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Title: An ethico-legal framework for the regulation of biobanks in South Africa

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Submitted in fulfilment of the degree of

Doctor of Philosophy (PhD) in Bioethics and Health Law,

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Declaration

I, Safia Mahomed, declare that this thesis is my own, unaided work. It is being submitted for the Degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Signature 

Signed on the 19th day of March 2018 in Johannesburg.

Publications and presentations arising from this research

Publications:

1. **Mahomed S**, Slabbert MN & Pepper MS. “Ownership and human tissue - the legal conundrum: A response to Jordaan’s critique.” South African Medical Journal 2017; 107(3):196.

2. **Mahomed S,** Behrens K, Slabbert MN, Sanne I. “Managing Human Tissue Transfer across National Boundaries: An approach from a South African Institution.” Developing World Bioethics 2016; 16(1): 29.

3. Dhai A, **Mahomed S**, Sanne I. “Biobanks and human health research: Balancing progress and protections.” South African Journal of Bioethics and Law 2015; 8(2):55.

4. **Mahomed S**, Sanne I. “Benefit Sharing in health research.” South African Journal of Bioethics and Law 2015; 8(2):60.

Presentations:

1. Presented my research at the United Nations Educational, Scientific and Cultural Organisation’s (UNESCO) 12th World Conference on Bioethics, Medical Ethics and Health Law in Cyprus, from 21-23 March 2017. Title of presentation: “A comparative ethico-legal analysis of human biobanking in specific developed and developing countries.”

2. Invited to present a guest lecture on the ethical and legal implications of Material Transfer Agreements, in the Advanced Research Ethics Unit hosted by the Steve Biko Centre for Bioethics on 23 February 2017. The lecture was to students in the Masters in Bioethics and Health Law, the Masters in Public Health and Short

Course Delegates.

3. Invited to present at the B3Africa workshop at Stellenbosch University in Cape Town, on the ethical and legal implications of Material Transfer Agreements, 9 December 2016.

4. Invited to present a seminar at the National Health Laboratory Service on the ethical and legal considerations for biobanking in South Africa, 9 November 2016.

5. Presented my research on Material Transfer Agreements and chaired a session at UNISAs Biotechnology and Medical Law Seminar, 18 October 2016.

6. Presented my research at UNISAs Research Indaba@Law, 10 October 2016.

7. Invited to present at a conference by the Centers for Disease Control and Prevention (CDC) co-convened by World Health Organization (WHO) and the African Society for Laboratory Management (ASLM) titled: “Optimizing the creation and utilisation of sample repositories for remnant dried blood spot samples used for early infant diagnosis or HIV viral load in Africa: priorities, legal and ethical considerations, best practices, and public health application,” on 25 & 26 July 2016.

8. Invited to present at the South African Clinical Hematology Conference on 28 May 2016. Title of presentation: “Human Biobanking: Ethical and legal considerations for the developing world.”

9. Presented at a Research Ethics CME (Continuing Medical Education) hosted by the Health Research Ethics Committee (HREC), Steve Biko Centre for Bioethics and the Wits Health Consortium on 19 November 2015. Tile of presentation: “Understanding the Wits Material Transfer Agreement.”

10. Presented at UNESCOs 11th World Conference on Bioethics, Medical Ethics and Health Law in Naples, Italy. Title of presentation: “Managing human tissue transfer across national boundaries – An approach from an institution in South Africa,” 20-22 October 2015.

11. Invited to present and attend the European, Middle Eastern and African Society for Biopreservation and Biobanking (ESBB) during their annual conference during October 2015 in London. Title of presentation: “Managing Human Tissue Transfer across National Boundaries: An approach from a South African Institution.”

12. Presentation as part of the South African Stem Cell Working Group on 20 August 2015. Title of presentation: “Benefit Sharing in Health Research.”

13. Invited to present at the University of Pretoria Faculty Day Ethics Session on 19 August 2015. Title of presentation: “Material Transfer Agreements in research collaborations.”

