sharing data that would assist investigators' work and improve health for the community and general public. It was felt that linking data to medical records to improve the accuracy

of patient treatments was acceptable. However, most respondents felt strongly that certain types of participant data should be kept confidential and shared only under strict conditions, like an individual's HIV status subject to specific laws (Health Professions Council of South Africa, 2016).

Generally, informing individual participants about the potential opportunities and pitfalls of sharing data is crucial to the way personal and private decisions are made public in their own interests. This was seen as representative of their experience or participation and was viewed as the first most important step in ensuring sharing data would be acceptable. However, the argument for using blanket consent was challenged by one respondent, who asserted that how openly data should be shared came down to the individual person's attitude in saying she was *"open about taking [part in] the [trial] to those around me"* (FGD A, R5). The tiered modified form of obtaining appropriate consent would in this instance both protect and promote the respondent's interests.

5.1.3 Potential advantages

FGD respondents thought that sharing data could assist the community both presently and in the near future. Being made aware and being kept up-to-date about progress in health research and related developments (much like data-driven systems) had the added benefit of helping people grow intellectually as part of a democratic society:

> *"getting more information about things [...] might expand my thoughts and help me […] have* a bigger and *better understanding about different things"* (FGD B, R4).

Another advantage of sharing data regarded *"the government [and] department of health [should involve taking steps to allow] all their knowledge [on public health] can be spread and be made available to us [the community]"* (FGD B, R5). In this way, sharing data via the national health information infrastructure on public health can result in knowledge on the issues pertinent to the participants' contexts, demonstrating the virtuous cycle of public research supporting public health.

In general, FGD respondents felt that social media posed a risk to the privacy of personal information when it came to thinking about sharing data. The harm created by the publication of specific social dynamics was described during the FGD sessions as having some impact on the sense of well-being, causing internal turmoil and worry about discrimination and stigmatisation, making it difficult to continue with normal life. Another concern included the way "t*he credibility of the researcher"* would be affected by an error in data handling. Similar views expressed in the present study suggest that high standards and integrity in data management were important elements of participants' trust in data sharing.

5.1.4 Informed consent

Discussions about informed consent with respondents from site A acknowledged that participation in clinical research was done with respect for individual participants' autonomy. For instance, it was remarked on how *"[investigators] never forced us [participants]"* to join the study (FGD A, R1). The choice of whether to participate or not was *"based on the explanation [… and] reasons given"* for participating in research (FGD A, R1). Adequate information to consent included investigators' justifications for why the research was needed, highlighting the potential benefits to participants.

Respondents from site B did not discuss individuals' views of classic informed consent for health-related research. The procedural function of informed consent was seen to be instrumental in achieving the study objectives. It delineated the rights and responsibilities between research participants and investigators, for example:

> *"[at the beginning] they [the researchers] told us that the people who are heading the research, what the whole thing is about, and when we talk about it, what are the rules that we are supposed to follow and abide by... so that whatever we are gathered about can be successful... as you have just explained about the importance of respect and working hand in hand. And other rules you have to follow if you signed […]"* (FGD B, R4).

5.1.5 Broad informed consent

Broad consent was introduced in the FGDs, which asked respondents to consider communicating research concepts about how datasets would be made accessible to the wider scientific community. Admittedly, respondents were not familiar with broad consent before the FGD commenced in discussions. The information shared during the presentation on broad consent was also found to be novel by respondents. Adjustments to the information presentation expanded on the details involving participants' rights after respondents from site A had difficulty understanding the new premise on sharing data bought by broad consent. This premise entails only one statement of permission required from a participant to share data in multiple further research processes.

The additional information provided through the presentation on South African legislation on health research and citizen rights had perhaps helped respondents from site B to be more deliberative in their thinking regarding board consent and its broader application over specific forms of consent. Participants expressed an interest in learning more about what happens to outcomes (i.e., service delivery, planning or policies) downstream from data collection. They also seemed to recognise that consent to share data comprised an individual's decision to either elect for sharing data in favour of

improved health or else reject and raise concerns about the potential risks and harms with relevant IPs. In short, empirical health-related data were viewed to have importance for some respondents.

5.1.6 Data governance

Recognising that sharing data involved practices conducted as a part of the research enterprise by investigators, respondents wished for all sharing adhered to formal agreements and protocols of exchange (e.g., Material Transfer Agreements, typically applied for biomedical research). A respondent from site A suggested that sharing data should be on the premise of fairness and democracy, saying:

> *"as long as they [IPs] have permission [to sharing data] and if it was the way [they] work then it is okay […] if they [the relevant stakeholders] have an agreement and they both exchange and share from both sides then it is okay […] it be must fair"* (FGD A, R1).

This point of view is indicative of the role that data stewardship plays with researchers and institutions.

5.1.7 Issues with data governance

Some of the respondents recognised the trade-off played between the right to privacy and the mandated actions in the public interest (e.g., the regulations relating to the surveillance and the control of notifiable medical conditions, section 90(1) the National Health Act, 2003 (Act No.61)). Opinions from site A were changed by talking about how individual participants might be benefited from giving national and international institutions access to health data out of public interest. However, the competing interests over SIPD were in one respondent's words:

> *"a bit tricky because we do want to get help but [even if] I did not give them access to my information, I would not say no to help"* (FGD A, R5).

Suggesting that although the collection and releasing of public health data was considered undesirable at perhaps a cost on a personal or private level, should an event constitute a public health emergency of international concern (PHEIC), realising community health datasets would warrant overriding the freedom of choice expressing that

> *"if [participants] are taking in a study there are risks that will happen because in terms of us [participants & South Africans], our standards of living are not the same as those [of another country]. We need to have our study [done] in South African and [others] their own study. They can see and compare our [results] only, but not take our [outputs away]"* (FGD A, R7).

Remarking on the standards of investigators and data collection for further processing was viewed by one respondent

> *"[…] the problem first is [about] understanding. […] When someone else gets information about me, how did they get it... if they got a good understanding and [explained it] to someone in a good way, they will be able to use my information in a good way... but if [the investigator] explains it to them in a wrong way, they will perceive it in a wrong way"* (FGD B, R4).

Another issue was the question of "how did second users get access to their IP data? Remarking that if secondary investigators received quality metadata, they would surely then be able to use "my" "information in a better manner. Also, the opposite would surely be true in that if they received poor metadata, their perception of the issues would be "wrong".

Other respondents from site B saw a duality to data sharing activities. On the one hand, sharing data may offer more efficient responsiveness from responsible institutions; while on the other hand, some regretted that the aspirations of promoting greater access to health datasets had not been witnessed before, especially from Government departments, which may be short-lived and not sustained in efforts due to political competition and scepticism. Already noted by the literature, respondents advised that participants were likely to not tolerate contradiction in how they are treated if investigators and representatives of the health research community failed to honour their expressed wishes to valid informed consent. However, these issues were not evenly captured from respondents from site A. That is to say that proper governance would be an infrastructure capable of overseeing functions free from sporadic action and harm.

5.1.8 Rights and obligations

FGD respondents made the following requirements and their obligations deemed appropriate when research datasets are subjected to further analysis:

(i) An explanation of where further processing would take place needed to provide details about the respondents' responsible and right to know such decisions of governance processes.

One respondent from study site A said that *"they [the secondary analysts] would need my permission to have access to that information"* (FGD A, R5). Similarly, respondents during FGD B felt that *"[they as participants] are supposed to know [about further using IPD in research]"* (FGD B, R2).

Moreover, information on the South African Constitution and the human rights enshrined within it was covered at length in the second presentation conducted with respondents from site B. The additional information focused on the obligation of the State to respect, protect, promote and fulfil all human rights with Dignity, Equality and Freedom. Perhaps, with respondents' sense of justice it was asserted saying:

> *"if [a person] starts something that involves people's personal details, they [i.e., investigators] have to let [participants] know how they can protect that information […] and that it [shared data] could happen that it [the IPD] may be leaked and how it can affect [them – participants] if it gets leaked […]. They [investigators] need to make [participants] aware so that when [participants] are signing [i.e., giving consent], [they] are aware of what can happen if [IPD] gets leaked* (FGD B / R4).

(ii) The investigators carrying out further processing of IPD must be recognisable as credible investigators in the field. Adding credibility would give respondents confidence in deciding to share their data.

Two women from site A spoke of how they would want to be able to *"… see [the secondary analyst] by his uniform that he has permission to access my information"* (FGD A, R4), such as *"… something that verifies that he holds that position [indeed as] he says he holds [it]"* (FGD A, R5).

(iii) Releasing and accessing study datasets should only permit further processing after secondary analysts obtain authorisation from a regulatory body. Many respondents would have liked to be able to verify who is using their data and know that they gave consent for IPD to be further processed. It was suggested by respondents that

"they would first have to verify my information […] so I can see that it is that person 'exactly'. Or maybe they should first ask me if I give them permission to have access to my files" (FGD A, R7).

(iv) Also, when sharing IPD, the host research institution should be seen as acting on behalf of the community's interests.

This last point addresses the obligation accompanied with researchers duty to act in respectful ways that demonstrate concern for the wellbeing of participants and ensure to uphold the public accountability for health-related research.

5.1.9 Respect and trust

If the community and its members had participated in the research and the study shared its datasets, it was deemed important for the institution and investigators to uphold the community's trust for investigators *"to work hand in hand"* with their own private d share study datasets, it was important for the institution and invested public interests. Respondents felt *"it was important for the community to trust [research processes]"* by acknowledging that trust is binding in and built on throughout the research study process (FGD A, R4). A respondent elaborated on the trust for public health research and sharing health-related data in saying that

> *"because [secondary researchers] work with [the host research institution] I would allow them [to further process IPD], because they [i.e., secondary users] work hand in hand with [the host research institution]"* suggesting in part an extension of the community as well (FGD A, R5).

5.1.10 Suggestions on better governance

Respondents from study site A were content to give the host institution proxy consent (i.e., broad consent or data custodian) to share their data for further analysis. Indicating respondents' level of trust in investigators discernment over reusing IPD and assuredly with investigators discretion to act on behalf of individuals and the community's interests. It was remarked by one respondent in saying

> *"that if that second person [data analyst] can get help through my information, they would have to get in contact with the organisation where [they] got my details from in the first place and then it would be up to them to agree for them to use my details"* (FGD A, R2).

creating the means to share was important – proper governance

Recording data anonymously was viewed as a good practice, especially when sharing data with external institutions. Being told about how, why, when and where datasets would conduct further research was another important requirement for respondents. One female respondent felt having more confidence in knowing if the study was going to be shared with "*someone [she] already knew […], but if it was someone [she] did not know, then [she would] not*" give consent (FGD A, R1).

This suggests that with a priori knowledge of respondents' own contribution to the original study and learning of the potential role participant datasets have in generating additional studies can be seen to demonstrate good faith. For instance, respondents wished for IPD to be implemented within the national context, which would be fruitful in yielding additional scientific outcomes. A simple anecdote

of sharing data between investigators and other stakeholders, in the context of public health research. Involved referring respondents' attention to the names of different universities, institutions and funders, listed at the bottom of the posts adorned on the walls of the boardroom to show the possible kinds of partnerships and exchanges site B would potentially share data with (figure 4, slide 17, Appendix C).

Knowledge of knowing where the datasets could potentially be stored and shared with others could reassure prospective participants. The social choice of whether to further process IPD or not was seen to have some bearing on knowing that a formal protocol, such as classic informed consent with blood samples, would adhere to standard practices under national regulatory frameworks. In this way, communication was seen to be a binding element. Trust in sharing IPD was seen to come from instrumental functions that demonstrated how they would use IPD, as many respondents were not willing to agree for agreements' sakes. The fact that participants are required to adhere to scientific and ethical standards while participating in the study - so too then shall secondary investigators be required to follow scientific and ethical instrumental functions.

It was suggested during the FGD of datasets having case number that could be tracked as well retrieve information about the interests linked to study IPDs. It was strongly required that data governance and stewards of data practices seek quality output (such as metadata) to ensure best standards and respectful handling of datasets. *Hence, unscientific data sharing was viewed as unethical. Moreover, the public accountability of sharing data could be improved by allowing individuals to further use study datasets and demonstrate both social and scientific value. Therefore, research participants and community members who knew the means to receive feedback, and follow with interest developments, perhaps regarding a publication or formulating a linked policy to the study data and its outcomes, would *foster trust and cultivate a culture of transparency.

5.1.12 Focus group respondents' views

The focus group respondents offered insights into their views and reasons for sharing research datasets, such as the benefits to verify and *"check that the investigation or [study] was indeed working [or conducted as intended]"* (FGD A, R7), or for instance referring to the National Clinical Trials Registry (NCTR). It was seen that sharing data was important in the applications of teaching, studying and research. By making good use of institutional and human resources data sharing possesses the ability to mutually exchange "better knowledge" in a collaborative process (FDG B, R3).

This argues for access to research results in health-related research based on a moral claim and reciprocity advocating that *"[…] if they [external investigators or institutions] have information that can help us too we [should] also gain [access to data]"* (FGD B, R1).

Sharing data involves knowledge sharing to those who do not yet have the empirical informational basis of evidence to improve the community,

> *"so […] those who have the knowledge can advise other people who do not have the information we have […], so we can all have information and not just keep it with us"* (FGD B, R4).

This information also enriches the relationship between the community and host research institutions by demonstrating that data produces applications and knowledge in other ways *"that is, it does not end here"* and can potentially go on research in other analyses (FGD B, R4).

In summary, SIPD was viewed as necessary in responding to problems in public health and ensuring research benefits are implemented in advancing knowledge. Respondents saw data sharing activities as reflexive to and representative of the private and personal interests in receiving better public health services through investigators inventions and social procedures when having access to quality data (a win-win scenario for multiple stakeholders).

FGD respondents were shown to have a good grasp of research protocols related to their respective cohorts and research concepts associated with classic informed consent rhetoric. Commentators raise concerns about research stakeholders being adequately informed about the responsibilities associated with the sharing and further processing of datasets collected from participants. The literature reviewed above and study respondents valued democratic tenets such as fairness and transparency in reciprocal exchanges between investigators and institutions; and between research participants and the data collected.

Although FGD respondents were not familiar with the idea of broad consent, its implication for individual participants and secondary analysts was understood in similar ways with the notions of governance, stewardship or public accountability. It was, therefore, easier for FGD respondents to require investigators to ensure a professional or institutional commitment to assuring the legitimacy of further processing IPD. In this way, sharing data with members of the public health research community could yield both social and scientific value through the formation of collaborative research as constituted within transparent systems of accountability.

The value of science is a social practice that is contextualised to local experiences. Distinguishing social value and local professional norms from perceived research benefits indicate the importance of the development of both human capital and public health infrastructure at individual and community levels (Lutge et al., 2017). However, the measures that are taken to ensure the public is involved and informed about research requirements and mandates are reportedly obstructed and not readily available (Marais et al., 2017).

5.2 Results from empirical research:

The empirical materials were used to address the second research question: *how do participants' views on sharing health-related data compare with those of other stakeholders?* The findings revealed that all participants with experience as research participants prioritised informed consent and recommended that receiving information was key to public accountability.

5.2.1 Awareness of sharing data

Although sharing individual health-related datasets was increasingly supported, research showed that lay stakeholders are largely unaware of the significant advances in digital health data sciences. The administration of health establishments manage EHRs in accordance with national health-information systems, but despite it being routine practice, individuals were routinely not informed by practitioners about storing and sharing EHRs (Whiddett et al., 2006) or about the re-use of identifiable personal/patient medical information (Parkin & Paul, 2011). Inadequate information received by participants received gives rise to several uncertainties about research data released to public data repositories. Some participants supposed that SIPD would apply to only local researchers, perhaps not realising that public health benefits through global research (McGuire et al., 2008). Additional concerns included the unrealistic expectations of participants' desire for having a say over data re-use downstream from the study (Haga & O'Daniel, 2011; Lemke et al., 2010; Parkin & Paul, 2011; Robling et al., 2004), and the potential direct benefits imparted to individuals by sharing data (Jao et al., 2015a; Merson et al., 2015). Together with FGD respondents in the present study, lay stakeholders felt that public lack of awareness of data sharing was a major barrier to public support. FGD respondents and the empirical literature caution that although people do not know where their medical records are stored or how records are further used, they would generally feel that their privacy rights were invaded by research use (Asai et al., 2002).

5.2.2 Acceptable and unacceptable standards of sharing data

Research datasets are a valuable resource acknowledged for providing empirical results useful to aid in decision-making on public health policies and research systems. The most favourable use of IPD involved contributing to additional research, public service planning or when necessary for auditing purposes intended to improve health administrators functions (Robling et al., 2004; Stone et al., 2005; Whiddett et al., 2006). In contrast to participants' altruism toward sharing data, exchanging data with companies for for-profit was the least acceptable reason for consenting to independent future data use. These stakeholders and institutions included the pharmaceutical industry and health insurance companies and to a lesser extent large institutions because of the potential misuse of individuals confidential and sensitive health records. Another common institution was Governments, most likely because of the potential of arbitrary interference based on sensitive personal, family or home information.

Individuals' distrust of particular investigators and institutions was expressed as a major concern, *"with over 50% of [patients] not wishing to share their information with private health insurers or with government agencies"* (Whiddett et al., 2006, p. 537). Privacy and safety, common concerns in sharing data with stakeholders, were seen to be alleviated when investigators removed all identifiable information before storing and sharing study IPD. Research participants were shown to be more trusting in sharing IPD with medical researchers than with any other profession (Lemke et al., 2010; Parkin & Paul, 2011). Traditional means of sharing information, such as scientific, academic or scholarly modes of disseminating knowledge consider being unacceptable, such as sharing data during conferences, seminars or meeting presentations (Haga & O'Daniel, 2011).

To share research participant data without first obtaining informed consent from people was unanimously considered intolerable in one report: *"(n = 256, 70%) of respondents said it would have been completely or somewhat unacceptable if their research information had been sent to the databank without any communication from [the research institution]"* (Ludman et al., 2010, p. 13). It was said that this ignored common courtesy, removed individuals' personal choices and showed a lack of respect for persons rights (Robling et al., 2004). Participants thought that any further data analysis that was different from the terms of conditions that consent was granted demonstrated a disregard for participants' trust in investigators (Jao et al., 2015a). *This is highlighted in revised research guidelines, such as the 2016 CIOMS (van Delden & van der Graaf, 2017) that is to capture empirical data for scientific purposes it is research stakeholders' responsibility to ensure that participants provide informed consent for proper and sustainable research governance.

5.2.3 Potential advantages and disadvantages

Research stakeholders generally supported sharing data citing the potential benefits to public health and research systems. Access to quality datasets can promote new refined research and may enable translational scientific knowledge such as hypothesis testing or theoretical knowledge applied to problem-based learning (see chapter 2.1). The pooling of research resources is claimed to enhance the efficiency of data production, thus increasing the robustness of scientific evidence, and supporting *"science in fundamental ways, including ensuring the reproducibility, integrity and transparency of science and potentially improving the quality of data"* (Jao et al., 2015b, p. 6).

In general, sharing data tended to be seen as a public good. Respondents felt that exchanging EHRs added value and credibility to research, possibly also providing benefit to other public health systems. Some research participants could appreciate the high level of competition in awarding scientific funding, and conveyed that investigators should be allowed to share study data because of its beneficial economic effect. Additional advantages were "identified by participants [in] three broad categories: increased research efficiency, benefit to patients and society, and respect for research participants" (Trinidad et al., 2010, p. 493). Other terms used by qualified stakeholders described "the potential to move the field of science forward by opening up new avenues of science and by closing knowledge gaps through collaborative communication between different research programs" (Denny et al., 2015, p. 293).

Salient potential disadvantages involve the misuse and mismanagement of research datasets. The perceived harm includes concerns about potential arbitrary, unethical interference of the rights to privacy and the freedom from risks of confidentiality. For example, personal or familial health information may result in the extortion of individuals or loaded rates from health insurance providers or health services because of disclosed information that would be otherwise protected and confidential (Robling et al., 2004; Stone et al., 2005). Similar concerns discussed potential harm from being tracked, targeted or exploited by identifying information (Haga & O'Daniel, 2011). However, these concerns could be addressed with adequate information and knowledge on safeguarding IPD (e.g., anonymising and deidentifying IPD). It was noted that any further use of data obtained without individual participants' consent amounted to an invasion of individuals' rights to privacy (Asai et al., 2002).