14. Invited to present at Esco Technologies Biobank seminar on 10 June 2015. Title of presentation: “Biobanks and Human Subjects Research.”

15. Invited to present at the Perinatal HIV Research Unit (PHRU) Workshop on 8 May 2015 at Baragwanath Hospital. Title of Presentation: “The Wits Material Transfer Agreement: Principles and Processes.”

16. Presented a guest lecture on a proposed legal framework for the Regulation of Biobanks in South Africa, in the Advanced Research Ethics Unit hosted by the Steve Biko Centre for Bioethics on 12 February 2015. The lecture was to students in the Masters in Bioethics and Health Law, the Masters in Public Health and Short Course Delegates.

17. Presented at the Faculty of Health Sciences Research Day and Post-graduate Expo at the University of Witwatersrand on 17 September 2014. Title of presentation: “Developing a Material Transfer Agreement for Biobank Research.”

18. Joint presentation at the South African Clinical Research Association (SACRA) Conference on 4 September 2014. Title of presentation: “Biological Sample Transfer Agreements & Feedback on Bio-Sample Banking.”

19. Invited to present at the Stem Cell Flagship Project Collaborators Workshop at the University of Pretoria on 1 September 2014. Title of presentation: “Managing human tissue transfer across national boundaries: An approach from a South African Institution.”

20. Invited to present a guest lecture on Biobanks and the legal implications thereof, in the Advanced Research Ethics Unit hosted by the Steve Biko Centre for Bioethics on 27 February 2014. Lecture was to students in the Masters in Bioethics and Health Law, the Masters in Public Health and Short Course Delegates.

21. Invited to present on the legal issues surrounding Biobanks, at the National Health Laboratory Services Biobank Convention on 2 October 2013.

Dedication

I dedicate this thesis to both my parents, Mahomed Faruk Mahomed and Amaboo (Ames) Dhai. For your sacrifices, love and unwavering support.

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I would like to acknowledge:

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Abstract

The notion of biobanking in health research is not new. Despite this fact, ethico-legal frameworks have struggled to keep pace with the fast evolving scientific arena. Currently, biobanks function in a fragmented way and with regard to our South African situation, an ethico-legal *lacuna* exists in respect of guidance for the concerns that biobanks raise. Even though biobank research has now been incorporated into national ethical guidelines, its complexities call for the establishment of firm principles with regard to informed consent and secondary uses, ownership of materials, privacy and confidentiality, benefit sharing, and Material Transfer Agreement (MTA) requirements. In addition, the South African legislative framework remains silent with regard to its application, leaving the regulation of biobank research up to the researcher, sponsor and Research Ethics Committees (RECs). Using a normative and legal enquiry, this study aims to critically examine the ethical and legal requirements for biobank research in South Africa, with the intention of identifying gaps and areas for improvement towards the development of a framework that responds to and promotes South Africa's needs, which includes the protection of populations, communities and individuals involved in biobank research, while at the same time, facilitating improvements to promote necessary research in the field. This study has resulted in the creation of a detailed MTA template and a draft set of Regulations for biobank research in South Africa, thus providing a starting point to the creation of a concrete ethico-legal framework in this regard.

ACRONYMS

ABS	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.
ABN	Australasian Biospecimens Network.
BA	Biodiversity Act 10 of 2004.
BEC	Biobanks Ethics Committee.
BMC	BioMed Central.
BMJ	British Medical Journal.
CBD	Convention on Biological Diversity.
CIOMS	Council for International Organisations of Medical Sciences.
CILSA	Comparative and International Law Journal of Southern Africa.
CIPRO	Companies and Intellectual Property Registry Office.
CSIR	Council for Scientific and Industrial Research.
DNA	Deoxyribonucleic acid.
DPA	Data Protection Act 1998.
DWB	Developing World Bioethics.
ECTA	Electronic Communications and Transactions Act 25 of 2000.
EEA	European Economic Area.

EMBO	European Molecular Biology (Reports).
EU	European Union.
GDP	Gross Domestic Product.
H3Africa	Human Heredity and Health in Africa.
HBGRD	Human Biobanks and Genetic Research Databases.
HBM	Human Biological Materials.
HPCSA	Health Professions Council of South Africa.
HRA	Human Research Authority.
HR Act	Human Rights Act 1998.
HREC	Human Research Ethics.
HTA	Human Tissue Act 2004.
IBRH3AU	Integrated Biorepository of H3Africa Uganda.
IPR Act	Intellectual Property Rights for Publically Financed Research and Development Act 61 of 2008.
J	Justice.
MTA	Material Transfer Agreement.
NDoH	National Department of Health.
NHA	National Health Act 61 of 2003.
NHREC	National Health Research Ethics Council.

NHS	National Health Service.
NHMRC	National Health and Medical Research Council.
NIPMO	National Intellectual Property Management Office.
NRES	National Research Ethics Service.
NSA	National Security Agency.
OECD	Organisation for Economic Co-operation and Development.
PA	Patents Act 57 of 1978.
PAA	Patents Amendment Act 20 of 2005.
PAIA	Promotion of Access to Information Act 2 of 2000.
PLoS	Public Library of Science.
POPIA	Protection of Personal Information Act 4 of 2013.
PI	Principal Investigator.
R&D	Research and Development.
REC	Research Ethics Committee
SOP	Standard Operating Procedures.
THRHR	Tydskrif vir hedendaagse Romeins-Hollandse Reg. (Journal for Contemporary Roman Dutch Law).
UCLA	University of California, Los Angeles.
UK	United Kingdom.

UMIC	Ugandan Medical Informatics Centre.
UNESCO	United Nations Educational, Scientific and Cultural Organisation.
UNCST	Uganda's National Council for Science and Technology.
UNHRO	Ugandan National Health Research Organisation.
USA	United States of America.
WHO	World Health Organisation.
WITS	University of the Witwatersrand.

Definitions

Biobank	means an organised collection of Human Biological Material and associated data from different individuals, which are usually kept for an unlimited period of time, for the purposes of health research.
Data	means any information, including personal information in any form, derived directly or indirectly during the conduct of research or clinical care.
Human Biological Material	means material from a human being including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof.
Materials	means Human Biological Materials and Data.

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Chapter 1

An ethico-legal framework for the regulation of biobanks in South Africa:

Background

1.1 Introduction

1.1.1 Background, Literature Analysis and Critique

The first worldwide endeavour into "big biology" was initiated by the Human Genome Project (1990-2003).[1] This project involved an astonishing effort on the part of scientists, to map and sequence the entire human genome, with the ultimate purpose being that of improving the effectiveness of healthcare and advancing human health.[2] The massive amount of human biological materials (HBMs) stored and data generated from this project is immeasurable, and other subsequent genomic-related projects have also involved research on an equally ambitious scale.[3] As Meslin and Quaid aptly write: "Now that the human genome has been sequenced, the future of medicine will depend largely on the ability of investigators to gain access to large quantities of HBMs. However, this research can only proceed with careful consideration of the ethical, legal, and social implications of such access."[4] In order to meet the increasing demand for human specimens and data, the world has witnessed the emergence of biobanks on a scale not seen before.[5]

There is consensus in the scientific community that progress in understanding disease will depend on the establishment, harmonisation and broad use of biobanks

[1] Green ED, Watson JD & Collins FS. 2015. "Human Genome Project: Twenty-five years of big biology." *Nature* 526 (7571): 29-31. doi:10.1038/526029a.

[2] "Overview of the Extramural Research Program." National Human Genome Research Institute (NHGRI). Accessed November 07, 2017. https://www.genome.gov/12010633/overview-of-the-extramural-research-program/.

[3] Dove ES. 2015. "Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework." *Journal of Law, Medicine and Ethics* 43 (4):675–89. https://doi.org/10.1111/jlme.12311.