Possible discrimination against individuals or harm to individuals was seen as a potential result of unauthorised access to stored data, or else accessed to harm individuals (Lemke et al., 2010). Sharing data could potentially diminish public trust in health-related research if data sharing ever became a

public scandal exposed by mass media (Haga & O'Daniel, 2011). Datasets and published research on marginalised and vulnerable groups of people run the risk of creating stigmatisation for those groups and perpetuating skewed and biased reports (Jao et al., 2015a). The misuse and poor representation of individuals' data from their research participation could demonstrate "disregard for community dignity" and undo public accountability of research (Anane-Sarpong, Wangmo, Sankoh, et al., 2018, p. 104).

5.2.4 Informed consent

Past research examined the social choices of lay research stakeholders' preferences for sharing data after either providing or not providing informed consent. Although there were some conservative views about the significance of obtaining informed consent from people, in that informed consent *"does not matter at all to me"* and was unnecessary for some citizens (Asai et al., 2002, p. 3), for most lay research stakeholders, the value of receiving informed consent prior to sharing datasets was "*seen as a way of making patients feel that they were helping*" (Robling et al., 2004, p. 106). Also, as a *"courtesy"* to participants done out of *"obligation"* to respect individuals' rights to autonomy, *"it was important that researchers had asked for [individual] consent"* before releasing IPD or making datasets accessible to investigators (Ludman et al., 2010, p. 14). Many participants thought that giving informed consent was essential and predicated on the *"specific information"* received in advance of releasing datasets (McGuire et al., 2011, p. 949), that explained the *"potential risks and benefits"* associated with sharing health-related datasets (McGuire et al., 2008, p. 52).

5.2.5 Data governance

The literature highlights the importance of striking *"a balance between the requirements of research on behalf of social welfare and an individual's right to privacy"* (Asai et al., 2002, p. 8). The protection and behaviour undertaken by the research enterprise require appropriate regulations that mutually reinforce individuals' participation in sharing data and the promotion of scientific data benefits. Thus, past research into *"whether existing policies achieve an appropriate balance or whether they are overly restrictive"* (McGuire et al., 2011, p. 954) has investigated *"the relationship between researchers and study participants"* (Trinidad et al., 2010, p. 494). Research governance has undertaken a shift in participant-centricity regarding attention to personal commitment and trust in systems of accountability, which are enacted on ethical "*principles or issues of confidentiality and privacy, data ownership, data sharing and integrity, transparency, trust, accountability, openness and global justice*" (Anane-Sarpong, Wangmo, Sankoh, et al., 2018, p. 100).

5.2.6 Issues with data governance

Among conservative societies (i.e., Asia), participants (namely patients and health administrators) felt that they could not refuse what investigators had requested of them, because of their unequal relationships with them. As one woman stated: *Problems in powers*

> *"[T]here is no way for us to know whether or not our personal information is dealt with anonymously. We are so naive about what medical research is and how it proceeds. Such powerlessness and ignorance make me uncomfortable*" (Asai et al., 2002, p. 6).

Merson et al. (2015) found that hospital stakeholders thought that the use of IPD was "*such a trivial thing to consider. Moreover, [the] sharing of my information [or IPD] does not affect my life in any way"* (p. 254). However, when the request for access to *"raw data"* came from a professional (e.g., fellow investigator), *"it [was] synonymous with being disrespectful"* (Merson et al., 2015, p. 255). While public health focuses on social goals and communal benefits, the implementation of data exchange networks occurs globally, challenging traditional views of cultural collectivism in conflict with more individualistic ideals (i.e., wealthier nations) (Anane-Sarpong, Wangmo, Sankoh, et al., 2018). *health establishments* and the legislated/regulated use of health records mandated by Health Act & National Archive*

This suggests that although data sharing promises to offer public health responsiveness from responsible institutions, the aspirations of public consultation in policy formation have not been realised. Therefore, the national health information system, jointly directed by the South African Departments of Health, Science and Technology and Education, may require political and legislative intervention to inform a democratic public of further processing scientific datasets.

5.2.7 Rights and obligations

The association between trust in science and respect for individuals' rights and public interest suggests that the role of regulatory controls placed in health-related research enhances social value when acting on behalf of societal justice. In terms of research, social justice regards fairness, reciprocity and collaborative partnership in sharing the benefits and risks derived from science.

Fairness broadly addresses the problem of not receiving appropriate acknowledgement of the individual or collective participants' contribution to health-related research from their datasets. Discussions about reciprocity and participants' contribution to research reflect their desire for sharing data to benefit their community directly or indirectly. In addition to emphasising the importance of

protecting individuals from harm, participants suggest that primary data investigators should be allowed to conduct further data analysis collaboratively with investigators in global health research. Ensuring appropriate acknowledgement of further data processing would develop local investigators' capacity (Bull, Cheah, et al., 2015).

Science and health in research with human participants requires proper ethics and science review of protocols and practices. In LMICs, investigators may face a myriad of ethical, legal, social, scientific and political implications raised by the growth of international health research collaborations. Therefore, collaborative partnerships involving scientific data sharing should also assist with capacity building, aiming to "contribute to a host country's sustainable capacity for health-related research and ethical review" (Council for International Organizations of Medical Sciences, 2016, pp. 29–30). Equity in decision-making and action is a core part of respect for participants' rights, which entails the obligation to promote better inclusion among diverse stakeholders, mutual learning and social justice through the routine collection of scientific data, in responding to the responsiveness of local public interests and health priorities.

The obligation to public accountability for sharing health-related research data, awareness of participants' rights over data sharing, and the interests in interactions between research stakeholders (namely investigators) would foster transparency. Past research emphasised that investigators were *"obliged to officially state that [an individual's EHRs] were to be used for research purposes"* (Asai, 2002, p. 4). For instance, *"it was either very important or extremely important that they [the participants] be informed about the possibility that their [health-related data] may be shared with others"* (McGuire et al., 2008, p. 50).

As a minimal condition to obtaining valid and informed consent, the decision to consent has been suggested as being influenced by the preferences and social choice of individual participants' rights and interests (Stone et al., 2005). Also, most participants wished *"to know what organisation [or] agency had oversight responsibilities for genetic research data as well as to clearly understand the research goal and motivation"* (Lemke et al., 2010, p. 372). This might ensure that participants' choices are predicated on relevant information and knowledge about the research context. It is the investigators' responsibility to inform participants in enough detail about the plans for sharing data, to ensure SIPD was meaningful to participants and deliberated about views during the consent process (Denny et al., 2015). By receiving an account of the norms surrounding data collection, storage, analysis, reporting, sharing and further scientific processing, participants are enabled to become responsible stakeholders and active in self-governance. Furthermore, the provision of such

participatory information could help lead *"towards full disclosure of confidential data"* by participants in consenting to secondary analysis (Robling et al., 2004, p. 107). Participants saw that there was *"a need for trustworthy governance to ensure that both practical and ethical goals advancing science and protecting research participants would be achieved"* (Trinidad et al., 2009).

5.2.8 Respect and trust

The data indicate that respondents' trust in health-related research is influenced by perceived investigators' professionalism and respect during interactions with prospective participants and community members (Stone et al., 2005). This involves being empathetic towards the laypersons' possible technical disadvantage and willingness to deliberate about research stakeholders' different views and values, while giving sufficient information to satisfy their understanding of the issues and factors. Thus, were investigators able to educate individuals that IPD is required and desirable for further better public health, prospective participants would be more likely to give valid consent to SIPD. Trust for consent would be based on the institution's accountability to individuals and the community. This is primarily because of the community's and respondents' admiration for the institution and investigators to promote public benefit from research as having both scientific and social value.

The empirical literature suggests that participants' trust regarding sharing data for health-related research was not necessarily predicated on individual protections and regulatory controls articulated in research by obtaining valid informed consent. Nor were assurances of data security and individual privacy the fundamental factors in trust. Instead, it was found that participants wanted:

> "*researchers to promise that they would protect study data to the best of their ability, provide an honest accounting of any breaches that may occur, and make their 'best effort' to mitigate any negative effects"* (Trinidad et al., 2010, p. 493).

Therefore, for an institution or investigator to share data, it is granted by way of social licence to carry out particular research activities, even though to do so may involve deviating from common modes of conduct. The licence used by "the professions ... claim[s] a broad legal, moral and intellectual mandate", and hence they must be able to convince society that their practices will "not succumb to the profane" (Dixon-Woods & Ashcroft, 2008, p. 382). Debate over the dichotomous "consent or anonymise" approach to further processing health datasets in research has undergone an ethical legalistic transition towards systems of accountability based on interpersonal commitments (Trinidad et al., 2010). Defining good data governance now includes the composition of the relationship

between investigators, the institutions and research participants; and stewardship of stakeholders' accounts on their respective interests (Carter et al., 2015; Chambers, 2003).

However, discussions on sharing data in global health research have tended to come from the perspective of stakeholders leading data science infrastructure and policies mandating research to share datasets, which might go "beyond compliance with legal requirements" (Carter et al., 2015, p. 405). For instance, in Africa, the "levels of individual awareness about rights and abilities to exercise them are generally at developmental stages" (Anane-Sarpong, Wangmo, Sankoh, et al., 2018, p. 99). The situation may result in the stakeholders responsible for generating datasets not being given the opportunity to contribute to research practices and the sharing of datasets (Kaye et al., 2018; Kaye et al., 2015).

5.2.9 Suggestions on better governance

The literature recommended four areas of improvement for good data sharing governance: first, the lack of awareness on SIPD among lay research stakeholders; second, the importance of high-quality data management and curation standards entrusted to custodians; third, having internal regulations in place to control data processing, much like the formal ethics review process already governing health-related research with human participants; and lastly, ensuring that SIPD policies are inclusive of community representatives and interested groups, or individuals, in developing research practices and public health systems.

Institutional trust between investigators and research participants could be improved by acknowledging the wishes of respondents for SIPD to result in an extension of the original work, assuming the study objectives have continuity between the primary and secondary analysts (Kaye et al., 2009). However, the risk of secondary analysts disregarding the cultural dignity of the host study community and research participants does raise concerns (Anane-Sarpong, Wangmo, Sankoh, et al., 2018).

It was suggested during the FGDs that datasets having case numbers might be tracked as well as retrieve information about the interests linked to study IPDs. It was strongly argued that data governance and stewards of data practices seek quality output (such as metadata) to ensure best standards and respectful handling of datasets. Hence, unscientific data sharing was viewed as unethical. Moreover, public accountability for sharing data could be improved by allowing individuals to use study datasets further and demonstrate both social and scientific value. Therefore, research participants and community members who knew the means to receive feedback, and follow with

interest developments, perhaps regarding a publication or formulating a policy linked to the study data and its outcomes, would foster trust and cultivate a culture of transparency.

5.2.10 Recommended informed consent

Past research recommends giving concise information on the aims of sharing data; the procedures are undertaken by investigators to protect individuals' rights (i.e., privacy) and the community's values; what possible benefits and harms might arise from further IPD analysis; and the opportunity to learn more about the expected outcomes when sharing data (i.e., scientific, political and educational applications). With communication that further data analysis would promote both scientific and social value, informed consent could also provide a chance to understand the importance of research concepts and the health public policy system. It is suggested that, in this way, *"better understanding of the significance of research may motivate subjects to cooperate"* with the goals of a study and better health in additional research (Asai et al., 2002, p. 8).

Supporting the need for additional information to clarify explanations on research concepts about the nature of using health-related datasets when obtaining informed consent highlights the importance of ensuring that participants are made adequately aware of how sharing data might affect them (Stone et al., 2005). Acknowledging the difficulty in anticipating potential further research data reanalyses and limitations in obtaining valid informed consent has led investigators to identify *"finding the optimal way of communicating key information about data sharing"* (Ludman et al., 2010, p. 14). For example, the hybrid model of consent proposed to base the informational requirements on research variables and circumstantial factors justifying the further use of IPD (Whiddett et al., 2006). Others argue for using dynamic consent, giving both specific research and participant information, with an interactive, personalised online interface to select preferences and alter their consent choices over time (Kaye et al., 2015). Relatedly, the *"disclosure of data-sharing practices was important in order to make a truly informed decision and fulfil the fundamental ethical principles of participant autonomy and respect*" (Haga et al., 2011, p. 223). Informed consent protocols detailing complicating and technical research concepts run the risk of becoming ill-informative for participants.

Much discussion about the validity of informed consent has focused on understanding how participants' contributions to the study would be reused in further research. It was also argued that participants would be more accepting of sharing data if they knew where their data had been provided to secondary researchers. Thus, obtaining valid informed consent is instrumental in understanding participants' contributions to the study and the relationship with the broader research enterprise.

5.2.11 Views on sharing data

This study aimed to identify research participants' views on sharing data obtained from two South African research cohorts and compare their perceptions to attitudes previously reported in the empirical literature. The insights into SIPD from research participants responded to several different study problems, investigating the trade-offs between what was found acceptable and issues that respondents rejected. Participants tended to identify acceptable trade-offs that supported public interests, shared values and policy preferences (Molster et al., 2011). Policy surrounding open access to datasets requires that research stakeholders be acceptable to different cultural settings and the regulatory landscape regarding "types of values and interests, degrees of privacy versus facilitation of research, and individual control of samples versus consideration of community risks and benefits" (O'Doherty & Burgess, 2009, p. 203).

Although participants cannot be expected to be aware of technical research concepts, their views and attitudes were clear on sharing data to further process datasets in the interests of social and scientific value (O'Doherty & Burgess, 2009). Most lay research stakeholders expressed general support for sharing data, but there were concerns about further processing data without adequate consent. Past research participants had strong preferences for control in the decision-making process, and for such information to be provided. Not obtaining valid consent and lack of transparency were construed as being *"dishonest"* (McGuire et al., 2008, p. 50) and likely to make people feel uncomfortable (Hate et al., 2015).

Past research has indicated a causal relationship between social choice in research participant consent models' giving control over decisions about data sharing, and the creation of public anxiety about protecting privacy and loss of social support (Carter et al., 2015; McGuire et al., 2011). However, this requires research into understanding what informs acceptance by citizens and society and determining appropriate criteria to access IPD (Taylor & Taylor, 2014). This would also involve examining policies on how datasets are maintained in the long term, noting that while they may risk being overly restrictive through managed access to datasets (Jao et al., 2015a), the potential value of accessible and quality datasets to society and researchers is gradually improved through innovative scientific applications driven largely by novel data sciences.

5.2.12 Issues with informed consent

The problem with obtaining valid informed consent was discussed in terms of the relationship between investigators and participants. In particular, this covered how informed consent is communicated to participants, or the lack thereof; and the potential for broad informed consent to

cause therapeutic uncertainty[3]. Given the diverse number of research stakeholders representing a wide range of interests, it was found to lead to the possibility for their attitudes to be very different towards sharing IPD without obtaining prior informed consent (Asai et al., 2002).

Experiences of powerlessness where *"the relationship between medical doctors and patients are socially unequal"* indicated a belief that individuals could not but accept what researchers were doing (Asai et al., 2002, p. 4). A health practitioner admittedly stated that, as investigators, practitioners *"do not perhaps explain [sharing EHRs] or discuss it with patients as much perhaps [practitioners] could"* (Stone et al., 2005, p. 785). The assumption of receiving implied consent from individuals when particular services are sought leads practitioners to believe that they *"do not always [require] further clarification when distributing patients' health information"* (Whiddett et al., 2006, p. 537).

The literature further suggested that the current approaches to obtaining informed consent for participant data inadequately met their informational needs, nor was there a satisfactory level of control in making informed decisions about sharing data. Participants thought that the lack of specificity on sharing data for further research processes would result in therapeutic misconceptions, where participants held *"false assumptions"* about the accessibility of IPD (McGuire et al., 2008, p. 51). However, to give participants an involved account of the regulatory context on sharing data was not widely supported by investigators and senior scientists from two African settings, who feared "*that additional information about how data would be shared during consent might discourage research participation"* (Denny et al., 2015, p. 295). They acknowledged that the *"impracticalities of obtaining consent"* in the traditional sense of giving specific consent for health-related research, pose particular challenges to research with datasets routinely captured on population health (Anane-Sarpong et al., 2016, p. 3). The infeasibility of obtaining valid consent was owed in part to the complexity and volume of datasets taken from different populations.

5.2.13 Suggestions on best informed consent practices

Past research recommends giving concise information on the aims of sharing data; the procedures undertaken by investigators to protect individuals' rights (i.e., privacy) and the community's values; what possible benefits and harms might arise from further IPD analysis; and the opportunity of learning more about the expected outcomes when sharing data (i.e., scientific, political and educational applications). Where it is communicated that further data analysis would contribute to promoting both scientific and social value, informed consent could also provide a chance to facilitate

[3] Therapeutic uncertainty is defined as misunderstanding the research purpose or how research differs from individualised care.

understanding the importance of research concepts and the public health policy system. In this way, it is suggested that *"better understanding of the significance of research may motivate subjects to cooperate"* with the goals of a study and better health in additional research (Asai et al., 2002, p. 8).

The need for additional information to clarify explanations about the nature of using health-related datasets when obtaining informed consent highlights the importance of ensuring that participants are made adequately aware of how sharing data might affect them (Stone et al., 2005). Acknowledging the difficulty in anticipating potential further research data reanalyses and limitations in obtaining valid informed consent has led investigators to identify *"finding the optimal way of communicating key information about data sharing"* (Ludman et al., 2010, p. 14). For example, the hybrid model of consent proposed to base the informational requirements on research variables and circumstantial factors justifying the further use of IPD (Whiddett et al., 2006). Others argue the use of dynamic consent, giving both specific research and participant information, with an interactive, personalised online interface for participants to select preferences and alter their consent choices over time (Kaye et al., 2015). Relatedly, the "*disclosure of data-sharing practices was important in order to make a truly informed decision and fulfil the fundamental ethical principles of participant autonomy and respect*" (Haga et al., 2011, p. 223). Informed consent protocols detailing complicating and technical research concepts run the risk of becoming ill-informative for participants.

Much discussion about the validity of informed consent had focused on understanding how participants' contribution to the study would be reused in further research. Thus, obtaining valid informed consent is instrumental in understanding participants' contribution to the study and the relationship with the broader research enterprise.

5.2.14 Data governance

The literature highlights the importance of striking "*a balance between the requirements of research on behalf of social welfare and an individual's right to privacy*" (Asai et al., 2002, p. 8). The protection and behaviour undertaken by the research enterprise require appropriate regulations that mutually reinforce individuals' participation in sharing data and the promotion of scientific data benefits. Thus, past research into *"whether existing policies achieve an appropriate balance or whether they are overly restrictive"* (McGuire et al., 2011, p. 954) has investigated *"the relationship between researchers and study participants"* (Trinidad et al., 2010, p. 494). Research governance has undertaken a shift in participant centricity regarding attention towards personal commitments and trust in systems of accountability, which are enacted on ethical "*principles or issues of confidentiality and privacy, data*

ownership, data sharing and integrity, transparency, trust, accountability, openness and global justice" (Anane-Sarpong, Wangmo, Sankoh, et al., 2018, p. 100).

5.2.15 Issues with data governance

In traditional societies (e.g., Asia), participants (namely patients and health administrators) felt that they could not refuse what investigators had requested of them because of their unequal relationships with them. As one woman stated:

> *"[T]here is no way for us to know whether or not our personal information is dealt with anonymously. We are so naive about what medical research is and how it proceeds. Such powerlessness and ignorance make me uncomfortable"* (Asai et al., 2002, p. 6).

Merson and co-authors found that hospital stakeholders thought that the use of IPD was *"such a trivial thing to consider. Moreover, [the] sharing of my information [or IPD] does not affect my life in any way"* (Merson et al., 2015, p. 254). However, when the request for access to *"raw data"* came from a professional (e.g., fellow investigator), *"it [was] synonymous with being disrespectful"* (Merson et al., 2015, p. 255). While public health focuses on social goals and communal benefits, the implementation of data exchange networks occurs globally, challenging traditional views of cultural collectivism in conflict with more individualistic ideals (i.e., wealthier nations) (Anane-Sarpong, Wangmo, Sankoh, et al., 2018).