[4] Meslin EM & Quaid KA. 2004. "Ethical issues in the collection, storage, and research use of human biological materials." *Journal of Laboratory and Clinical Medicine* 144(5): 229-34. doi:10.1016/j.lab.2004.08.003.

[5] Rothstein MA, Knoppers BM & Harrell HL. 2016. "Comparative Approaches to Biobanks and Privacy." *The Journal of Law, Medicine & Ethics* 44 (1):161–72. https://doi.org/10.1177/1073110516644207.

and genetic research databases. As there is currently no uniform and universally accepted definition for biobanks and genetic research databases, a general definition of these are offered by the Organisation for Economic Co-operation and Development (OECD) guidelines (to which South Africa subscribes as a key partner).[6] According to the OECD guidelines, a human biobank and genetic research database are:

> structured resources that can be used for the purpose of genetic research and which include: (a) human biological materials and /or information generated from the analysis of same; and (b) extensive associated information.[7]

The objectives of a biobank are to foster research that generates new science with the intention of benefiting human wellbeing and health; to make data and materials accessible to researchers in order to advance knowledge and understanding; and to ensure the integrity of samples in perpetuity.[8] However, the ability to successfully establish biobanks and genetic research databases will depend on participants' willingness to contribute their HBMs and data. It is therefore imperative that research respects the participant and is conducted in a manner that upholds human dignity, fundamental freedoms, human rights and is carried out by responsible researchers.[9]

The importance of research involving human genetic information analysed together with other personal or health data for the understanding of multifactorial diseases has increased rapidly over the past few decades.[10] Despite the fact that the notion of biobanking in health research is not new, ethico-legal frameworks have struggled to keep pace with the fast evolving scientific arena.

Research into the formation of an ethico-legal framework specific to biobanks in South Africa could not come at a more significant time. As talks of the creation of a national

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[6] "South Africa and the OECD." Accessed November 07, 2017. http://www.oecd.org/southafrica/south-africa-and-oecd.htm.

[7] OECD Guidelines on Human Biobanks and Genetic Research Databases (OECD Guidelines) (2009) 1. Accessed November 07, 2017. http://www.oecd.org/sti/biotech/44054609.pdf.

[8] The Human Research Ethics Committee Medical: Principles and Policy on Biobanks, Faculty of Health Sciences, University of the Witwatersrand. Accessed November 07, 2017. https://www.wits.ac.za/media/wits-university/research/documents/HREC%20principles%20and%20policy%20on%20biobanking.pdf.

[9] OECD Guidelines at 1.

[10] Dhai A & Mahomed S. 2013. "Biobank research: Time for discussion and debate." S*outh African Medical Journal* 103(4): 225-27. doi:10.7196/samj.6813.

biobank as well as the H3Africa (and similar) initiatives[11] emerge,[12] the pressing need for a considered and focussed framework is of great importance and will contribute meaningfully to scholarship in the field and the improvement of human wellbeing. It is important to establish a balanced approach to ethico-legal protections in order to ensure that much needed research is not unduly impeded. In this chapter, I briefly introduce the structure of the South African legal system, the concept of biobanking in the context of health research and justify the relevance of performing this study. I then conclude this chapter with an outline of the thesis.

1.1.2 Hierarchical structure of the South African legal system

Currently, as no set of specific legislation exists with regard to the regulation of biobank research, differing pieces of legislation, guidelines and policy documents have to be drawn upon in determining the current framework in which we operate. It is therefore important to understand the hierarchical structure under which the South African legal system functions, in order to appreciate the practical applications of legislation, policies, procedures, ethical guidelines, local documents and international instruments in South Africa.

South Africa's legal system operates under the umbrella of constitutional supremacy. This means that all legislation may be challenged, amended or removed, should it be found to be inconsistent with the provisions of the Constitution of the Republic of South Africa, 1996. The role of the Courts is to interpret and apply such legislation and make certain rulings. These decisions will add up to form a body of law called judicial precedent or common law. Legislation and judicial precedent (depending on the seniority of the Court) is binding. Policies, ethical guidelines and local documents may be considered when rendering a decision but are not legally enforceable. Included within policies and guidelines are international instruments. These may be used as guidelines in instances where local laws are silent; however, it will be in the relevant judge's discretion whether to consider these guidelines or not.[13] Should the law be

[11] Human Heredity & Health in Africa Accessed November 07, 2017. http://www.h3africa.org/.