5.2.16 Rights and obligations

The association between trust in science and respect for individuals' rights and public interest suggests that the role of regulatory controls placed in health-related research enhances social value when acting on behalf of societal justice. In terms of research, social justice regards fairness, reciprocity and collaborative partnership in sharing the benefits and risks derived from science.

Fairness broadly addresses the problem of *"not receiving appropriate acknowledgement of the*" individual or collective participants' contribution to health-related research from their datasets. Discussions about reciprocity and participants' contribution to research reflect their desire for sharing data to benefit their community directly or indirectly. In addition to the importance of protecting individuals from harm, participants suggest that primary data investigators should be afforded the opportunity to conduct further data analysis collaboratively with investigators in global health research. Ensuring appropriate acknowledgement of further data processing would develop local investigators' capacity (Bull, Cheah, et al., 2015).

Fairness broadly addresses the problem of not receiving appropriate acknowledgement of individual or collective participants' contribution to health-related research. The literature on reciprocity and participants' contribution to research reflect their desire for sharing data to directly or indirectly benefit their communities. In addition to the importance of protecting individuals from harm, literature (reviewed in section XYZ above) suggested that primary data investigators should be allowed the freedom to enjoy research benefits typical of the global health research community (e.g., secondary research, opportunities for research collaboration, produce publications, or co-author reports) (Howe et al., 2018; Jao et al., 2015a, 2015b).

The conduct of science and health in research with human participants requires proper ethics and science review of protocols and practices. In some LMICs, investigators face ethical, legal, social, scientific and political implications raised by the growth of international health research collaborations. Therefore, collaborative partnerships involving scientific data sharing should also assist with capacity building, aiming to "contribute to a host country's sustainable capacity for health-related research and ethical review" (Council for International Organizations of Medical Sciences, 2016, pp. 29–30). Equity in decision-making and action is a core part of respect for participants' rights, which entails the obligation of promoting better inclusion among diverse stakeholders, mutual learning and social justice through the routine collection of scientific data, in responding to the responsiveness of local public interests and health priorities.

The obligation to public accountability for sharing health-related research data, awareness of participants' rights over data sharing, and the interests in interactions between research stakeholders (namely investigators) would foster transparency. Past research emphasised that investigators were *"obliged to officially state that [an individual's EHRs] were to be used for research purposes"* (Asai, 2002, p. 4). For instance, "it was *either very important or extremely important that they [the participants] be informed about the possibility that their [health-related data] may be shared with others"* (McGuire et al., 2008, p. 50).

As a minimal condition for obtaining valid and informed consent, the decision to consent was suggested to be influenced by the preferences and social choice of individual participants' rights and interests (Stone et al., 2005). While, most participants had wished *"to know what organisation [or] agency had oversight responsibilities for genetic research data as well as to clearly understand the research goal and motivation"* (Lemke et al., 2010, p. 372). This might ensure participants' choices are predicated on relevant information and knowledge about the research context. It was the investigator's responsibility to inform participants in sufficient detail about plans for sharing data so

as to ensure SIPD is meaningful to participants and deliberated about views during the consent process (Denny et al., 2015). By giving participants an account of the norms surrounding data collection, storage, analysis, reporting, sharing and further scientific processing, participants are enabled to become responsible stakeholders and active in self-governance. Furthermore, the provision of such participatory information could help lead "*towards full disclosure of confidential data"* from participants in consenting to secondary analysis (Robling et al., 2004, p. 107). Participants saw that there was "*a need for trustworthy governance to ensure that both practical and ethical goals advancing science and protecting research participants would be achieved*" (Trinidad., et al 2009).

5.2.17 Respect and trust

Reports suggest that respondents' trust in health-related research is influenced by investigators demonstrating professionalism and respect during interactions with prospective participants and community members (Stone et al., 2005). Namely, being empathetic about laypersons' relative ignorance and willingness to deliberate about research stakeholders' different views and values; while receiving sufficient information so as to satisfy their understanding of the issues and factors. Thus, where investigators were able to educate prospective participants that IPD was required and desirable for better future public health, prospective participants would be more likely to give valid consent to sharing data. Consent would be based on the institution's accountability to individuals and the community. This is primarily because of the community and respondents' respect for the institution and its investigators to promote public benefit from research as having both scientific and social value.

The empirical literature suggests that participants' trust in sharing data for health-related research was not necessarily predicated on individual protections and regulatory controls articulated in research by obtaining valid informed consent. Nor were assurances of data security and individual privacy the fundamental factors in trust. Instead, it was found that participants wanted:

> "*researchers to promise that they would protect study data to the best of their ability, provide an honest accounting of any breaches that may occur, and make their "best effort" to mitigate any negative effects"* (Trinidad et al., 2010, p. 493).

Therefore, sharing of data is granted by way of social licence to carry out particular research activities, even though to do so may involve deviating from common modes of conduct. The licence used by "the professions to claim a broad legal, moral and intellectual mandate" and hence must be able to convince society that their practices will "not succumb to the profane" (Dixon-Woods & Ashcroft, 2008, p. 382). Debate over the dichotomous "consent or anonymise" approach to further processing

of health datasets in research has undergone an ethico/legal transition towards systems of accountability based on inter-personal commitments (Trinidad et al., 2010). Good data governance to should consider the composition of the relationship between investigators, the institutions and research participants; and stewardship of stakeholders' accounts on their respective interests (Carter et al., 2015; Chambers, 2003).

However, discussions on sharing data in global health research have tended to come from the perspective of stakeholders leading data science infrastructure and policies mandating research to share datasets, which might go "*beyond compliance with legal requirements"* (Carter et al., 2015, p. 405). For instance, in Africa, the *"levels of individual awareness about rights and abilities to exercise them are generally at developmental stages"* (Anane-Sarpong, Wangmo, Sankoh, et al., 2018, p. 99). The situation may result in the stakeholders responsible for generating datasets not being given the opportunity to contribute to research practices and the sharing of datasets (Kaye et al., 2018; Kaye et al., 2015).

Chapter 6. Discussion

6.1 Purposes of investigation

Observations on the 'Meso-level' of analysising secondary and grey literature (see Figure 1) acknowledge that scientific research is increasingly policy[4] bound at national and international levels (i.e., journal publication, access to funding, and knowledge management). They are accomplished "by identifying and documenting innovations and models for replication elsewhere" in a responsive manner (WHO, 2016b, p. X). What becomes clear from the 'Meso-narrative' is the responsibility institutions have with the relationship of individuals, communities and other members of society in dense networks (see Figure 2). It is, therefore, necessary for regulators and policymakers to ensure that PIs and national or international stakeholders protect individuals' freedoms, autonomy and security of privacy (Parker et al., 2009).

Investigators from the UK explored participants' views in relation to the Data Protection Act of 1998, and the UK Health and Social Care Act of 2001, where Rodling and co-authors discussed issues regarding the disclosure of confidential information and the identification of persons through EHRs (2004). The same UK Health and Social Care Act 2001 also addressed concerns related to permitting secondary data uses in patient care and public health with respect to human rights (Stone et al., 2005). The study by Whiddett on New Zealand's national health information systems surveyed hospital patients' views about the distribution of individual EHRs, investigating the national health identifier numbers system as a legitimate and principal means of sharing health data (2006). Other investigators were interested in understanding research participants' attitudes and judgments about the then "*current research policy"* to develop recommendations sensitive to adapted types of informed consent process's to share data (McGuire et al., 2008).

The primary sources drawn from the literature on LMICs in Africa and Asia took a more developmental approach towards establishing the following: (i) good practice guidelines amidst data-sharing plans (Anane-Sarpong, Wangmo, Sankoh, et al., 2018; Anane-Sarpong, Wangmo, Ward, et al., 2018; Lötter & van Zyl, 2015; Merson et al., 2015) (ii) stakeholder consultation and public relations (i.e., public engagement) (Cheah et al., 2015; Denny et al., 2015; Hate et al., 2015; Jao et al., 2015b), (iii) the use of broad consent informed consent (Jao et al., 2015a; Munung et al., 2016). Interviews, FGD studies, and consultations were conducted with diverse community members and research stakeholders to discuss the potential implications of informing novel HPRS (Anane-Sarpong, Wangmo, Sankoh, et al.,

[4] In its broadest definition, Oxford Lexicon refers policy to mean "a course or principle of action adopted or proposed by an organization or individual." https://www.lexico.com/definition/policy

2018; Anane-Sarpong et al., 2019; Anane-Sarpong, Wangmo, Ward, et al., 2018; Cheah et al., 2015; Denny et al., 2015; Lötter & van Zyl, 2015{Hate, 2015 #8{Jao, 2015 #6; Merson et al., 2015; Munung et al., 2016; Nordling, 2019; Staunton et al., 2019).

Kenyan public health stakeholders, for instance, investigated principle insights on policies outlining the trust and social relations intersecting between researchers, community members and the public (Jao et al., 2015a, 2015b). Patients and stakeholders were interviewed and generated discussions about clinical and biomedical research proposals formulating data (e.g., EHRs) and secondary analysis for Vietnamese stakeholders' training purposes and reward capacity building action (Merson et al., 2015).

Although exchanging data may appear instrumental, there still is a general lack of procedural operations worldwide (Kaye et al., 2018; Yeoh, 2015). Many LMICs fail to govern competent research practices capable of translating data exchange into social value (World Health Organization, 2016c). The lack of transparency of external regulations for sharing data was shown to have persisting limitations on obtaining valid informed consent and appeared to undermine public support for the wider implementation of sharing data mechanisms(Staunton et al., 2019). The lack of empirical evidence was shown to motivate the need for research in creating public awareness about the benefits and cautions associated with SIPD.

6.2 Informing research participants

Despite being common in many countries, national health information infrastructure in LMICs have pitfalls for patients and health administrators (Haga & O'Daniel, 2011; World Health Organization, 2016c). This use of EHRs effectively communicates epidemiological trends, which improves the quality of healthcare and the delivery of services (Health Professions Council of South Africa, 2017; South African National AIDS Council, 2017). Research participants' views of sharing health-related data involve factors that influence actions taken by investigators and international, national and institutional stakeholders in conducting health research. The evolving field of data-based health science has little clarity on what distinguishes research data from data for research. (U.S. Centers for Disease Control and Prevention [CDC], 2010). Any incorrect interpretations of sharing and reusing datasets might frustrate stakeholders and annoy the public or cause harm to those individuals affected (Carter et al., 2015).

Literature between the years 2002 to 2006 included studies related to confidentiality and privacy issues from the reuse of records for research purposes. Asai (2002) investigated patients’ perceptions of health practitioners' re-use and exchange of personal medical records (EHR) in the use of

epidemiology studies and assessed patients' opinions on practices surrounding informed consent. In recognition of UK legislation protecting the privacy of individuals and the law that permits the disclosure of patient, personal and identifiable health-related data present a dichotomy in ethical conduct that protects individual privacy and the conservation and dissemination of records for public benefit. Robling and colleagues acknowledge that little is known about the general public's views on the practical use of patients' medical records for research purposes (2004). They interviewed citizens and health administrators about whether using EHRs would be acceptable by individuals with or without consent in the interest of public health (Robling et al., 2004). Additional research in the UK, with patients and healthcare practitioners, discussed the possible ethical fallout the National Health Services could face from negatively influencing "patients' willingness to divulge clinically relevant information of [health] professionals" for research use (Stone et al., 2005, p. 784).

Amidst the scaling up of science infrastructure, investigators are obligated to follow open data access policies already mentioned above (see Chapter 2.3) in releasing sequence data to public repositories. The pressure to share data is due to the magnitude of projects and costs required for international collaborations, but this challenges how investigators collect, store, use and share participant datasets.

In McGuire's paper, sharing data highlighted two major ethical problems: (i) informed consent processes did not mention the possibility that genomic data would be released into publicly accessible databases. (ii) This denotes that the investigator who obtains informed consent is not typically responsible for and often does not anticipate the re-use of data later downstream nor appreciates the care shown by investigators and participants or community members (2008). However, recent sophisticated forms of broad informed consent should be responsive to research participants' attitudes and judgments, questioning participants' preferences for possible varied levels of control in modified informed consent over decision-making (CIOMS, 2016).

A collection of eight articles supported sharing of datasets from 2008 to 2011 on the position of enacted policy, for instance, the National Institutes of Health's (NIH) policy on sharing data in support of prospective or conducted in the genome-wide association studies (Lemke et al., 2010).

Chapter 7. Limitations

The complexity of the research design set out to synthesise three different data sources in an integrated manner containing the matrix review, framework and thematic analysis of FGD data. Grey literature and secondary materials were analysed by the matrix method to delineate information about a deliberative scope in relation to South Africa's research enterprise. The value of democratic deliberation in eliciting respondents' views is its utility in producing ethical understanding using supportive education to address the research topic comprehensively. Recommendations on achieving this require (i) developing accurate statements that are (ii) balanced in view of the claims both motivating and reasons against sharing data; (iii) that FGD respondents' involvement be voluntary and that (iv) the merit of individual contributions should reflect data engaging with the topic and not merely be the result of general discussion. Two improvements could be implemented by (i) a pre-screening of the research information to evaluate its content before the FGDs and, if possible, (ii) the inclusion of an additional expert witness or co-moderator (Rothwell et al., 2016). The impact of these would firstly, optimise participants' connection with the research problem and then explore participants' deliberations with accurate feedback from the independent expert witness. Both measures would build trust within the group setting around the participant's study objectives.

Another limitation of this study may be that an overinclusion of non-empirical literature lacked rigour regarding identifying specific accounts of how the research topic might have a role in health research for individual participation. However, the mapping of this macro-perspective might have been better managed (e.g., the accuracy of material selection and timekeeping) by employing the PRISMA approach to scoping research. The PRISMA approach has been developed to guide scoping reviews (Page et al., 2021). The strengths of using a scoping review in future research would aim to rapidly develop a framework for reporting the synthesis of qualitative health research.

As a methodological framework for future research, the common language of Mesh (medical subject heading) would have added rigour and transparency with framework analysis to the literature review. Due to the sophistication by which pre-determined outcomes can be researched and those results assessed for quality decision-making to control for specific vocabulary terms, the application of Mesh to strategize literature searching would also have allowed a string of keywords to be focused when applied to popular bibliographic databases (i.e., CINAHL, MEDLINE, PubMed and OVID).

The limitations identified in relation to the deliberative scope and analysis of primary sources played a role in how focus group discussions were approached. The presentations conveyed information

regarding the topic, which reflected the author's experiences with sharing health-related research and the accounts provided of South African legislation and human rights. The small group deliberations cannot claim to be representative of the whole South African research participant community. Future studies might explore a greater range and depth of cultures, experiences, and perspectives of research participants.

An integrated approach used three sources of information to identify research participants' views on sharing data. These were (i) deliberative democratic theory to guide the study design and methodological decisions bearing on the analytical treatment for each dataset; (ii) the matrix method used to review literature revealing the depth and range of relevant topics to this study together with thematic and framework analysis empirical insights provided a good record of data triangulation, and (iii) reiterative steps taken in sharing information with and eliciting views from FGDs with research participants. These steps are intended to increase the accuracy of data elicited from FGD participants' perceptions on sharing data for research (Srivastava & Hopwood, 2009).

This study had several additional limitations. Firstly, the collective literature review used broad search terms to cover a wide sample of grey literature from 1972 to 2020. Secondly, there is limited evidence available on the present research topic, with the result that the literature leads to either the over-representation of few studies and the under-representation of many under-researched groupings consisting of very different experiences and informational needs. Past empirical studies analysed a variety of sources. Thirdly, this thesis was limited in its scope and could not investigate important current academic and social-scientific issues, such as the significant role of data sharing in national and international responses to coronavirus disease (COVID-19) in networked societies, especially the rapid scaling up of tools and improvements in global governance.

Chapter 8. Conclusions

While data collection, storage and sharing are ubiquitous in advanced civil systems, it is important to note the scale at which data increasingly lie at the start and end of research science. Therefore, this growth in the sciences is of legitimate, ethical, legal, and social concern. The further use of IPD primarily undergoes far removed from individual participants and study communities, especially in some LMIC settings This study suggests that there remains a need for more substantive guidance for scientists concerned with data sharing. The following are concluding comments on the two main research questions posed in this thesis.

8.1 What are research participants' views on sharing health-related data?

The present thesis investigated research participants' views on sharing health-related data in South Africa. All the FGD respondents were unaware of how individual participants' research datasets led to additional activities and transactions with external institutions for future data processing. Although FGD respondents were sceptical about broad informed consent, there was a great appreciation for research-driven public health research improvements and a keen interest in understanding the underlying democratic structures that involve the public and community members in social science settings.

Public accountability and trust in a host research centre were shown in this study to resolve concerns about potential re-identification of shared IPD and strengthened participants' confidence in researchers' ethical duty and trust in their discretion in managing individual datasets. Relationship building and a sense of community and cooperation with public health research seemed to influence participants' positive attitudes that promote altruism, demonstrating good faith in society and valuing science.

Many FGD respondents thought that lack of awareness was a potential barrier to other participants agreeing to data sharing. Explanations and relevant information that boosted awareness of research concepts appeared to produce better acceptance of SIPD. Broad consent practice describing the future use of data would better support stakeholders' interest in further processing health-related datasets. This suggests that having *a priori* knowledge of how respondents' contributions to the original study could generate additional studies or contribute to other studies would improve trust in data sharing. For instance, respondents wished for IPD to be used within the national context and believed it would be fruitful in yielding different scientific outcomes.

The value of democratic deliberation in eliciting participants' thoughts on ethical issues helped solicit public opinion on health, education, science and civil policymaking. Health research would benefit from conditions that simultaneously produce individual ethical understanding within a public platform and appreciate the interpretations of others on social choices. Based on this study, some suggestions for similar future research on this topic are to develop an understanding of appropriate communities' informational needs to reassure individuals and communities that democratic systems protect their constitutional rights.

8.2 How do these views compare with those of other research stakeholders?

While the original findings of this study's empirical (FGD) component largely concur with the published literature suggesting that there is a general perception that sharing data assists investigators and improves public health institutions, understanding and awareness of the ethical and legal provisions of sharing health-related data remain relatively underdeveloped in the present samples studied. Participants suggested that attitudes to health-related research are changing towards more active involvement of research participants and their potential democratic role in decision-making. FGD participants emphasised the need for research to consider and incorporate public perceptions and cultural awareness, at a developmental level, of health policies and research practices congruent with local and general social expectations.

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Appendix A: Research and information leaflet

INFORMATION SHEET AND INFORMED CONSENT FORM

Who I am
Hello, my name is Spencer Denny. I am a junior researcher and a master's student from the School of Applied Human Sciences at the University of KwaZulu-Natal (UKZN). The research I am doing will inform the completion of a Master of Social Science degree. The title of the study is ***'Research participants' views on sharing health-related data in South Africa***'.

What I am doing
I am conducting research on the views and attitudes that people, involved with health research, might have about sharing health-related research data. The purpose of this study is to understand what people think sharing data means, how they believe it could be improved in order to best meet their desires for participating in health research, and what their concerns might be when data are shared with other researchers from different organisations.

Your participation
I am inviting you to join me in a focus group study. The study will involve talking about some general questions, like:

1. What does sharing health-related research data mean?
2. Why do people participate in health research?
3. What are the different reasons for using participants' data in research?
4. What are the benefits to individuals and researchers when health-related research data are shared?
5. What are the risks to individuals and researchers when health-related research data are shared?

The focus group study is intended to last for 2 hours. Snacks and refreshments will be provided. The study will provide participants with the necessary papers and pens. Participants will be reimbursed with cash for their time and inconvenience.

If you agree to take part in this study, I will ask you to please read and sign the **informed consent document** on the last page.

Please understand that **your participation is voluntary** and you are not being forced to take part in this study. The choice of whether to join or not is yours alone. If you choose not to take part in this study you will not be affected in any way whatsoever. If you agree to participate, you also have **the right to stop** your involvement in the research at any time. Please tell me if and when you wish to leave. If you do this, there will be no penalties and you will not be prejudiced in any way.

Confidentiality
Everything that is said during the focus group study will be respected and used for research purposes only. All identifying personal information will be anonymised and kept safe on a password protected computer hard drive. The information you provide will not be made available to other people outside of the study and will be kept confidential to the full extent

possible by law. The records from your involvement may be reviewed by people responsible for making sure that research is done properly, including members of the Research Ethics Committee at the University of KwaZulu-Natal and by other research members involved in this study (All of these people are required to keep your identity confidential).

I would like to ask you for permission to **tape-record** the focus group study so that I can accurately record what is said by each participant during the discussions. I will not record your name anywhere in the results of the study. No one will be able to connect you to the study. All future use of the stored data will be subject to further Research Ethics Committee review and approval. The information that is recorded will be stored and used for research purposes now as well as at a later date in ways that will not reveal who you are in the study.

Risks/discomforts
There are no foreseeable risks or harms that could result from your involvement in this focus group study. The research is intended to explore ethical and social notions of research concepts, it is not necessary nor advisable to disclose sensitive information of a personal nature during the discussions. The focus group study questions, as I am sure you will see, are not of a sensitive nor personal nature.

Benefits
There are no immediate benefits to individuals from participating in this study. However, the results of the study will be extremely helpful in completing my master's degree as well as contribute to scientific knowledge on the essential information about sharing health-related research data for prospective research participates.

If you would like to receive feedback on this study, I will write down your contact details and email address on a separate sheet of paper and can contact you about the results from the study when it is completed sometime after December 2018.

Who to contact if you have been harmed in anyway or have any concerns
This research has been approved by the Humanities and Social Sciences Research Ethics Committee at UKZN.

If you have any concerns or questions about the focus group study you may contact me – Spencer Denny – on either 071 864 1438 or spencegd@gmail.com.

You are also welcome to contact the research supervisor – Professor Douglas Wassenaar – on either (033) 260 5853 or wassenaar@ukzn.ac.za.

Appendix B: Informed consent form

INFORMED CONSENT FORM

I hereby agree to participate in this focus group study about the views and attitudes that I have with regards to sharing health research data. I understand that I am participating freely and without being forced in any way to be involved in research. I also understand that I have the right to stop my involvement at any point should I not want to continue and that this decision will not in any way affect me negatively. I understand that the purpose of this research study is not necessarily to benefit me personally in the immediate or short term. I understand that my participation will be respected and remain confidential in accordance with guidelines set by the National Health Research Ethics Council.

……..
Signature of participant **Date**:……..

CONSENT TO BE TAPE RECORDED
I hereby agree to the tape-recording of my participation in the study.

……..
Signature of participant **Date**:……..

I understand that the information that I provide will be stored electronically and will be used for research purposes now as well as at a later stage.

……..
Signature of participant **Date**:……..

Appendix C: Sharing information presentation

Slide 1

Research participants' views on sharing health-related data in South Africa

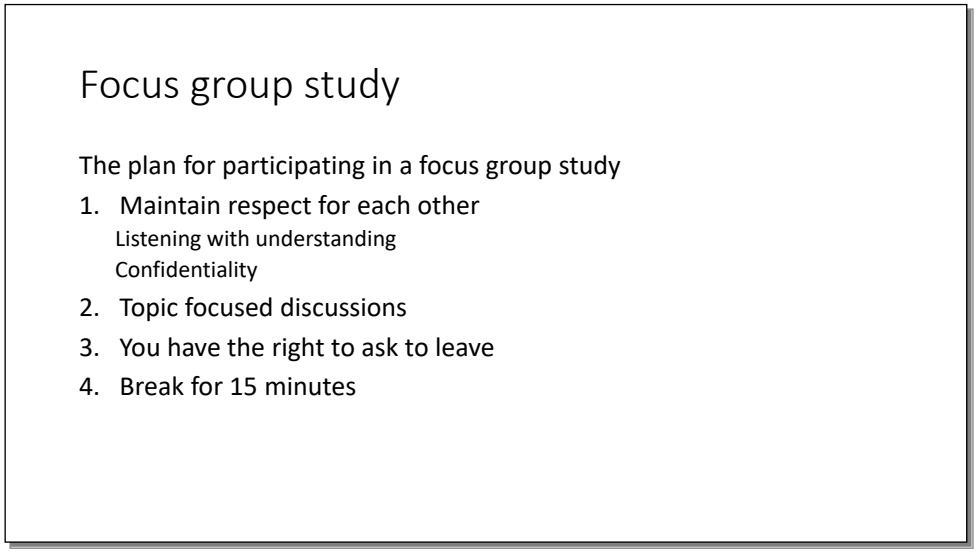
Focus group study by Spencer Denny

Slide 2

Outline

- Purpose of the study
- What is data sharing
- How health research data can be shared
- How data sharing affects participants and society
  - The potential benefits of sharing data
  - The potential risks and harms of sharing data
- Informed consent
- Research participants protection

Slide 3



The rules for participating in a focus group study
Respect for each other

Listening to what other people say and understanding that every person is entitled to their own point of view

Confidentiality – I wish to ask each one of you in the group to keep a level of confidentiality maintained when we leave here today. This is about trust between you and me, as well as between each of the group members.

I will not gossip about you when we leave and I hope that you can do the same.

We only have 2 hours together so we must keep discussions focused on the topics

this also means not expressing anything that is to personal or inappropriate

Break for 15 minutes

You have the right to ask to leave

Slide 4

Todays focus group study follows on from an international multi-study that started in 2013 – 2015. It was called the (PHRDS) and the project was a WT grant awarded to Oxford University, of which this study has been partially funded.

The aim was to engage with research stakeholders to explore their understanding of the issues surrounding sharing health-related research data.
Although most of the research stakeholders believed that sharing data had public benefits, many stakeholders were unaware of a local precedents on sharing data that related to a national governance framework.

The reason for this study is to learn more about what people and potential research participants in South Africa think sharing data is, to understand the ways sharing data can benefit the public and identify the ways sharing data might be harmful to people and their rights to autonomy and privacy.

Slide 5

Why are research participants' views important

Feedback from the public on issues with the way research is done can help to improve National health policies and research systems.

It helps researchers, professionals and policy makers to learn more about the problems and issues people and the community face.

Therefore, by understanding what the public thinks and believes about health research can have big impact on the wellbeing and living conditions of many people in South Africa.
- Making complaints

We can realise that sharing our public views on research (opinions) is in fact a constitutional right.

Page 7 of the constitution, chapter 2 section 16 says that
Everyone has the right to freedom of expression,
Which includes the freedom to receive (get) or send (give) information

Slide 6

Chapter 2: The Bill of Rights

- The state must respect, protect, promote and fulfil all human rights
  - **Dignity**
  - **Equality**
  - **Freedom**
- All of South African laws and the court system are made by the human rights
  - All found equal before the law

Slide 7

Freedom and security of the person

- Protects freedom and security of all South African citizens

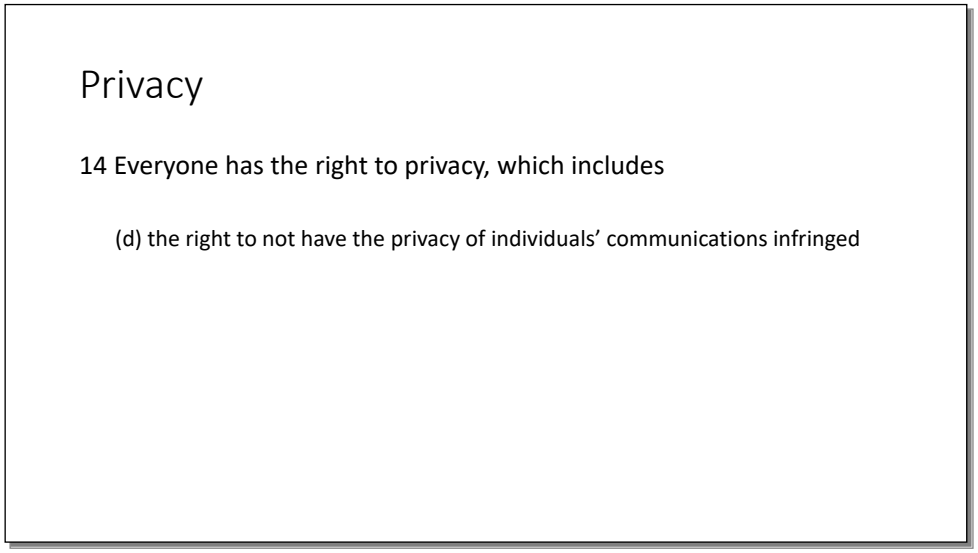
12 (2) Everyone has the right to bodily (physical) and psychological (mental) integrity

(c) The right not to be subjected to medical or scientific experiments without their informed consent

Sticking with the Constitution, we will look at only 6 principles of the bill of human rights, quickly.

Okay, page 6, section 12 states that Everyone has the right to bodily (physical) and psychological (mental) integrity. This means that we have the right to be free from not doing medical or scientific experiments or tests if we do not give consent.

Slide 8

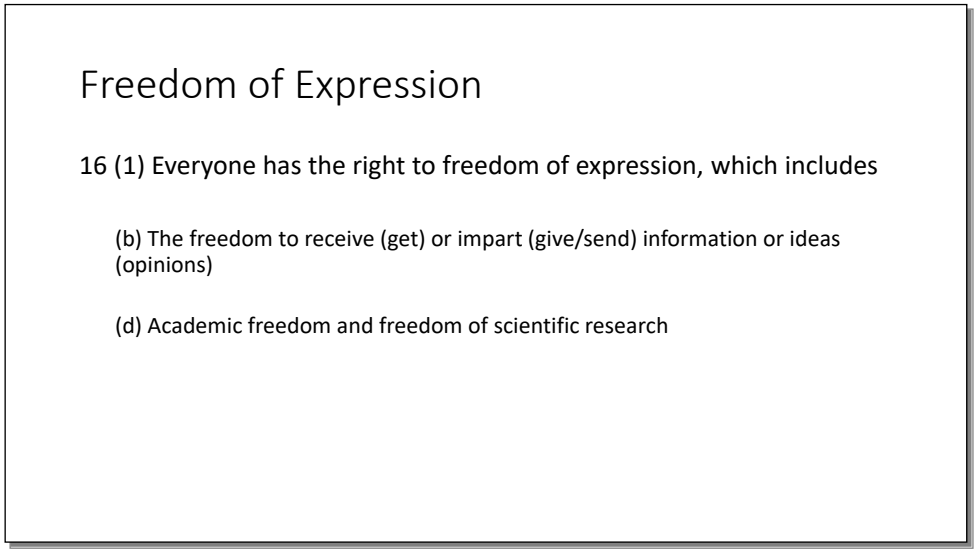


Another principle, on page 6 of the constitution under the Bill of rights.

States in section 14 that everyone has the right to privacy
Privacy means keeping our lives and information about who we are separate/distant from other people – the public-private

Here it says, that we have the right to not have the privacy of individuals' communications infringed.
What this means, is that what we say and the different types of information about who we are cannot be used against us.

Slide 9



The freedom of expression is on page 7.

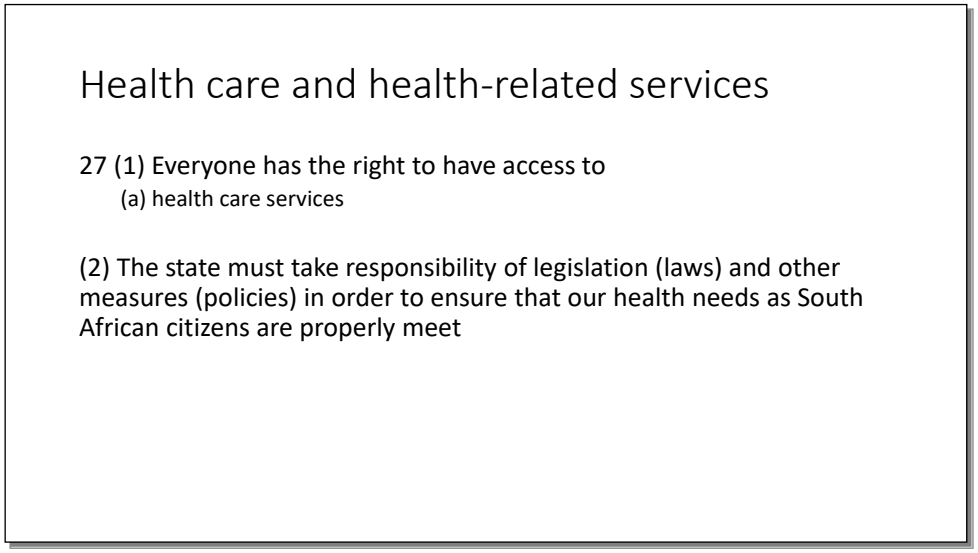
The right here, under section 16, says two things that I have selected on the slide show.
1st - The freedom to get or give information or ideas (opinions)

2nd – that there is academic freedom and freedom of scientific research

These two principles (b) and (d) are similar, in that we as citizens have the freedom to get or sharing information from other people – like government building / a company. If we are a shopper at checkers we can ask them for information about the latest special sales. Also in the same way that we could send information to the manger of checkers in a letter explaining that the eggs were all bad…

And with academics or scientific researcher and other professionals. The constitution gives those people the right to freely share scientific information without being forced by a political or religious agenda.

Slide 10



Pg. 11 in the constitution states clearly, under section 27
that everyone has the right to have access to health care services

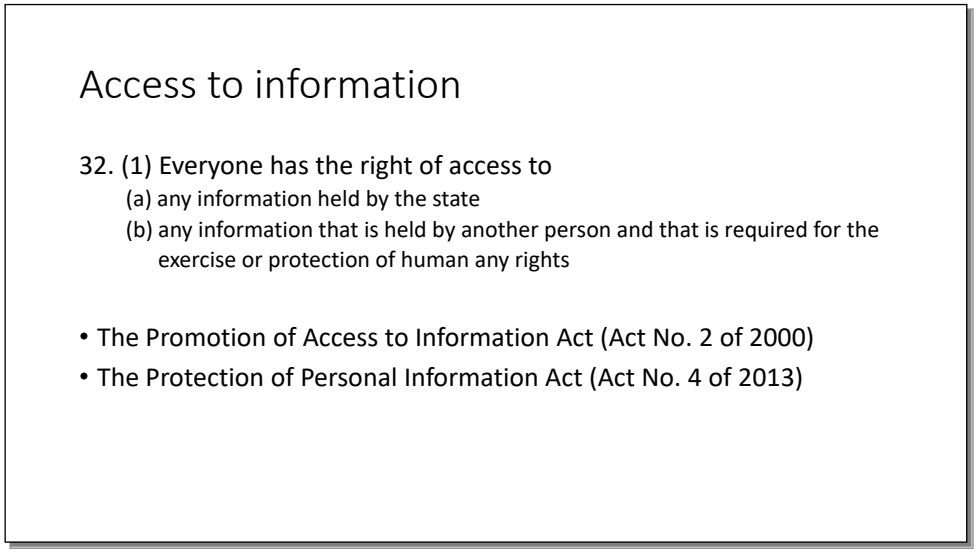
And that the state / Government must take responsibility of legislation (laws) and other measures (policies) in order to ensure that our needs as South African citizens are properly meet.

Now lets take a moment to think about how public health research helps to make a good and better public health system.

Surely, some of us can see that if research participants' share their views about public health problems, or when they participated in a research study that made you think that it was a waste of time, or that the scientists did not give you or the bigger community any benefits.

Then by sharing those experience would be important for making positive and better changes to how the public and future participants would be treated better, maybe with more respect or making sure that the study did something to uplift the living conditions in the community.

Slide 11



In Pg.13, the Bill of Rights uses the right of access to information (section 32) to make sure that the government and all departments (incl. companies) are transparent and open to the public view.

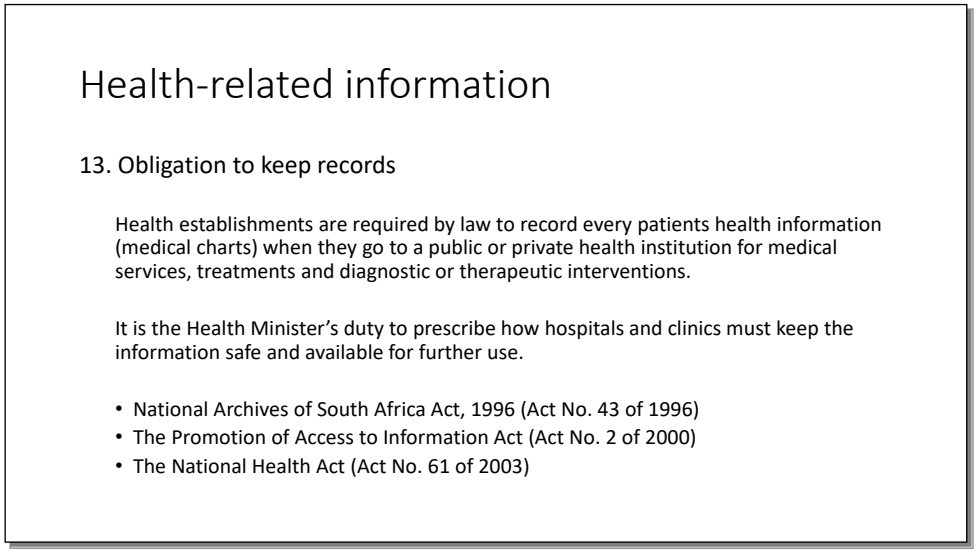
This constitutional human right also works to allow the government and other companies to have access to information from individual persons.

This topic is cover by national legislation 1 being
The Promotion of Access to Information Act (Act No. 2 of 2000) – which discusses the manner of access to information.

And the 2nd is the Protection of Personal Information Act [No 4 of 2013] -

We won't have enough time to go through these two legal documents in detail.

Slide 12

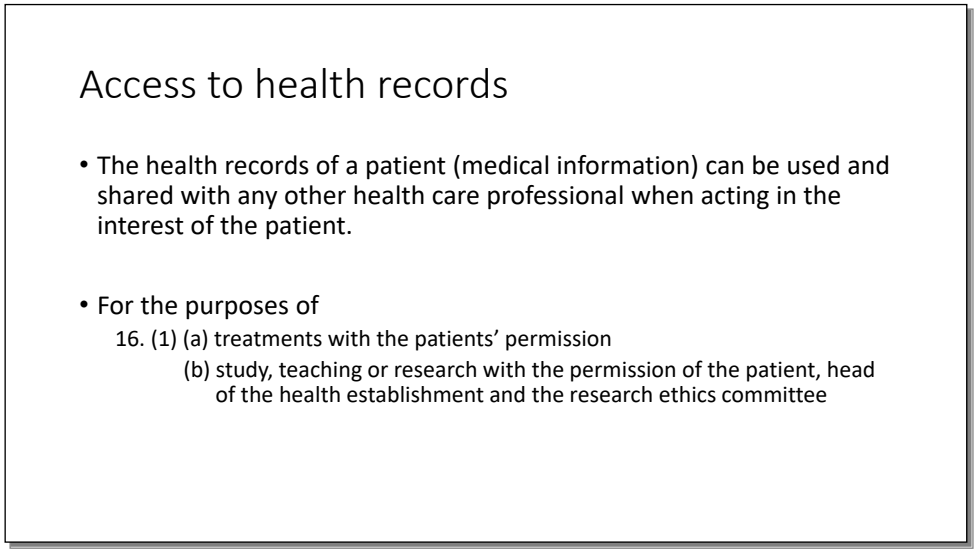


There is a need for keeping health-related datasets stored. There is a number of national laws that stipulate that health-related information and personal medical records must be kept in a health establishment by laws.

Subject to the National Archives of South Africa Act, 1996 (Act No. 43 of 1996) and the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), says that every health institution is required by law to record patient health information regarding the health services rendered.

These Acts are covered by National Health Act (No. 61 of 2003), which deals with policies and research systems, including the way health-related data / personal health information are made accessible and regulated.
It is the Health Minister's duty to prescribe how hospitals and clinics must keep the information safe and available for further use.

Slide 13



A health practitioner has access to patients' health records. The personal health information in a patients' medical records can be shared (disclosed) with any other health practitioner as long as that person is acting in the interest of the patient's wellbeing.

Pg.14 of the National Health Act, 2003 (Act No. 61 of 2003)
Section 16 says that access to health records may be permitted for the purposes of study, teaching or research.

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Next we are going to go through what sharing health research data is and just quickly how it works.