[12] Dhai A. 2013. "Establishing national biobanks in South Africa: The urgent need for an ethico-regulatory framework" *South African Journal of Bioethics and Law.* 6 (2): 38-39.

[13] According to section 39(1) of the Constitution of South Africa, 1996 (The Constitution, 1996): "When interpreting the Bill of Rights, a court, tribunal or forum….b. must consider international law; and c. may consider foreign law." Also see section 233 of the Constitution, 1996 which states: "When interpreting any

unclear, ambiguous or silent on an issue in certain areas, institutions may develop their own set of procedures or regulatory outlines. Yet, problems of uniformity may arise in these instances as specific outlines may differ substantially from each other. It is also important to consider that only legislation is legally enforceable and binding, whereas policies, ethical guidelines and international instruments may provide direction and guidance in certain circumstances. In the context of health research, acting contrary to ethical guidelines may lead to unprofessional conduct, or professional misconduct, which could in turn present a legal challenge. Therefore, the status of our ethical guidelines, specifically in the health care setting, should not be reduced or diminished. Should biobanks each develop their own set of standards, one biobank may operate on a system completely different to another similar biobank without consistency. It is on this basis that I argue for the development of one harmonised national framework for biobank research, that incorporates both ethical and legal principles, which are legally recognised.

1.1.3 Current ethico-legal framework governing health research in South Africa

The National Health Act[14] (NHA) assented to by the President on 18 July 2004, came into force on 2 May 2005. At that time however, Chapter 8 of the NHA (concerned with the control of use of blood, blood products, tissue and gametes in humans) was not enacted, and matters pertaining to human tissues continued to be legislated under the Human Tissue Act.[15] Currently though, all of the sections of Chapter 8 of the NHA have since been enacted: section 53 came into force on 30 June 2008, sections 55, 56 and 68 on 17 May 2010, and on 1 March 2012, the remaining sections, 54 and 57 to 67 were enacted.[16] In addition to the enactment of the final sections of Chapter 8 of the NHA, several sets of regulations pertinent to Chapter 8 were published on 2 March 2012, namely regulations relating to:

legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law."

[14] 61 of 2003.

[15] 65 of 1983.

[16] Proclamation No 11 *Government Gazette* 35081 of 27 February 2012.

1. Artificial fertilisation of persons;[17]
2. Rendering of clinical forensic medicine services;[18]
3. The use of human biological material;[19]
4. Blood and blood products;[20]
5. The general control of human bodies, tissue, blood, blood products and gametes;[21]
6. The import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes;[22]
7. Tissue banks;[23] and
8. Stem cell banks.[24]

In addition, in 2014, a little over two years after the regulations to Chapter 8 of the NHA were published, the Regulations relating to Research with Human Participants[25] were published. These Regulations seek to address the treatment of human subjects as research participants and also consider the treatment of minors, mentally ill persons, women and vulnerable populations. Yet, these extensive sets of regulations do not include any framework for biobank research in South Africa.

In terms of the NHA, health research includes:

> any research which contributes to knowledge of –
> (a) The biological, clinical, psychological or social processes in human beings;
> (b) Improved methods for the provision of health services;
> (c) Human pathology;
> (d) The causes of disease;
> (e) The effects of the environment on the human body;
> (f) The development or new application of pharmaceuticals, medicines and related substances; and
> (g) The development of new applications of health technology.[26]