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Sharing research data is the practice of making data (i.e., individual participant data) from scientific research available for secondary uses.

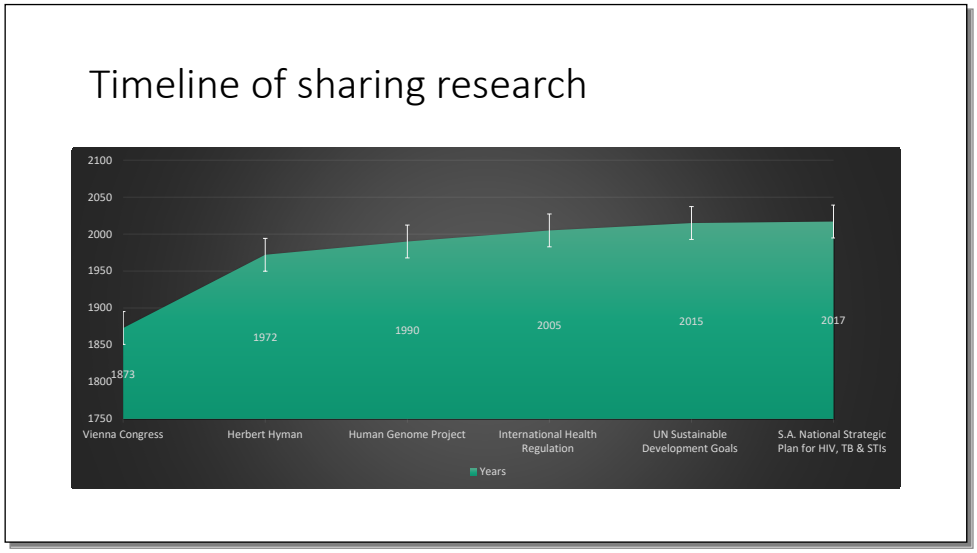
Data are the parts of information collected from participants in a study by researchers to answer questions about the health of South Africa's public.

Research is the way (the scientific method) of collecting and analysing data to create evidence. This evidence helps people to understand of the health issues by explaining what the problems are.

The full definition given by the **South African National Health Research Ethics Council** is that:
Health research – contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to disease; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals' medicines, interventions and devices; new technologies to improve health and health care. PAGE 78

What investigators have realised, in developed countries (like America and Europe) is that primarily data can be useful for different researchers to answer completely different research questions.

Slide 16



Timeline briefly demonstrates the chronological dates by events relating to sharing empirical data in science.

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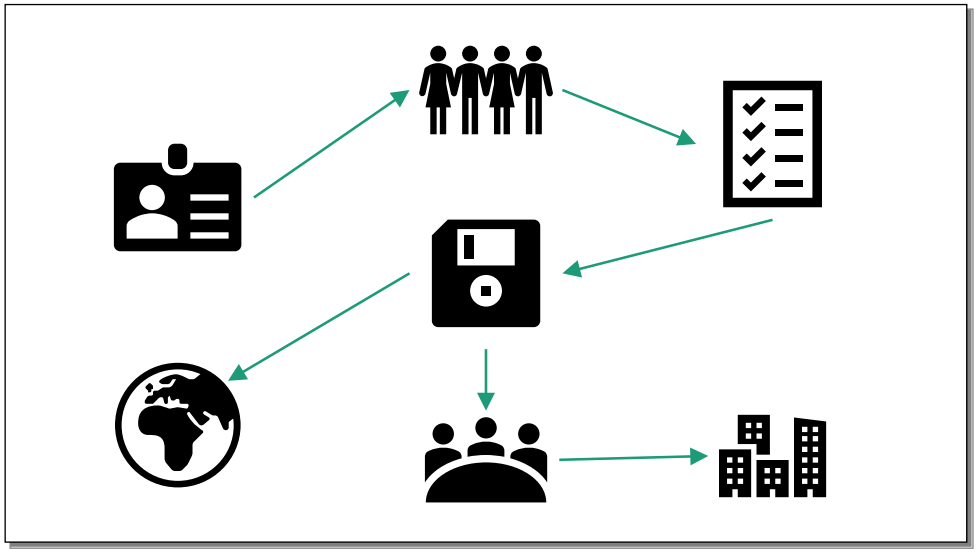
Figure 4: sharing datasets generated by research for further use



Let's think about how health research data are shared in general looking at a simple example.

1. A researcher's wishes to approach (2.) a group of community members from Zulu land about how they access health care and services from district clinics where they live.

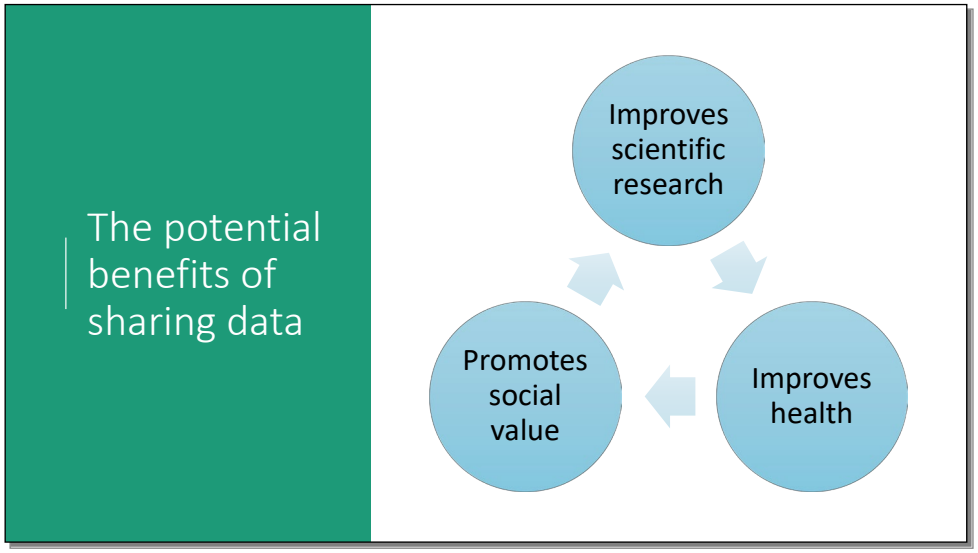
(3.) The researcher asks individuals to fill in a detailed survey.

(4.) After collecting and analysing all of the surveys the data and information gets stored in a South African database - the National Health Research Database.

(5.) The researcher gets contacted by a group of investigators form (6.) an organisation outside of South Africa to share the survey data and use it in their own research.

(7.) This kind of data sharing is identified as a global goal by the World Health Organisation and the United Nations' Sustainable Development Goals .

Slide 18



The potential benefits of sharing health-related research data comes down to 3 main things:

•Sharing data improves the quality of scientific research in a number of ways:
By having access to quality and available data researchers are able to increase the power of research studies. E.g., Data can be used to help train students to become researchers and biostatisticians.

•Having access to quality health data researchers are able to respond to health problems sooner. This can also mean that policy-makers and leaders in public health (i.e., in business and government) are able to make decisions with the best available evidence – i.e., knowing where to focus public funding on and developments.

•Sharing data is thought to reduce “risks to future volunteers from undisclosed harms identified in previous [health-related] studies”.

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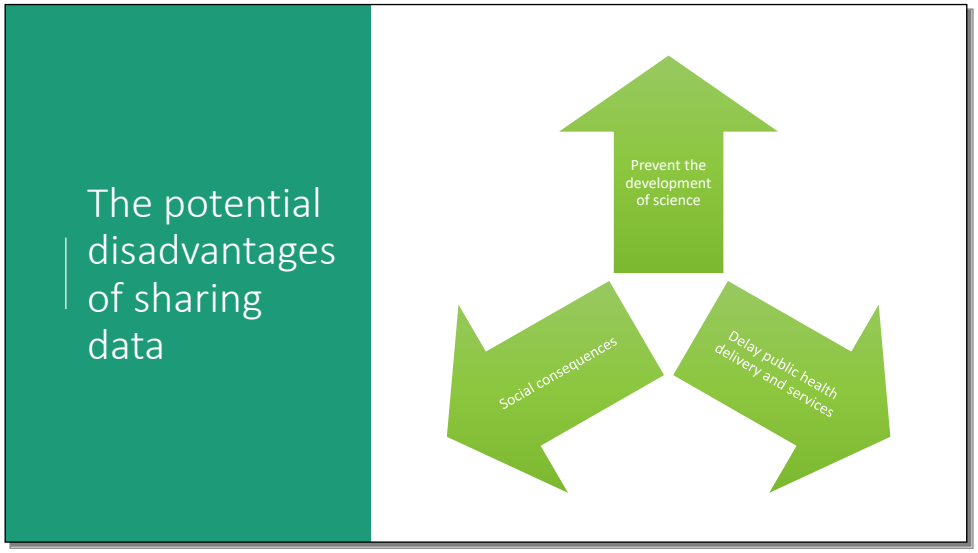


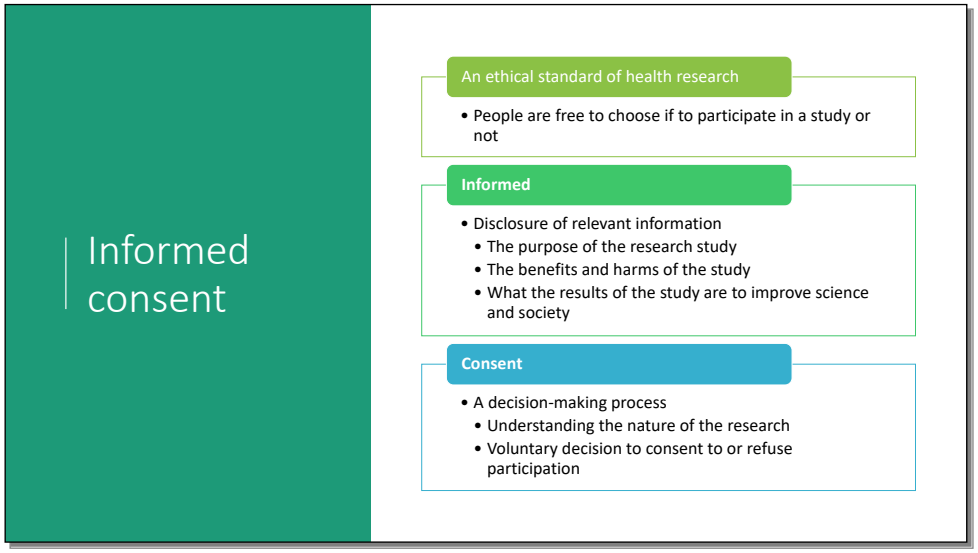
There are potential disadvantages of sharing data, too, in 3 different ways.

1. When data are made available to other people there is always a threat that it might be misused. Researchers could fight with each other about who said they were first or better.
2. Research data could be shared with only elitists in Europe and America and *POSSIBLY* not allow researchers in Africa to be shared with them. This would prevent the development of science and technology.
3. This could affect the way evidence and policies are used to shape public health decisions and the way public health institutions (establishments) deliver care and services to the people who need it the most.

This kind of political situation is only one kind of disadvantage and harm.
One of the biggest issues with sharing health research data has to do with how participants identities (i.e., who they are, where they come from and what is their health status) and the community on the whole are more vulnerable to no having privacy.

Privacy – is concerned with who has access to personal information and records about the individual participant.

Slide 20



Informed consent is one of the ethical standards of health research.
It is made up of two main parts:

Being **informed** about the nature of the study.
It is always important to be told about purpose of the study.
I.e., how the research study will be done, for how long, what will people get out of the research study, will you be rewarded for you time and energy?

It is good to know if the research study is going to harm people in any ways. This might be a physical injury – like in clinical researcher where a new surgery is being conducted or like a new drug that might contain serious side effects.
It is also important to know what researchers plan to do you the results of the study.
E.g., how might health-related research help support the local clinics and nurse staff by the outcomes of the study.

People have the right to give **consent** to participate or not in research. This involves making a decision whether to agree or not, based on all of the relevant information about the study. Therefore, being informed also includes understanding what participation in the study means for each persons.

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Social and scientific value of research

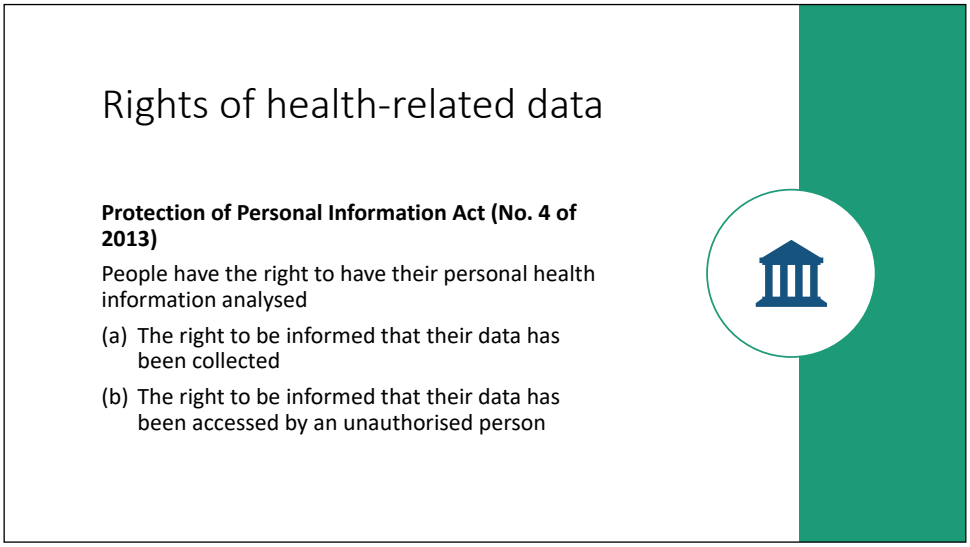
Research conducted with human participants must show that it has two ultimate goals:

1. Research must have social value.
2. Research must show scientific value.

- A research study that has social value produces information / knowledge that is significant for the needs of people who are affected by the research study.
- (The South African Constitution states that all people must be helped and supported by all good public and private works and therefore not harm and disrespect there human rights).
- A research study must been shown to have scientific value, by ensuring that a study produces reliable and valid results and is able to answer the objectives of the study. (i.e., if research uses a weak scientific method the research study is not going to be of good quality research standards and is therefore unethical because it would not lead to helping people and society)

Participants and the public play a vital role in supporting the research enterprise. Research that lacks both social value and scientific value no longer has public accountability for health-related research.

Slide 22



Pg. 20, section 5 People have the right to have their personal health information analysed
•Including the right to be informed of the fact that their data has been collected and where it is stored and how it might be used through further analysis processing
•The other is The right to be informed that their data has been accessed by an unauthorised person

the “data subject” has given their informed consent;
if data shall be analysed in terms of the reasons and purposes as expressed by consent;
researchers analyse participants’ data in ways that are respectful of their legitimate interests.

concerning a participants health andividual health data may only be shared for secondary research analysis if:
•the “data subject” has given their informed consent;
• the data is be analysed in terms of the reasons and purposes as expressed by consent; and
(c) not to be subjected to medical or scientific experiments without their informed consent.

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The use of health-related data for researchers

Researchers do not need to follow the requirements outlined above if:

(a) If the health data will –

i. not be used in such a way to make the persons' identity become known
Ii. Be used for historical, statistical or research purposes

Slide 24

Thank you for attending this presentation!

Table 1: Focus group presentations

Information presented at both Sites A & B
These claims contained definitions of: • social and scientific value • data and health-related research • how IPD are shared for further research (Diagram 1). Three potential benefits of sharing data were discussed, namely: • that sharing data improves scientific research • the responsiveness of public health increases • the social value of public health research is promoted Similarly, three potential disadvantages of sharing data covered: • the lack of sharing data procedures prevents developments of science • the underutilisation of sharing data impedes the responsiveness of public health (i.e., in health care, delivery and services) • the social consequences of violations in privacy and vulnerable confidentiality The role of informed consent described three components of valid informed consent discussed: • why it is an ethical standard in health research with humans • information provision • giving voluntary consent The Bill of Rights on research participants protections: (a) to security in and control over their body (c) not to be subjected to medical or scientific experiments without their informed consent
Additional information presented for site B
The obligation of the State to respect, protect, promote and fulfil all human rights with Dignity, Equality and Freedom. Claims about the importance of respondents' views involve: • Constitutional rights • The promotion of access to information • The public accountability of health-related researchers • The protection of personal information and health data The Bill of Rights was expanded to include: • Freedom and security of the persons • Privacy • Freedom of Expression

- Health care and health-related services

Access to information claim that “Everyone has the right of access to:
(a) any information held by the state
(b) any information that is held by another person and that is required for the exercise or protection of human rights

Legislation mandates the obligation to record health-related data from patients by health establishments, namely:

- National Archives of South Africa Act No. 43 of 1996
- The Promotion of Access to Information Act No. 2 2000
- The National Health Act No. 61 of 2003

Access to and sharing of health records by health practitioners are permitted when:

- To disclose records acts in the interest of the patient
- For the purposes of study, teaching or research
- Authorisation of health records obtaining no identifiable information is not necessary

The rights of health-related data include:

- The right of citizens IPD to be further processed
- Being informed of data collection, storage and analysis of IPD
- Requests of the correction, destruction or deletion of IPD To opt out or object the collection or analysis of IPD

Appendix D: Topic guide schedule

Awareness

1. **What kind of information are research participants normally given about research at the beginning of a study?**

- E.g., The purpose of study and why research is important
- What types of people the study will involve
- What methods will be used in the research
- For how long participants are going to be researched
- How people and the public might benefit from the study
- What kind of risks are involved in the study
- How researchers will ensure to take care of participants during and after the study (i.e., maintain confidentiality / feedback on the study / contacts for complaints

2. **How familiar are participants with what happens to their research data after the study has ended?**

- Data are typically analysed by professionals in order to produce results from a study (i.e., scientific readings / managerial / administrative output)

3. **Are research participants aware that research data is often stored for up to 5 years after the study concluded and where this may be stored?**

- This may also include institutional archives (i.e., the national health research database)
- There are also specialised scientific and research databases (i.e., Global research collaboration for infectious disease preparedness GloPID-R)

4. **What do participants think some of the reasons for storing research data are?**

- E.g., For auditing purposes,
- verification of original findings,
- to support similar research in the future by the same researcher
- used to support a different study by the same researcher
- improve the way studies conduct research
- eliminate the need for duplicate studies and putting new participants through the same study again
- to maximise the usefulness of the time and effort of participants and the researcher

5. **Are participants aware of their health data sometimes being shared with other researchers and professionals for scientific purposes (normally as datasets & not as identifiable information)?**
6. **What might be some of the reasons for sharing research data?**

- E.g., Researchers can be held accountable by participants and the public – data can be audited and re-checked at any future time
- to support similar research in the future (with a junior researcher, or colleague, or a person in a different profession)
- to support a different study (from a junior researcher, or colleague, or a person in a different profession)
- existing data can be used in new and experimental ways thus advancing science innovation and creative use of existing data
- improve on scientific methods and the way research is conducted
- reduce the need of new or repeated research with humans
- reduce the costs and time of conducting large-scale research projects
- attract international collaborations

- identify public health issues faster which means authorities can respond more rapidly.

Benefits

7. **In what ways could sharing health research data benefit society?**

- Should researchers be allowed to link health medical information from patients with health research data? Why & why not?
- In what ways could these kind of links with health-related data benefit the public?
- E.g., Professionals would be able to understand public health problems in more detail
- The public could receive better health care and services
- Health practitioners could provide better treatment based on the best available evidence and recommendations
- Standards in database documentation and management skills could be improved

Disadvantages / harms

8. **In what ways could sharing health research data harm people?**

- E.g., Stigmatisation
- loss of privacy
- a break in confidentiality between the public and research or other authorities
- misused for various intentions (commercial / political gain)
- misinterpretation of data raising unwarranted concern or fear (fake news)
- Used to target people and communities on the basis of race / believes

9. **What kinds of health data would people consider to be too sensitive to share?**

Attitudes

10. **Are there any differences between sharing health research data with other researchers and sharing health medical information from a doctor for research purposes?**
11. **Could sharing health research data be seen as riskier than sharing medical information from a doctor in hospital?**
12. **If the South African government decided to share health information and research data about a *rare* disease (i.e., Ebola) with researchers and health practitioners from a different African country like Nigeria, how would people respond?**

- I.e., Would people be accepting of this?
- Why would people be unaccepting of sharing health data with other African researchers?