[17] *GN* R 175 in *Government Gazette* 35099 of 2 March 2012. On 30 September 2016, the Department of Health issued a new set of Regulations relating to the Artificial Fertilisation of Persons (*GN* R1165 No: 40312). However, at the time of writing this thesis, this new set of Regulations was not yet in force.
[18] *GN* R 176 in *Government Gazette* 35099 of 2 March 2012.
[19] *GN* R 177 in *Government Gazette* 35099 of 2 March 2012.
[20] *GN* R 179 in *Government Gazette* 35099 of 2 March 2012.
[21] *GN* R 180 in *Government Gazette* 35099 of 2 March 2012.
[22] *GN* R 181 in *Government Gazette* 35099 of 2 March 2012.
[23] *GN* R 182 in *Government Gazette* 35099 of 2 March 2012.
[24] *GN* R 183 in *Government Gazette* 35099 of 2 March 2012.
[25] *GN* R 719 *GG* 38000 of 19 September 2014.
[26] Section 1 of the NHA.

This definition is very broad and encompasses any research which contributes to factors, (a) to (g) above. Although this definition does not provide specifically for biobank research, the factors mentioned in the definition could include all possible outcomes of biobank research, depending on the nature of the research undertaken. At the Human Biobank Convention hosted by the National Health Laboratory Service on 2 October 2013, argument was made that biobanks could be governed by the Regulations relating to Tissue Banks.[27] In accordance with those regulations, a tissue bank is defined as:

> an organisation, institution or *person* that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals *for transplantation purposes*… (*my emphasis)*

Therefore, in accordance with this definition, a tissue bank could be a person. In addition, this definition's reference to "transplantation purposes" causes it to be very limited. Biobank research involves participants contributing their samples and data for health research purposes and cannot be limited to purposes of transplantation. While the practical challenges to the definition of a tissue bank are obvious, it is evident that a biobank (as defined above) and a tissue bank (as defined in the NHA regulations) are quite different.

The National Health Research Ethics Council (NHREC) was established in accordance with section 69(1) of the NHA. One of the responsibilities of the NHREC is to determine guidelines for the functioning of health research ethics committees, in order to facilitate best practice.[28] Accordingly, the first edition of the National Department of Health, National Ethics Guidelines were published in 2004 and the second edition was published in 2015. The second edition of the Guidelines is the only document which attempts to define and regulate biobank research in South Africa. The

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[27] Presentation by Mr B Duma at the National Health Laboratory Service (NHLS) Human Biobank Convention held on 2 October 2013. NHLS, Sandringham, Johannesburg, Convention. Cited in Dhai A. 2013. "Establishing national biobanks in South Africa: The urgent need for an ethico-regulatory framework" *South African Journal of Bioethics and Law.* 6 (2): 38-39.

[28] Section 72(6)(a) of the NHA. See also: National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Ethics Guidelines) *Second Edition.*

Guidelines use the term “biobank” and “repository” interchangeably. In accordance with the Guidelines, a repository is defined as:

> A collection, storage and distribution system for human biological materials[29] for research purposes including blood, urine, faeces, bone marrow, cell aspirates, diagnostic specimens, pathology specimens and so on. Usually demographic and medical information about the donors is included in the repository as are codes that link the material to the donors.[30]

The challenges with this definition, as well as with certain other aspects of these ethical guidelines, include issues of informed consent, privacy and confidentiality, ownership of HBMs and data, benefit sharing and Material Transfer Agreement (MTA) requirements, which will be addressed later in this study. In addition, there are gaps around the same themes in our existing legislative framework which will similarly be identified.

1.1.4 Potential risks associated with biobank research

Conventional research usually entails one researcher or an already recognised set of researchers; samples are obtained and used in defined ways for research in discrete areas; informed consent from each research participant is obtained for use of their sample; and permission is sought to obtain, use and disclose the participants’ health information.[31] With biobank research, those obtaining the samples may be brokers or intermediaries who may supply specimens without necessarily being involved in the research; the biobank sample repository may be used for many research projects and often in numerous scientific areas; and this type of research usually entails future research by investigators which cannot be specified at the time of sample collection.[32] Biobank research may typically involve extensive networking of materials. It may therefore be impossible to contemplate a final, foreseeable end point to where the materials may culminate, when drafting the initial research protocol. It is also

[29] According to the National Guidelines, Human Biological Material is defined as: “materials including blood and blood products, DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors.” at 76.