13. **Do people think it is better to share health data locally with only researchers in South Africa rather than share data with researchers from wealthier countries – i.e., England or Japan?**
14. **If researchers just shared research data without checking with participants first, would it make a difference to the way people might feel towards participating in research and science?**
15. **When should researchers not be allowed to share health research data?**

- Specify what participants find unacceptable about data sharing, and substantiate why

Governance

16. **How important is trust in the research process?**
17. **In what ways can trust in the research process improve the way people participate in a study?**

- E.g., When someone feels trusted they might become comfortable enough to talk openly about personal health problems relevant to the study
- Thus, participants might give more detailed and accurate information which leads to better research?

18. **In what way could "broad informed consent" for sharing data give research participants confidence?**
19. **What should people be told to make sharing health research data more acceptable?**
20. **What kind of information explaining the sharing research process would be helpful?**

- E.g., where an individual's research data was going to be stored
- Who would have access to it
- How access to it would be regulated/controlled
- How individual research data will be protected against hackers
- How research data would be kept confidentiality and anonymised
- Who had access to individual health data for some general specific ways

21. **Would research participants be more accepting if they knew more about data sharing practices and understood how sharing data was improving public health?**
    How could potential harms be minimised?

- E.g., restrict access to only qualified health professionals or authorised researchers (what about students or junior researchers?)
- Making data internationally accessible only after 5 years or once the South African researchers have made the best use out it

Appendix E: Empirical research tables

Table 3: Prominent topics broadly bearing on sharing data

Scope of sharing data	Range of deliberations	Sources
Significant events of social change and research practices	• Information societies • Innovation systems • Science and technology policies • Infrastructure science • Open-access • Knowledge economy	(1992; Clubb et al., 1985; de Wolf et al., 2006a; Department of Health, 1997, 2001; Department of Science and Technology, 1996; Estabrooks & Romyn, 1995; Glenn, 1973; Kaye et al., 2009; Lowrance, 2003; Lundvall & Borrás, 2005; Marshall, 1990; Mauthner et al., 1998; National Research Council, 1985; Pisani et al., 2010; Rani & Buckley, 2012; Sieber, 1991, 2006; United Nations, 2015; Weil & Hollander, 1990)
National and international health policy and research systems	• Academic, research, policy nexus • Access to information • Personal data protection • Global governance • Research stewardship (social licence)	(Abdool Karim et al., 2009; Amatayakul, 2008; Chopra, Daviaud, et al., 2009; Coovadia et al., 2009; Department of Health, 1997, 2001, 2014; Department of Science and Technology, 1996; 2000; Lutge et al., 2008; Mayosi et al., 2009; National Health Research Ethics Council, 2015; Poreau, 2014; Senkubuge & Moayosi, 2013; South Africa, 2003; Republic og South Africa, 2013; South African National AIDS Council, 2017; Toronto International Data Release Workshop Authors, 2009; U.S. Centers for Disease Control and Prevention, 2010).
Commentary and observations from non-empirical sources	• Research participants' well-being • Research benefits bearing on SIPD • Texts bearing on regulations • SIPD in LMICs • Data conventions • Standards in data management • Sharing resources democratically • Obligations to study stakeholders • Investigators responsibility Principled issues on: ○ Apt acknowledge ○ Fair competition ○ Respect for trust	(Aitken et al., 2016; Alter & Vardigan, 2015; Ceci, 1988; Cheah et al., 2015; Clubb et al., 1985; de Wolf et al., 2005, 2006a, 2006b; Delamothe, 1996; Denny et al., 2015; Emanuel, Wendler, & Grady, 2000; Estabrooks & Romyn, 1995; Fischer & Zigmond, 2010; Glenn, 1973; Hanson et al., 2011; Harris & Wyndham, 2015; Howe et al., 2018; Kaye et al., 2009; Kost et al., 2013; Lang, 2011; Lowrance, 2003; Lutge et al., 2008; Marshall, 1990; Mauthner et al., 1998; Pang et al., 2003; Parker & Bull, 2015; Parker et al., 2009; Parry & Mauthner, 2004; Pisani & AbouZahr, 2010; Pisani et al., 2010; Remme et al., 2010; Roberts, 1990; Rosenberg, Aminoff, Boller, & et al., 2002; Sanderson et al., 2017; Sankoh & Ijsselmuiden, 2011; Senkubuge & Moayosi, 2013; Serwadda et al., 2018; Shabani et al., 2014; Sieber, 1991, 2006, 2015; Smith, 1994; Stanley & Stanley, 1988; Tabor et al.,

	○ Regulated access to datasets ○ Ownership	2012; Tangcharoensathien et al., 2010; Taylor & Taylor, 2014; Toronto International Data Release Workshop Authors, 2009; U.S. Centers for Disease Control and Prevention, 2010; Vickers, 2006; Walport & Brest, 2011; Weil & Hollander, 1990; Zarin, 2013)
The empirical literature on individuals views about sharing health-related data	• Reviewed past research metadata: • Research question • Study design • Research methodology • Approach of analysis • Means of data collection (qualitative & quantitative instruments) • Sampling frame, technique & size • Findings on stakeholders' views	(Asai et al., 2002; Cheah et al., 2015; Denny et al., 2015; Haga & O'Daniel, 2011; Hate et al., 2015; Lemke et al., 2010; Ludman et al., 2010; McGuire, Hamilton, Lunstroth, McClullough, & Goldman, 2008; McGuire, et al., 2011; Merson et al., 2015; O'Doherty & Burgess, 2009; Parkin & Paul, 2011; Robling et al., 2004; Stone et al., 2005; Trinidad et al., 2010; Whiddett et al., 2006)

Table 4: Types of datasets reviewed

Authors	Electronic health records (EHR)	Genetic data	Research data	Public health data
(Asai et al., 2002)	X			
(Robling et al., 2004)	X			
(Stone et al., 2005)	X			
(Whiddett et al., 2006)	X			
(McGuire et al., 2008)		X		
(O'Doherty & Burgess, 2009)		X		
(Lemke et al., 2010)		X		
(Ludman et al., 2010)		X		
(Trinidad et al., 2010)		X		
(Haga & O'Daniel, 2011)		X		
(Parkin & Paul, 2011)		X		
(McGuire et al., 2011)		X		
(Cheah et al., 2015)			X	
(Denny et al., 2015)			X	
(Hate et al., 2015)			X	
(Jao et al., 2015a, 2015b)			X	
(Merson et al., 2015)			X	
(Anane-Sapong et al., 2018)				X
(Anane-Sarpong et al., 2018)				X

Table 5: Lay research stakeholders

	Lay research stakeholders					
Authors	Citizens	Patients	Research participants	Surrogates	Family members	Community representatives
(Asai et al., 2002)	X					
(Robling et al., 2004)	X					
(Stone et al., 2005)		X				
(Whiddett et al., 2006)		X				
(O'Doherty & Burgess, 2009)						
(McGuire et al., 2008)			X			
(Trinidad et al., 2010)			X	X		X
(Lemke et al., 2010)	X		X			
(Ludman et al., 2010)			X			
(Haga & O'Daniel, 2011)	X					
(McGuire et al., 2011)		X		X	X	
(Parkin & Paul, 2011)	X					
(Cheah et al., 2015)						X
(Denny et al., 2015)						X
(Hate et al., 2015)						X
(Jao et al., 2015a, 2015b)						X
(Merson et al., 2015)			X		X	
(Anane-Sarpong, et al., 2018)						
(Anane-Sarpong, et al., 2018)						

Table 6: Research stakeholders

	Research stakeholders						
Authors	Health practitioners	Health administrators	Nurses & staff	Managers	Project implementers	Policymakers	Executive heads
(Asai et al., 2002)	X						
(Robling et al., 2004)		X					
(Stone et al., 2005)	X		X				
(Whiddett et al., 2006)							
(O'Doherty & Burgess, 2009)							
(McGuire et al., 2008)							
(Trinidad et al., 2010)							
(Lemke et al., 2010)							
(Ludman et al., 2010)							
(Haga & O'Daniel, 2011)							
(McGuire et al., 2011)							
(Parkin & Paul, 2011)							
(Cheah et al., 2015)			X				
(Denny et al., 2015)				X		X	X
(Hate et al., 2015)	X			X	X		X
(Jao et al., 2015a, 2015b)		X	X				
(Merson et al., 2015)						X	
(Anane-Sarpong, et al., 2018)		X		X		X	
(Anane-Sarpong, et al., 2018)					X		

Table 7: Investigators and official stakeholders

	Investigation stakeholders					Governmental stakeholders	
Authors	Field workers & junior research	Senior researchers	Primary Investigators	REC members	Scientists & clinicians	Governmental & public health officials	Health Minister
(Asai et al., 2002)							
(Robling et al., 2004)							
(Stone et al., 2005)							
(Whiddett et al., 2006)							
(O'Doherty & Burgess, 2009)							
(McGuire et al., 2008)							
(Trinidad et al., 2010)							
(Lemke et al., 2010)							
(Ludman et al., 2010)							
(Haga & O'Daniel, 2011)							
(McGuire et al., 2011)							
(Parkin & Paul, 2011)							
(Cheah et al., 2015)	X	X					
(Denny et al., 2015)	X	X					
(Hate et al., 2015)	X		X	X	X		
(Jao et al., 2015a, 2015b)	X	X	X				
(Merson et al., 2015)			X	X	X	X	X
(Anane-Sarpong, et al., 2018)		X		X	X	X	
(Anane-Sarpong, et al., 2018)			X				

Table 8: Methods and instruments

	Data collection method				Data collection instruments				Data sources			
Authors	Interviews	Focus groups	Public consultation	Self-report items	Topic guide	Vignettes	Public jury	Info packages	Seminar	Case study	Senarios	Experts
(Asai et al., 2002)		X			X							
(Robling et al., 2004)	X	X				X						
(Stone et al., 2005)	X				X							
(Whiddett et al., 2006)				X				X				
(O'Doherty & Burgess, 2009)		X					X					
(McGuire et al., 2008)			X		X			X				
(Trinidad et al., 2010)		X				X					X	
(Lemke et al., 2010)		X			X			X				
(Ludman et al., 2010)		X						X				
(Haga & O'Daniel, 2011)		X		X		X			X			
(McGuire et al., 2011)	X				X			X				
(Parkin & Paul, 2011)			X				X	X				X
(Cheah et al., 2015)	X	X			X							
(Denny et al., 2015)	X	X			X	X						
(Hate et al., 2015)	X	X			X	X						
(Jao et al., 2015a, 2015b)	X	X			X	X				X		
(Merson et al., 2015)	X	X			X							
(Anane-Sarpong, et al., 2018)				X				X				
(Anane-Sarpong, et al., 2018)	X			X	X							

Table 9: Theoretical and analytical approaches

	Theoretic framework		Analytic procedures					
Authors	Grounded theory	Deliberative democracy	Simple induction	Narrative	Content	Thematic analysis	Framework analysis	Statistics
(Asai et al., 2002)			X					
(Robling et al., 2004)				X				
(Stone et al., 2005)	X						X	
(Whiddett et al., 2006)								X
(O'Doherty & Burgess, 2009)		X						
(McGuire et al., 2008)			X					
(Trinidad et al., 2010)					X			
(Lemke et al., 2010)			X					
(Ludman et al., 2010)								X
(Haga & O'Daniel, 2011)					X			
(McGuire et al., 2011)								X
(Parkin & Paul, 2011)		X	X					
(Cheah et al., 2015)							X	
(Denny et al., 2015)							X	
(Hate et al., 2015)							X	
(Jao et al., 2015a, 2015b)		X					X	
(Merson et al., 2015)							X	
(Anane-Sarpong, et al., 2018)								X
(Anane-Sarpong, et al., 2018)						X		

Table 10: Codebook: General nodes

Name	Files	References	Modified On
Codebook - General nodes	37	617	2019/03/02
Barriers & Oppurtunities	1	1	2018/07/13
Awareness & understanding	15	55	2018/09/26
Consent	17	100	2019/05/15
Broad consent	2	5	2018/06/24
Issues arising during consent processes	12	37	2018/09/27
Opt-out	3	4	2018/06/24
Suggestions for best practices	8	23	2018/07/12
Experiences	2	2	2018/08/06
Developing & implementing data sharing processes	0	0	2018/06/11
Personal experience of sharing or accessing data	0	0	2018/06/11
Personal experiences of research where sharing data relevant	2	6	2018/06/12
Governance & policy	18	37	2018/08/06
Issues arising	13	40	2018/09/25
Obligations & responsibilities	8	13	2018/09/25
Ownership, rights & recognition	8	20	2018/09/27
Suggestions for best practice	13	53	2018/08/06
Trust	9	19	2018/08/06
Qualitative research interview topic guide	7	14	2018/09/22
Research Items	30	441	2018/09/25
Paper Findings	23	237	2018/09/25
Results and themes	2	48	2018/09/25
Privacy + confidentiality	0	0	2018/03/23
Research Stakeholders	3	6	2018/03/22
Willingness to share data	4	4	2018/09/25
Stakeholders	5	6	2018/08/06
Data accessors & secondary data users	0	0	2018/06/11
Junior researchers	0	0	2018/06/11
Managers, CEOs, policy makers	0	0	2018/06/11
Participants & community memebers	0	0	2018/06/11
Senior researchers	0	0	2018/06/11
Views	9	16	2018/08/06
Acceptable sharing data	12	24	2018/08/06
Unacceptable sharing data	10	24	2018/07/12
Advantages & potentional benefits of sharing data	11	36	2018/09/27
Disadvantages & potentional harms of sharing data	13	42	2018/08/06
Attitudes & views towards sharing & data	13	43	2019/06/26
Perceptions of sensitivity	10	26	2018/09/27
Suggestions for best practices in sharing data	8	13	2018/08/06

Table 11: Codes on research and systems

Name	Files	References	Modified On	Description
Nodes open to research & systems	99	1587	2022/05/11 16:42	An inclusive code book of grey and secondary literature.
About source	73	633	2022/05/01 19:51	
Purpose	51	82	2021/04/28 14:49	
Content & Texts	46	242	2021/04/28 14:49	This node codes content that describes the paper or report - the scope of the material
Observations on sharing data	27	48	2021/04/28 14:49	Codes can be general, quite broad
Range and limits of past research	14	21	2019/11/14 11:02	
The growth of sharing data	21	187	2019/11/12 12:56	
International collaboration	10	65	2019/11/12 12:58	
Information systems	3	25	2019/11/12 13:46	
IHR 2005 & NICD	1	6	2018/02/21 16:53	
Barriers to information or data	1	1	2018/02/21 15:04	
Academic - research - policy nexus	4	21	2018/03/27 10:16	Code for items with content describing the exchange of data along the adcademic - research - policy nexus
Implementation research	2	9	2018/02/21 15:02	Clarify the operational definition and code for content relevant to data driven research systems involving social, health and scientific outcomes + outputs
Restrictions on global sharing of research data	2	3	2018/02/19 11:10	
Open access	6	6	2019/11/12 12:48	
Journal statements	2	2	2019/11/13 13:11	
Intellectual properties	4	4	2019/11/12 12:40	This codes issues specifically about profits, patents and related data technologies
Science infrastructure	14	42	2019/11/12 12:45	Code for the research-policy-academia nexus. Looking at interinstitutional transfer of data.
Computing technologies	9	20	2019/11/13 13:14	
ICTs	1	1	2018/02/21 16:08	
Big data	1	3	2018/02/10 13:02	
Large datasets	5	8	2018/03/27 10:05	Focuses on the scholarly role of research data
Databanks, databases	1	4	2018/03/08 12:15	
Data linkage	1	1	2018/03/08 12:18	
Innovation systems	5	38	2019/11/12 12:43	Provide broad clarification on science and technology and social and economic forces
Innovation policy	3	9	2022/05/03 13:18	
Science & Technology policy	3	15	2022/05/03 13:18	
Incentive systems	2	2	2019/11/12 12:39	Incentives implemented by organisation for the promotion of sharing data
Society and economy issues	1	5	2018/02/20 11:27	
Changes in research areas of focus	11	36	2019/11/12 12:43	
Information society	1	5	2019/11/12 12:39	Code for text that uses the rise of an information society alongside the rise of data in society, economics, science and governance.
Globalisation	2	7	2019/11/12 12:39	Re. Technology | Collaboration | Trade | Transportation | Health & Safety
Source items	13	35	2019/11/12 12:37	
Public policy	7	12	2019/11/12 12:33	
Open data	2	2	2019/11/12 12:33	
Low and middle income settings	9	18	2019/11/12 12:31	
Items bearing on science or interdisciplinary research	5	12	2019/11/12 12:30	
Items bearing on research ethics	16	51	2019/11/12 12:28	
Items bearing on data sharing	24	46	2019/11/12 12:27	
Items bearing on data protections	17	38	2019/11/12 12:26	
Responsible for quality data	1	1	2018/07/12 10:22	
2 Methods	31	213	2021/04/28 14:49	
Sample size	21	37	2021/04/28 14:49	
Analysis	17	27	2021/04/28 14:49	
Aims	11	17	2021/04/28 14:49	
Materials	17	37	2021/04/28 14:49	
Data collection	11	19	2021/04/28 14:49	
Limitations to proposed method	8	12	2018/09/20 21:27	
External threats to validity	3	3	2018/03/22 15:23	
References	21	44	2021/04/28 14:49	
Glossary of key terms	6	12	2018/08/06 10:56	
Definitions of sharing data	6	7	2018/03/16 11:40	
Questions raised	7	12	2018/08/06 10:56	
Curious keywords	12	17	2018/06/19 10:06	
Quotes	6	11	2018/06/17 19:07	
Reasons for sharing data	33	211	2022/05/01 19:51	This node codes for positive reasons
Advantages	25	118	2021/04/28 14:49	
Pedagagy Value	5	5	2018/08/06 10:55	Coding for the potential capacity for training and skills with developments in sharing research data
improves teaching resources	0	0	2018/04/23 08:42	
Economy of scales	5	9	2018/04/23 08:45	
inform research design and research funding	0	0	2018/04/23 08:42	
Academic profile	0	0	2018/04/23 08:43	
Social Value	1	1	2018/03/27 10:49	Codes for the various benefits to society by sharing research data
Reduces burden of research on participants	0	0	2018/04/23 08:43	
Public policy formation	0	0	2018/04/23 08:43	
Scientific Value	2	2	2018/03/27 10:49	Codes for the potential in sciences for sharing data
Supports interdisciplinary analysis	0	0	2018/04/23 08:44	
Increased standards of quality	0	0	2018/04/23 08:44	
Maximise use of data when rare	0	0	2018/04/23 08:41	
Increase study power	0	0	2018/04/23 08:41	
Enable novel analyses	0	0	2018/04/23 08:40	
Address biases and frabrications	0	0	2018/04/23 08:40	
Verification, replication and refinement	0	0	2018/04/23 07:32	
Disadvantages	10	29	2018/08/06 10:55	
Technical disadvantageses	3	3	2018/03/27 10:49	Can be distinguished from ethical limits
Limited resource	4	7	2018/03/27 10:49	
Unethical to share data	2	5	2018/03/27 10:49	
Agenda for sharing data	5	9	2018/08/06 10:55	Code for overarching goals
Recommendations	7	28	2018/08/06 10:55	
Scientific Validity	1	3	2018/02/27 12:07	Code for the seven ethical codes
Scientific + Social Value	4	8	2018/02/27 11:50	Code for the texts talking about the scientific value of sharing data
Ethics principles	22	49	2022/05/01 19:51	
Reconsenting	1	3	2018/03/08 12:11	
Optout consenting for sharing data	2	2	2018/03/08 09:40	
Favourable risk-benefit ratio	1	1	2018/02/28 11:35	
Rights	1	8	2018/02/26 12:08	
Equity in research	0	0	2018/02/26 12:08	
Independent review	0	0	2018/02/26 12:08	
Respect for enrolled participants	0	0	2018/02/26 12:08	

Governance, policies & protections	55	539	2022/05/01 19:51	
Safeguards	6	7	2019/11/13 13:36	
National research governance	17	169	2019/03/02 22:45	
Emergency response	2	2	2022/05/03 13:20	
Public Health Surveillance	2	2	2022/05/03 13:20	
For research	2	4	2022/05/03 13:20	
Non-research	2	4	2022/05/03 13:20	
Data to inform	2	2	2022/05/03 13:16	The relationships between data and evidence-based practices
White Paper - transformation of the NHS	1	47	2019/11/13 13:41	
Reorganising the health service	1	5	2018/02/21 13:26	Chapter 2
Mission, goals & objectives of the health sector	1	12	2018/02/21 13:07	Outline rationale
International Health	1	2	2017/06/29 14:50	
Role of Donor Agencies and Non- Governmental Organisations	1	8	2017/06/29 14:04	Outline the procedures relating the interaction between funders and NGOs
Academic health service complexes	1	4	2017/06/29 13:09	
Health information	1	8	2017/06/29 12:49	Chapter 6
Essential national health research	1	8	2017/06/29 12:17	Chapter 5
Financial and physical resources	0	0	2017/06/28 22:45	Chapter 3
Health research systems	8	41	2019/11/13 13:40	the conditions, feature and characterization of health research systems in South Africa
Distinguish between health OR research systems	8	32	2022/05/03 13:20	To distinguish between research and non-research
Primary Health Care	2	2	2017/06/18 17:55	The role of PHC in Health Research Systems
The functions of a health research system	1	4	2017/06/18 14:18	
Producing & using research	3	8	2017/06/18 18:01	
International collaberation	1	2	2017/06/18 15:16	
Utilizing research data	1	4	2017/06/18 14:59	
Health R&D financing	2	6	2017/06/18 15:12	
funders OR donors	1	1	2017/06/18 15:11	
Creating & sustaining research resources	1	3	2017/06/18 14:43	
Stewardship	1	6	2017/06/18 14:40	
White papaer on Sci & Tech	1	2	2017/07/02 16:16	
Towards MDGs	1	1	2017/06/29 14:52	Chapter 21
National Health Act	1	1	2017/06/26 22:30	
Health System	2	4	2017/07/11 16:42	The Act mandates a health system inclusive of the provision of information systems (coordinated information knowledge management) and health systems research. Executed by minister of NDoH and acted on across provinces including districts /
Information system	1	10	2017/06/26 22:25	Duty to disseminate - to coordinate health services efforts
Functions of national depts.	2	12	2017/06/26 22:24	Chpt 3 - National Health - S(21)
Access to patients' health records	1	6	2017/06/26 22:23	Includes following sections: 13 (Obligation to keep record); 14(Confidentiality); 15 (Access to health records); 16 (Access to health records by health care provider); 17 (Protection of health records)
Health research	1	5	2017/06/26 22:16	Health services for experimental or research purposes
structure of health system	1	4	2017/06/26 21:28	
Right for user to have full knowledge	1	1	2017/06/26 20:26	
Participation in decisions	1	3	2017/06/26 21:27	
Responsibility for health	1	2	2017/06/26 20:20	
Nature of research conducted	2	4	2017/06/26 17:28	
Consortiums	1	1	2017/06/26 10:11	
Sharing research data	1	1	2017/06/26 10:45	
Research data	1	1	2017/06/26 10:44	
HIV research led policy-making	3	6	2017/06/26 10:39	
Mandate of research	2	4	2017/06/25 17:19	
Data-intensive practices	1	4	2017/06/19 22:25	Includes the principles and practices of rapid early release data sets to biomedical fields
The Torontro Statement	1	1	2017/06/19 22:36	Outlines the key principles underpinning the rapid-release of large biomedical research data sets
Stakeholders roles & responsibilities	1	1	2017/06/19 22:38	
Data analysts OR users	2	3	2017/06/19 22:37	
Data producers	2	3	2017/06/19 22:37	
Funding agencies	1	3	2017/06/19 22:35	
Scientific journals	1	1	2017/06/19 22:34	
Attributes of rapid prepublication release	1	1	2017/06/19 22:30	
Data-intensive goals	1	6	2017/06/19 22:26	The goals and characteristics of data-intensive research
Health systems research	1	1	2017/06/18 17:58	
Available data	0	0	2017/06/16 14:19	The conditions of health-related (HIV/AIDs) data
Purpose of Health Research for South Africa	1	51	2017/06/16 13:32	Looking at the South African health research policy as the foundation upon which the early steps towards developing an health-related research data sharing framework (2001)
Capacity development	1	11	2017/06/16 13:36	The availabilty of scientific research data is crucial for urgent reform in the health sector.
Communication (sharing health-related research data)	1	11	2017/06/16 13:34	Engendered the importance of enhancing the impact of health-related research through better approaches to communicating and disseminating research knowledge in order to coordinate various stakeholders efforts
Equity in financing health research	1	7	2017/06/16 13:33	Monitoring & Evaluating health resources to adress gaps in information
Accountability	1	1	2017/06/26 10:25	
Priority setting for health research in South africa	1	4	2017/06/16 13:33	The importance of priorities based on equity and social justice through an inclusive process that is the result of consultation with stakeholders.
Institutional framework	1	9	2017/06/16 13:32	The structural policy established from 2001 to strengthen health research system
Stakeholders	1	3	2017/06/14 21:14	
Background	1	1	2017/06/14 21:13	
Legislation that constitutes health research	11	61	2019/03/02 22:40	
Protection of research information	8	41	2019/03/02 22:41	
Mandatory protection of research information	3	12	2022/05/03 13:16	
Participatory - Democracy	3	3	2022/05/03 13:16	The involvement, education and interaction of citizens on issues that affect themselves, their community..
NMC	2	4	2022/05/03 13:16	
Notify data subject when personal information is collected	2	2	2022/05/03 13:16	
Personal information	3	5	2022/05/03 13:16	
Termology from PAIA 2000 & PPIA 2013	2	6	2022/05/03 13:16	
Privacy & Confidentiality	5	12	2018/03/08 09:30	
What supports the broad use of data	0	0	2017/07/10 23:26	The looks at the various National legislation that supports ideas connected with transfer of health research data
Availablility of health research data	3	9	2018/06/14 11:37	How are health research data made avialable
Restiction of access to data	1	7	2017/07/11 13:43	PAIAct 2000
Character of SA health system	1	5	2017/07/16 20:54	
Research participant consent	2	4	2017/07/11 16:46	
Protection of health research data	2	2	2017/07/11 16:10	How are health research data protected
Obligation or mandate	7	13	2018/08/06 10:55	
Incentives	2	2	2018/08/06 10:55	
Democratic deliberation	6	21	2018/06/12 10:52	
Types of data	20	115	2018/06/12 09:33	This node can be inclusive of qual' + quant' research data; admin' + social data, as well as standards of quality data

How is data shared	7	21	2021/04/28 14:49	This node describes the many different ways empirical data is shared
Conventions about data	8	18	2019/11/13 13:34	Capture the different conventions that data adheres to in the sharing process
Standards in data sharing	14	39	2019/11/13 13:34	
Methods to protect data	1	2	2019/11/13 13:33	Code for text, cases, conditions, procedures and technigues for the purpose of protecting the collection, storage and re-use of data
Documentation quality	6	10	2018/03/16 13:35	
Data sharing agreements	1	1	2018/03/09 15:05	
Qualitative data	2	6	2018/03/16 13:46	Code for literature describing the sharing of qualitative research data
Software	0	0	2018/03/09 14:52	Code for content on sharing software
Scientific output publications	1	3	2018/03/09 14:52	Code for items and examples of changes in the journal and review process raised by the arrival of sharing research data
Sensitive + identifiable data	1	2	2018/03/09 14:52	Code for text, cases and views about the sharing of sensitive and identifiable data
Informed Consent	10	29	2018/03/28 18:31	Code to sharing research data and consent
Capacity building	1	1	2018/03/16 12:15	
Information & Data laws	6	13	2018/03/16 10:47	Changing roles and responsibilities for scientists & participants in relation to the use of data
Public policy	3	3	2018/03/27 11:17	Clarify how the shifts towards sharing data can be coded under the South African formation of innovation, science, technology and education systems
Disclosure techniques	3	3	2018/03/08 15:14	
Issues or debates with sharing research data	31	155	2022/05/01 19:51	
Factors on Trust	9	16	2019/06/10 08:58	This may include ensurance required as well as the issues surrounding concepts of trust
Fairness	5	9	2018/08/06 10:55	
Equity	3	3	2018/08/06 10:55	
Apt acknowledgement	7	12	2018/08/06 10:55	
Publication issues	4	6	2018/08/06 10:55	
Research stakeholders	15	36	2018/04/19 14:50	List the stakeholders and breifly describe their roles
Research funders	6	6	2018/08/06 10:55	Code to situate research funding in the context of data sharing
Participants	4	4	2018/04/19 14:50	Code for items on participants consent to data shared for secondary analysis
IRBs & RECs	2	2	2018/03/09 14:57	
Disciplines for sharing data	3	7	2018/03/08 12:58	Capture the different fields for whon sharing data is a common practice
And their different interests	0	0	2018/02/08 10:58	
Controled gained or lost	5	7	2018/03/27 11:23	
Academic freedom	0	0	2018/03/27 10:51	
Willingness to share data	6	7	2018/03/22 15:23	This include perceptions on the value of data
Competition	6	10	2018/03/16 11:55	
Promoting science by protecting it	1	1	2018/03/16 10:34	
Exclusiveness	3	6	2018/03/12 08:30	Code for items of data shared exclusively
Fair selection	1	12	2018/02/27 12:23	
Ownership issues	3	4	2018/02/19 10:38	Code for issues concerning ownership of research data among differing stakeholders
Support required to sustain open access data	2	3	2018/02/19 10:21	code for area in which supportis required to bolster data sharing procedures

Table 13: Framework analysis of primary sources

Authors Reference	Origins	Purpose	Study / Policy problems	Scope of study	Type(s) of Research Method	Interview + Survey Methods	Type(s) of Qualitative Materials	Informative materials	Sample frame + Setting	Sampling technique	Sample size	Stakeholders (participants)	Empirical Analysis
Asai, A., Ohnishi, M., Nishigaki, E., Sekimoto, M., Fukuhara, S., & Fukui, T. (2002). Attitudes of the Japanese public and doctors towards use of archived information and samples without informed consent: Preliminary findings based on	Japan	Authors explore the views and attitudes toward the application of existing archived medical records and biological samples taken previously in the course of medical diagnosis or treatment.	There was little to none national guidelines on epidemiological studies with past medical data.	Medical records (EHR)	FGDs + questionnaire	Face to face	2 Topic guides during study (citizens + HP)	instruments	Citizens drew from a recruitment research centre.	Convenience	21	Citizens + Health practioners	Basic induction
Robling, M. R., Hood, K., Houston, H., Pill, R., Fay, J., & Evans, H. M. (2004). Public attitudes towards the use of primary care patient record data in medical research	United Kingdom	Qualitative research explored citizens views and concerns with the use of patient medical records for health-related research purposes, without consent.	There was some disagreement over UK legislation on Data Protection Act 1998 and the Health and Social Care Act 2001.	Medical records (EHR)	FDGs + Interviews + demo questionnaire	Face to face	3 Vignettes		Electoral registery	Stratified (by gender, geographical setting & level of deprivation)	53	Citizens + Health administrators	Narrative
Stone, M. A., Redsell, S. A., Ling, J. T., & Hay, A. D. (2005). Sharing patient data: competing demands of privacy, trust and research in primary care.	United Kingdom	Qualitative research on the knowledge and attitudes of patients and healthcare practionors about sharing primary healthcare (medical) records for secondary research purposes; and the influence of patients'	Reports on the incongruency of research policy over the National Health Services and Health and Social Care Act 2001.	Medical records (EHR)	Interviews	Face to face	Topic guides during study		Health institutions (GP Offices)	Purposive	35	Patients + Health practitionors + nurses + staff	Ground theory + framework
Whiddett, R., Hunter, I., Engelbrecht, J., & Handy, J. (2006). Patients' attitudes towards sharing their health information.	NewZealand	Research on patients opinions and considerations about the sharing of health-related information and necessary preparitory information about sharing patients health information are key in forming public policy regarding the design and implementation of national health	The National Health Identifier Number system.	Medical records (EHR)	Questionnaires	Self report		Some preparative information on the research topics	Health institutions (Clinics)	Convenience	203	Patients	Statistical
McGuire, A. L., Hamilton, J. A., Lunstroth, R., McCullough, L. B., & Goldman, A. (2008). DNA data sharing: research participants' perspectives.	United States of America	This study aims to describe research participants' attitudes and judgments about data release and their preferences for the varying levels of control over decision-making afforded by these three alternative types of consent.	Responsible research must identify practices requires informed consent for realising DNA data and ethical informed consent policies should be responsive and open to research participants' attitudes and judgments.	Genetic data	FGDs	Face to face	Topic guides during study	Informative package: genetic research, DNA analysis, and data sharing, data release policies and comparabe three types of consent (traditional, binary, and	Epilepsy genes study	Convenience	15	Research particpants (epileptics + controls)	Basic induction
O'Doherty, K. C., & Burgess, M. M. (2009). Engaging the public on biobanks: outcomes of the BC biobank deliberation.	Canada	The project was motivated by an observation that current policy approaches to social and ethical issues surrounding biobanks manifest certain democratic deficits.	The public engagement was informed by political theory on deliberative democracy with the aim of informing biobanking policies, in particular in British Columbia (BC), Canada.	Biobanking and data exchange	Group interviews	Face to face		Informational booklet		Prospective participants were randomly approached on the basis of the 2001 Canadian	21		Descusive analysis
Trinidad, S. B., Fullerton, S. M., Bares, J. M., Jarvik, G. P., Larson, E. B., & Burke, W. (2010). Genomic research and wide data sharing: Views of prospective participants.	United States of America	Qualitative research on the social & ethical implications raised by sharing genetic data by assessing the perceptions, beliefs, & attitudes of research participants' about genome-wide association studies & secondary repository-based research.	The electronic Medical Records and Genomics (eMERGE) Network a research consortium funded by the National Human Genome Research Institute and the National Institute of General Medical Sciences to explore the feasibility ofusing electronic medical record (EMR) data to derive reliable phenotypic data for use in Genome-wide assosiation	Genetic data	FGDs	Face to face	Vignettes	Hypothetical scenarios in which they were to imagine that they were taking part in an ongoing genetic study.	Cohort study of dementia (Group Health eMERGE ACT study)	Simple random	79	Research particpants + surrogates + research host members	Content
Lemke, A. A., Wolf, W. A., Hebert-Beirne, J., & Smith, M. E. (2010). Public and biobank participant attitudes toward genetic research participation and data sharing.	United States of America	Qualitative research to assess the attitudes & perceptions of citizens and biorepository participants on participating in and sharing genetic data to research.	access to and sharing of genotypephenotype datasets from GWAS, the U.S. National Institutes of Health (NIH)	Genetic data	FGDs	Face to face	Topic guides during study	Fact sheet summarising the NIH Data Sharing Policy	Biorespository study (University + Public area)	Simple random (zip code) + convenience (citizens)	49	Research participants + citizens	Basic induction
Ludman, E. J., Fullerton, S. M., Spangler, L., Trinidad, S. B., Fujii, M. M., Jarvik, G. P., . . . Burke, W. (2010). Glad you asked: participants' opinions of re-consent for dbGap data	United States of America	Telephone survey to assess research participants perceptions, attitudes and reasoning for re-consenting to genomic data deposited with a datbase (dbGap).	Lack of policy consensus on re-consent for sharing data with dbGaP	Genetic data	Surveys	Self report	Open + close-ended items constructed	Informative package	Cohort study of dementia (Group Health eMERGE ACT study)	Convenience + invitation via mail	365	Research particpants	Statistical
Haga, S. B., & O'Daniel, J. (2011). Public perspectives regarding data-sharing practices in genomics research. Public Health Genomics, 14(6), 319-324. doi:10.1159/000324705	United States of America	Explores citizens perceptions about sharing genomic research data; how communiation of sharing data might influence consent to participantion; as well as different health research policies.	Public attitudes on how to balance datasharing with privacy and protection of research participants our data support informing research participants of the method(s) of datasharing, data access policies and database privacy protections. Specifically, the (NIH) policy on data-sharing of prospective genome-wide association studies (GWAS) recommended that investigators obtain consent from participants for data to be shared through the NIH-GWAS database.	Genetic data	FGDs + Self-report survey	Mixed method	Vignettes	Presentation overview of genomic research	Host research community	Convenience	100	Citizens	Content
McGuire, A. L., Oliver, J. M., Slashinski, M. J., Graves, J. L., Wang, T., Kelly, P. A., . . . Hilsenbeck, S. G. (2011). To share or not to share: A randomized trial of consent for data sharing in genome research. Genetics In Medicine, 13, 948. doi:10.1097/GIM.0b013e3182227589	United States of America	Qualitative research studied citizens perceptions about sharing genomicresearch data; paying attention to how communiation about sharing data might influence consent in participantion forms and note different health research policies.	policy shifts was prompted by evidence of the potential vulnerability of deidentified DNA data and related concerns about participant privacy. Our purpose was to assess the effect on research enrollment and data sharing decisions ofthree different consent types (traditional, binary, or tiered) with varying levels of control and choices regarding data sharing.	Genetic data	Interviews	Face to face	Debriefing sessions before & after	Relevant information on sharing data was specific for the cohort study	Cohort study of cancers (at Baylor College of Medicine)	Randomised controlled trail	323	Patients + parents/guardians + family members	Statistical
Parkin, L., & Paul, C. (2011). Public good, personal privacy: a citizens' deliberation about using medical information for pharmacoepidemiological research. Journal of Epidemiology and Community Health, 65(2), 150-156.	NewZealand	Authors used deliberative methods to assess the level of public interest when asked to consider knowledge about protecting public, the social value to re-using medical records and scientific value compared to threats of personal privacy.	The Privacy Act 1993 and Health Information Privacy Code permit Health information 1994	Medical records (EHR)	Public deliberative process	Public group formats (e.g., seminars)	Deliberative materials: questions for jury / expert witnesses / jurors / facilitator / choice of venue	Informative package: Copies of national ethics application & Code of Health and Disability Services Consumers' Rights	Electoral registry	Simple random	9	Citizens	Basic induction
Cheah, P. Y., Tangseefa, D., Somsaman, A., Chunsuttiwat, T., Nosten, F., Day, N. P. J., . . . Parker, M. (2015). Perceived benefits, harms, and views about how to share data responsibly: A qualitative study of experiences with and attitudes toward data sharing among research staff and community representatives in Thailand. Journal of Empirical Research on Human Research Ethics, 10(3), 278-289. doi:10.1177/1556264615592388	Thailand	Authors wanted to understand the perceptions, experiences, and values of relevant stakeholders in Thailand about what they consider to constitute good data sharing practice.	Public attitudes towards sharing data with indiviudals active in Malaria field research and other administrative particpants.	Research data	FGDs + Interviews	Face to face	Topic guides during study		University / institution + clinical study site	Convenience + purposive	25	Community representatives + research staff + primary investigators + junior researchers	Framework
Denny, S. G., Silaigwana, B., Wassenaar, D., Bull, S., & Parker, M. (2015). Developing ethical practices for public health research data sharing in South Africa: The views and experiences from a diverse sample of research stakeholders. Journal of Empirical Research on Human Research Ethics, 10(3), 290-301.	South Africa	Stakeholders' attitudes, views, and experiences identify the need for good data sharing governance procedures that are responsive to local interests.	Research conducted with research stakeholders derived from	Research data	FGDs + Interviews	Face to face	Topic guides during study	Vignettes	Host research community	Convenience + snowballing	32	Community research representatives + senior investigators + junior researchers + research managers + policy & department managers +	Framework
Hate, K., Meherally, S., Shah More, N., Jayaraman, A., Bull, S., Parker, M., & Osrin, D. (2015). Sweat, skepticism, and uncharted territory: A qualitative study of opinions on data Sharing among public health researchers and research participants in Mumbai, India. Journal of Empirical Research on Human Research Ethics, 10(3), 239-250. doi:10.1177/1556264615592383	India	Aimed to assess stakeholders' understanding concerns, and hopes about what would happen to data and their views on what might constitute good data sharing practice; to identify models of data sharing and governance currently in use; to examine contextual considerations affecting data sharing processes; to identify perceived principles of good practice in data sharing; and to consider suitable methods of developing appropriate data sharing processes.	Scant examples of action on national science and technology sharing data, and the health sector as well.	Research data	FGDs + Interviews	Face to face	Vignettes		Host research community	Convenience	66	Community members + field workers + REC members + junior researchers + investigators + primary investigators + project implementers + managers + heads	Framework
Jao, I., Kombe, F., Mwalukore, S., Bull, S., Parker, M., Kamuya, D., . . . Marsh, V. (2015). Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement. Journal of Empirical Research on Human Research Ethics, 10(3), 264-277. doi:10.1177/1556264615592385	Kenya	For -research & non-research persons perception of sharing data. Looks at what the challenges are and how these might be addressed in a way that is solution oriented.	Reflected on the integration of health + demographic surveillance + hospital-based clinical surveillance routine data used by the Ministry of Health + researchers in Kilifi to support health service delivery & research.	Research data	FGDs + Interviews	Face to face	Topic guides during the study	Casestudy + Visual aids	Host research community	Convenience	60	Key community informants (assistant chiefs) + host research communityrepresentatives + research admnistrators + fieldworkers + KEMRI personalle + investigators (12)	Framework
Jao, I., Kombe, F., Mwalukore, S., Bull, S., Parker, M., Kamuya, D., . . . Marsh, V. (2015). Research stakeholders' views on benefits and challenges for public health Research data sharing in Kenya: The importance of trust and social relations. PLOS ONE, 10(9), e0135545. doi:10.1371/journal.pone.0135545	Kenya	Explores local health research stakeholders' opinions on the need for public support, trust & confidence in the development of data sharing policies that are locally responsive.	Important ways of building trust in data sharing include involving the public in policy development and implementation, promoting scientific collaborations around data sharing, building close partnerships between researchers and government health authorities to provide checks and balances on data sharing, and promoting near and long-term translational benefits.	Research data	FGDs + Interviews	Face to face	Vignettes	Informative package	Host research community	Convenience	60	Key community informants (local administrative leaders) + host research community representatives (24) + research administrators + field workers + KEMRI personnel + investigators (12)	Framework