[30] National Guidelines para. 3.5.2.1 at 50.

[31] Rothstein MA. 2005. "Expanding the Ethical Analysis of Biobanks." *The Journal of Law, Medicine & Ethics* 33(1): 89-101. doi:10.1111/j.1748-720x.2005.tb00213.x.

[32] *Ibid*.

crucial to note that potential risks of biobank research can extend beyond the individual participant to population groups that the participant is associated with as well as the general public at large. Hence, societal interests merge on both the benefits and risks side of biobank research.[33]

Common risks associated with biobank research are social and dignitary. Social risks include stigmatisation and discrimination and are frequently group-based and implicate both research participants and non-participants.[34] Genetic stigma and discrimination is widely feared and may have a serious negative impact on an individual or community. Such stigma and discrimination may also result in legal challenges[35] and as a consequence, cause communities to distrust research projects and researchers. Dignitary risks occur when religious or personal values are violated.[36] Unidentifiable samples could lead to research which the donor may not approve of (e.g: the use of samples for research on termination of pregnancy).[37] These risks, together with risks to informed consent, privacy and confidentiality, ownership of the materials and contractual conflicts when materials are transferred, pose ethical and legal challenges to biobank research.

1.2 Rationale for the study

With regard to our South African situation, an ethico-legal *lacuna* exists in respect of guidance for the concerns that biobanks raise. The current ethico-legal framework lacks adequate direction, and hence, appropriate regulation. Even though biobank research has now been incorporated into national ethical guidelines, its complexities call for the establishment of firm principles with regard to informed consent and secondary uses, ownership of materials, privacy and confidentiality, benefit sharing, and MTA requirements. In addition, the South African legislative framework remains silent with regard to its application leaving the regulation of biobank research up to the

[33] Dhai A. Steve Biko Centre for Bioethics *Practical Ethics and Regulatory Guide for Researchers and Research Ethics Committee Members* (2015) at 110.
[34] Dhai A *op cit* (2015) at 86.
[35] Baulig LT. 2010. "Are there property rights in Human Tissue? The law "Lacks" definitive answers." *The Journal of Lancaster General Hospital* 5(3): 87-90.
[36] Dhai A *op cit* (2014) at 110-111.
[37] *Ibid* at 110.

researcher, sponsor and Research Ethics Committees (RECs). Therefore, there is a dire need to have an ethico-legal framework in the country that responds and gives direction to this ethico-regulatory requirement.

1.3 Research Question

This study asks what the appropriate ethico-legal framework for biobank research should be in South Africa, which will protect research participants and their communities against risks and harms, while benefiting them and facilitating ethical research.

1.4 Aim of the study

This study aims to critically examine the ethical and legal requirements for biobank research in South Africa, with the intention of identifying gaps and areas for improvement towards the development of a framework that responds to and promotes South Africa's needs, which includes the protection of populations, communities and individuals involved in biobank research, while at the same time, facilitating improvements to promote necessary research in the field.

1.5 Objectives of the study

The objectives of this study are:

1. To critically discuss and evaluate the current/ existing ethico-legal framework governing health research, with respect to informed consent, ownership, benefit sharing, and privacy and confidentiality in South Africa with a view to critiquing the hiatuses as regards biobanks;
2. To describe and review legislative and ethical frameworks of pertinent international counterparts with a view to developing the most appropriate model for the South African context; and
3. To evaluate and review MTAs from a local, regional and international perspective with a view to ascertaining the need for a generic MTA for biobank research in South Africa.