Merson, L., Phong, T. V., Nhan, L. N. T., Dung, N. T., Ngan, T. T. D., Kinh, N. V., . . . Bull, S. (2015). Trust, respect, and reciprocity: informing culturally appropriate data-sharing Practice in Vietnam. Journal of Empirical Research on Human Research Ethics, 10(3), 251-263. doi:10.1177/1556264615592387	Vietnam	The aim was to explore the data-sharing experiences, attitudes, perceptions, and expectations of stakeholders in health research, to inform the development of best practices in each region. This study explores stakeholders' understandings, perceptions, experiences, attitudes, and concerns about sharing individual-level clinical data. This study explores stakeholders' understandings, perceptions, experiences, attitudes, and concerns about sharing individual-level clinical data.	This article focuses on initiatives where clinical data generated in biomedical research are made available to secondary researchers to address novel research questions without direct collaboration with the primary researchers.	Research data	FGDs + Interviews	Face to face	Topic guides during the study	Debriefing session	Clinical studies in 3 government hospitals: a longitudinal influenza surveillance study + an observational study of dengue infection + a clinical trial of tuberculosis meningitis	Convenience	48	Research participants + family members + investigators + clinians + policy makers + REC members + governmental officials + Health Minister	Framework
Anane-Sarpong, E., Wangmo, T., Sankoh, O., Tanner, M., & Elger, B. S. (2018). Application of ethical principles to research using public health data in the global south: Perspectives from Africa. Developing World Bioethics, 18(2), 98-108. doi:doi:10.1111/dewb.12138	Ghana	assessed perspectives of stakeholders experienced or knowledgeable about RUPD in relation to research ethics principles. Although dependable, emerging public health research paradigms like research using public health data (RUPD) raise new challenges to their application.	The health and demographic surveillance system (HDSS). For many communities in the South, the protection and awareness of individual rights and liberties that support international research ethics implementation may be limited, unknown or undesired.	Public health data	Surveys	Self report	Vignettes informed by literature on Research Using Public Health Data (RUPD)	Balanced information	Scientific conference	Convenience	130	Researchers + REC members + public health officers + clinicians + data managers + research centre administrators + policy	Statistical
Anane-Sarpong, E., Wangmo, T., Ward, C. L., Sankoh, O., Tanner, M., & Elger, B. S. (2018). "You cannot collect data using your own resources and put it on Open Access": Perspectives from Africa about public health data-sharing. Developing World Bioethics, 18(4), 394-405. doi:10.1111/dewb.12159	Ghana, and Tanzania	Assessed professionals views of the scientific, socio-professional and ethical dynamics linked with sharing data. We undertook this study to explore relevant experiences, con- textual, and subjective meanings, as well as values that public health stakeholders in Africa attach to the scientific, socio-professional, and ethical dynamics of data- sharing. To the best of our knowledge, the extent of the risks and implica-	the results indicate that data-sharing is critically thought of in relation to ownership and funding, contrary to global interests and expectations.38 Some of the reasons underlying this persistence are underpinned by Africa's systemic resource constraints39 and an urge to maximize the value of data at the local level.	Public health data	Interviews	Face to face	Topic guides during the study		Research centre	Purposive	46	Public health experts + investigators	Thematic

Table 14: Thematic analysis and focus group data part 1

	Awareness + understanding	Attitudes on data + sharing	Acceptable data sharing	Unacceptable data sharing	Advantages	Consent	Broad consent	Issues with consenting	Suggestions for consent	Governance + policy
Study site A FGD length = 138 mins (A) Presentation length = 18 mins (site A) Females = 5 (A) Males = 2 (A)	Several respondents had knowledge of informed consent as it pertained to their respective participation in biomedical studies, such as deletion of Biosamples. Several respondents were aware that individual participant information (data) was accessible to investigators via the National Clinical Trials Registery. Similarly,several respondents showed undestanding about how investigatoRespondnets clincal observational data (notes) was shared with health-practioners in clinics and phramasists. However, none had prior knowledge of where IPD might be stored, nor of whether IPD were subject to further processing after the study. +B3	I got the impression that respondents felt Public health-related research was a community practice. By sharing data the community may be encouraged to be healthier in recognition of participants contribution to better public health for others. Also, it might provide public benefits to thecommunity - i.e. support from Govnernment. Recognising stigma "still" surrounds PHR participation, some Respondnets felt someIPD must be kept "secret" (private) - i.e. HIV status. Majority felt sharing IPD was important + different to medical practices (even tho literature highlights comparities). Data generates empirical output to other sectors that aids in decision-making with regards to PHR. Acknowledging sharing IPD improves the responsiveness of PHEICs many would not mind investigators sharing their data., and were confident in investigators discretion to conduct further processing - trust of being informed were it crucial.	Accepted the notion of linkingIPD from research study with medical records.	No data dealing with individuals HIVstatus shall be shared. Identifiable information must be shared. Respondents' were less willing for-profit companies to have access to IPD. The lack of forewarned knowledge ofsharing IPD was unacceptable.	It assists the community both now and in the nearfuture.	Participants recognise theirown autonomous agency &the potential to acknowledge their participation in achieving the research objections = the benefits + rationality underlying it. Respondnets discuss the instrumental (procedural) aspects of concluding the criterions of participant selection.	Respondents' had no knowledge of broad consent and were reluctantto accept broad consent for sharing IPD [perhaps the notion was abstract]. Respondnets accepted BIC when it was understood that IPD wouldbe used in support of the related field of study - Preventative HIV research.	Seeing Consent for IPD would bere-used across a wide range of institutions, the idea of BIC was understood to mean that the participant's participation was nolonger required, the result of IPDbeing "referred to another organisation" by 1 or 2 Rs	Respondnets input suggests that people wouldbe more accepting of sharing IPD for further processing within national health research systems if they could understand where the secondary researchers received their data	Interestingly little discussion aroseregarding research governance and public policy in comparison tosite FGD B.
	Awareness + understanding	**Attitudes on data + sharing**	**Acceptable data sharing**	**Unacceptable data sharing**	**Advantages**	**Consent**	**Broad consent**	**Issues with consenting**	**Suggestions for consent**	**Governance + policy**
Study site B FGD length = 124 mins (B) Presentation length = 92 mins (site B) Females = 4 (B)Males = 5 (B)	Respondents were reflective of there ownawareness about research, participation & their contribution to research outputs...Remarking on the instrumentals of informed consent & participant protocols... Respondents understanding of storing Biosamples was sometime inaccurate, buthey... Respondent had some understanding of biomedical practices, such as doctor - patient confidentiality. However, none were aware of IPD beingsubject to further processing and were interesting to learning how it applies to themselves.	Many Respondnets expected investigators could contact them to inform them ofdevelopments [a channel of trust]... Many felt sharing data is good for the community & in the interest of the next generation. It respects IPD contributions' to better public health. Respondnets acknowledged that IPD may be harmful to individuals & the community(stigma + sterotypes + discrimination). Again R's also spoke of international secrets *(Gupta family + Zuma)* & remarked that IPD must not be *marketable* - fearing it (*politically)* " bully" people. Far better it remain in sciences & academia then a trade. IPD should be shared on the basis it can contribute to public benefit. Health data lost was seen as a goss "waste" of scientific & theoretical materials. Though public health & modern medicine are both desirable. Researcherspovide a platform upon which knowledge can expand, stimulating better understanding of possible solutions to health problems - thus linking medical records with IPD is good. Respondnets expressed the obligation of having a regulatory framework in place togovern DS activities.	General acceptance of sharing IPD and linking it with other typesof non-biological data.	Identifiable information shall not beshared.	Being aware of DS helps us grow [intellectually] *asan information society - RE. DD "getting more information about things[...] might expand my thoughts [thus helping me individually]*". DS offers the possibilityfor hypothesis-driven discovery. The sharing of knowledgewhen data are shared.	Informed consent discussed less- except thatthey knew what the purpose of the use of bio samples....	The discussion on BC wasgenerally accepting & expressed an interesting knowing what would happen after the study.	Majority respondents felt that the lack of informed consent over further processing of IPD was unacceptable & they worriedabout the (*"secretive")* intentions being found in the wrong hands (to commit politicalabuses).	Respondnets had interest in learning more about IPD being subject to further processing by others and many favoured the idea of knowing wherethe data would be stored for re-use -(broad informed consent) [Valid informed consent is instrumental in maximising participants contribution to thestudy]	Health-related data collected by investigators in RSA should be shared with other African investigators were it to result in public benefits for the recipients - i.e. in the case of preventing an epidemic and investigators from RSA are to be shown as leading inresponding to health outbreak- outs. This idea of health research collaboration suggeted *'democracy to me' SGD,* when R4remarked that "hiding [health] information is not helpful"... Signifying that to hinder / impedepublic health would an unjust act.

Table 14: Thematic analysis and focus group data Part 2

	Issues arising	Obligations + responsibilities	Ownership + rights	Suggestions	Trust	Respect	Views	Disadvantages	Suggestions
Study site A FGD length = 138 mins (A) Presentation length = 18 mins (site A) Females = 5 (A) Males = 2 (A)	Respondents' raised concerns over how they might be affected when IPDs contributions shares the interest in the study. Asking if PIs disclosed IPD with other interested parties would be then disqualified / ineligible to part take in further research.. some Respondnets recognised the trade-off between individuals right to privacy + the mandated actions in the public interest when outbreaks occure (not *social value then?*). Although, some were at first against giving the Government access to their health-related information (data). Their thoughts were changed by talking about how they might be benefited from giving access to IPD. Suggesting that consent to sharing IPD byt other health agencies (then the one they know) seems to be circumstancial in that although it is generally undesirable on a personal & private level. Sharing IPD would be desirable should it be responsive to an urgent public health problem. Some Respondnetsassert themselves as participants that invovle risks to biomedical sciences and that to be used by more advanced investigators else for their own interests seems to be unfair in terms of the distribution of risks to participants... Parasitic data mining... Sharing data might be done fairly - meaning that foriegn scientists can not use RSA populations for their own gain - i.e. addressing health problem that are not responsive of RSA's context...	Individual participant permssision is required for IPD to be made available to the wider research community. Respondnetsfelt strongly about the following items: - an explaination of where further processing would take place - indicating that knowing of such processes are desirable. - The investigators carrying out futher processing of IPD must be recognisable as one in their field of profession - and that FP was the result of obtaining clearance. - Requests from original investigators for sharing IPD must show ensurance from their part, as a show of good faith - that the host community research institution is sharing IPD on behalf of the community's interests (TRUST). Knowing where IPD would be made accessible enables participants to be responsible citizens, such as asking questions and seeking answers - thus making investigators & institutions responible (accountable).	Some Respondnets would like to be able verify who is using their data and to know that they gave consent to it. Respondnets seemed to take ownership of their part in the study - their IPD - and wish to know that IPD aids to futher research. Being able to *track* their data (or study) over time would bring comfort.	Many Respondnets were comfortable with giving the host institution *proxy consent* - N.B data governance & stewardship. Confirming that anonymised IPD is a good practice when sharing data. Being told how when & where IPD was being conducted was important for Respondnets. *Being informed + transpart -> leads to better public accountability.* It is suggested by Respondnets that if IPD were intended to be shared with "someone [they] already know" it would be easier to give consent (someone friendly to their cause & the institution by extension). Being equiped with *a priori knowledge of respondents' own contribution to the original study and the large context maybe demonstrate good faith.* Public accountability is maintained through demonstration of both soical and scientific value.	If the community has participated in research it is important for the institution + investigators to upheld their trust to work hand in hand with their interests; while they share IPD with partners. Respondnets have trust in the instituion, built over time. Were investigators to explain that IPD was required and desirable for futher better public health they are likely to consent, because of the admiration the community & Respondnets have in the institution & investigators to promote public benefit.	DS benefits the community by contributing to research, which expands that benefit to the wider public health. Realising that DS promotes IPD to improve current health problems was experienced as an honour.	Views of the reasons for storing & releasing data inculded: - to verify the input and output of the study. - allow investigators to find similarities with different studies. Data gnereated by research provides empirical results that can aid in decision-making regarding public health systems. Collaborating research with IPD was seen to be a good thing. However, there was some scepticism wanting to see it before they beleive it. Learning more about the Respondnets part in the role of public health research was of interest - esp' with regards to protecting oneself from sickness.	The risk of IPD being leaked and resulting in social consequences - discrimination and the internal turmoil coming from it. The invasion of the rights to privacy.	Although sharing individual participant data support investigators and health sciences, Respondnetsfelt strongly that it was important for the community and members to demonstrate the social & scientific value of sharing data.
	Issues arising	**Obligations + responsibilities**	**Ownership + rights**	**Suggestions**	**Trust**	**Respect**	**Views**	**Disadvantages**	**Suggestions**
Study site B FGD length = 124 mins (B) Presentation length = 92 mins (site B) Females = 4 (B) Males = 5 (B)	Several Respondnets expressed that they thought were inadaquetly informed to "know which doors to knock on to get a better understanding [on how] to get information" with regards to there rights. Some Respondnets saw a duality to data sharing activities. On the one hand, sharing data may offer greater responsiviess from responsible instituions; while on the other hand some regretted that the aspirations of promoting greater access to health IPD have not been witnessed before - esp. from Gov. depts - which may be short-lived (not sustained in efforts) and *towards a political agenda?* Another issue was the question of "how did second users get access to their IP data? Remarking that if secondary investigators received quality metadata they would surely then be able to use "my""information in better manner. Also, the opposite would surely be true in that if they received poor metadata they quality of their perception of the issues would be "wrong". Respondnets advised that participants were likely to not tolerate contradiction in how they are treated - (item not captured *even over time)*	After understanding more about their rights as citizens - several Respondnets felt strongly that they were "supposed" to know. There is an obligation from investigators to participants that must be upheld when IPD are intended to be subject to further processing, such as: - being informed on how they can protect IPD. - In the case of failed IPD safegaurds how might participants be affected (it be minimised). - Preferably from the begining or the consent process. Although Respondnets were unclear of how access is granted by investigators, it was felt that IPD go to use of social and scientific value. This in turn lead several Respondnets to show support for this thesis by expressing their desire for their small contributions to be in aid of my own knowledge of the topics as well as for other readers. Seeing sharing empirical data is an intellectual pursuit (hypothesis driven research), and alikening it to a public library, made Respondnets wonder about alikening DS to a public library. The the pages in the books are materials provided by	Being aware of IPD being a public health + scientific + resource some Respondnets were thoughtful about having the opurtunity to know how the study has come about (either funded locally or foriegn), which would aid them in finding their own decision. Respondnets felt strongly about being supplied with "the right details of the (secondary) researchers." This adds a level of accountable should they / the public wish to make enquiries and confirm their consent.	Being aware of good practices and a regulatory framework to address public health issues & advances was found reassuring in complex times. Seeking individual consent for sharing IPD is a personal and private decision to make - thier right to consent must be established with sharing data. Data governance and sterwards of data practices must seek quality output (metadata) in ensuring best standards and better respectful - (unscientific data sharing is unethical). This then minimises the risk of harm from futher processing of IPD. The fact that participants are requied to adhere to scientific and ethical standards while participanting in the study - so too then shall secondary investigators be required to follow to scientific and ethical instrumental functions. Equiping participants with a forwarding address to lay complaints as well as to satisfy their curiosity was also seen as a good thing to know. Sharing IPD internationally must be subject to health & science policies with legal contracts with the focus on fairness.	Turst in health-related research was impressed upon by professionalism - being empathetic + open to deliberate about Respondnets different views & offer satisfying responses (reasonable / respectful). Communications that informing & transparent Rs about IPD was seen to be a binding element. Trust in sharing IPD was seen to come from instrumental functions that demonstrated how they would use IPD - & not just take it at face value. Activities concerning IPD re-use shall not be done in secret which would present a falsehoodness regarding the institution. Private information must not be shared in recognition of RSA's current burdern of HIV on community members in KZN fearing that people get targeted & bullied. Respondnets wished for IPD to be implemented within the national context & not the trading of IPD. Thoughts of hypothetical leaked IPD to a removed third party (beyond the scope of public health), were that it would have been done deliberately - Covert DS was viewed malicious & distrustful. Respondnets thought that being informed retrospectively of shared IPD (without consent) were: - they would be hurt & discouraged from further participation; - paint a picture of unscientific research & distrust further communications. Respondnets place trust in investigators to share IPD by the book (contractually). Trust frees Respondnets to participate & contribute openly. Institutional trust between investigators + Rs expressed a desire for sharing IPD to be an extension of the original work [see *McGuire* / *Kayle et.al.*]. Professionals were thought to more trusting then others to re-use IPD: Doctors - other health practioners - Social workers. Suggesting that *professionals that offer high social justic and public benefit would have social license* . They have close ties to the community & are seen to demonstrate human rights - social value - respond to public needs.	Respondnets were generally supportive of the FGD study and for sharing data to come to fruition. Knowing that Respondnets input is of both social & scientific value demonstrates respect as participants.	Making IPD accessible to other investigators in the wider public health sector (also medical aid companies & governemtn to an extant) was viewed important to respond to public needs + for advancing knowledge. Respondnets saw DS activities as being reflexive of there personal interests in recieving better care through investigstors access to IPD (a two way win). Given, foriegn research collaboration may yeild certain expertises & resources lacking locally, DS appeared a reasonable exchange. Seeing DS as a public benefit meant that Respondnets saw how they could add IPD in support of better public health - now and for the future. DS was viewed to also involve knowledge sharing in as much alike the way empirical data would lead to understanding about the health / policy / technological / scientific / academic in a more nuanced ways. So too were Respondnets interested for knowledge to be share from the knowledgable investigators to situate the community within the process of advancing public health. In this way demonstrating democracy were "we all can have information [about the importance of	If the public knew Respondnets were part of a health & disease study Respondnetswould be undermined (disciminated) by their support for public health on the basis of misinformed citicens / false news. Risk of IPD falling into the wrong hands it would harm all of them (including the community). Respondnets worry that leaked IPD could be used against them and hurt people. Misused IPD could make it difficult to continue with normal life- shame + interference of privacy -> leading to isolation and may prevent indiivduals from seeking help (or even to return to the institution).	