1.6 Research design

This study involves a normative and legal enquiry. As described by Sugarman and Sulmasy:

> Normative ethics is the branch of philosophical… inquiry that sets out to give answers to the questions, What ought to be done? What ought not to be done? … Normative ethics sets out to answer these questions in a systematic, critical fashion, and to justify the answers that are offered.[38]

In this study, the normative component draws from legal principles, as in general, the goodness of a just society is reflected in its laws. Jurisdictional questions i.e. the reach of legal authority is also analysed in the context of biobanks.[39] The main focus of this study requires an analysis of current South African law, regulations and ethical guidelines that are specific to biobank research.[40] There are a vast range of problematic issues that are contained within our current framework and in some instances, the current framework is incomplete and/ or silent. This does not only open the door to unscrupulous conduct but also creates a situation where no adequate minimum standard exists.

1.7 Study Method

The research undertaken will involve legal and normative research and analysis. It is based on desktop and library based research. No new data from study participants has been collected or analysed. The research does not involve study participants. It is an ethico-legal study drawing from the law and ethical literature relevant to the subject matter. During the course of the research, I consulted with various experts and/ or groups of experts within the field.

In studies of this type, the normative legal questions asked take the form of, What ought the law prescribe? What ought the law prohibit? What guidelines ought to be recommended? The descriptive component of this study asks what facts are relevant

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[38] Sugarman J & Sulmasy DP (eds) *Methods in Medical Ethics*. 2nd edition. Washington, D.C.: Georgetown University Press (2010) at 3.

[39] Hall MA & King NMP. *Legal Methods*. Chapter 8 in Sugarman J & Sulmasy DP (eds) *Methods in Medical Ethics* at 128.

[40] Sugarman J & Sulmasy DP. *Many Methods of Medical Ethics (Or, Thirteen Ways of Looking at a Blackbird)*. Chapter 1 in Sugarman J & Sulmasy DP (eds) *Methods in Medical Ethics* at 9.

to this ethico-legal enquiry. This is achieved by specific content analysis. This involves the collection of legislative and ethical documents (both national and international) which are analysed systematically, the consistent features of each recorded and an inference about their use and meaning established.[41] I shall therefore employ the typical research methods and standards applicable to ethico-legal research. This involves the interpretation and critical analysis of relevant legislation, case law, journals, articles, books and other relevant texts. My critical analysis of these relevant texts involves the definition and clarification of ethico-legal concepts, the identification and criticism of assumptions, the analysis and evaluation of ethico-legal frameworks, the development and defences of arguments, and the articulation of the most plausible interpretation of significant concepts found in ethico-legal sources.

An important aspect of the research was to engage in a comprehensive review of the existing literature on the ethical and legal controversies surrounding biobanks, and related topics, including the debate on what type of informed consent would best suit biobank research, who owns the materials (HBMs and data), how benefit sharing should be approached, how privacy and confidentiality issues should be addressed, and what provisions a MTA should include. It was also necessary to give attention to the literature on the ethical evaluation of the law.

Literature surveys and studies were conducted by means of internet search engines such as Google Scholar and electronic databases of scientific journals and books as well as legal resources (for example, PubMed, SAFLII, Juta Law Online Publications, Sabinet). Examples of phrases and keywords which were used include: law, ethics, biobanks, privacy, confidentiality, ownership, justice, informed consent, benefit sharing, material transfer, international laws, regulations and guidelines regarding biobanks.

[41] Hall MA & King NMP. *Legal Methods*. Chapter 8 in Sugarman J & Sulmasy DP. (eds) *Methods in Medical Ethics* at 128.

1.8 Outline of the thesis

As biobank research entails a variety of complexities and concerns, I have grouped the most relevant issues, which require immediate clarity, into four broad topics, and attempt to answer the following five questions:

1. What type of informed consent should be used for biobank research and how should secondary uses be treated?
2. Who owns the materials?
3. Should benefit sharing be a requirement?
4. To what extent should privacy and confidentiality be protected?
5. What provisions should be included within an MTA?

In light of the above, Chapter 2 begins with an examination of the impact of conventional and biobank research implications on the traditional informed consent model. The South African legislative and ethical framework which currently governs informed consent in the health research context and specific international guidelines that highlight the importance of respect for autonomy and informed consent are analysed. The types of consent models which could best suit biobank research in the context of health research are also examined. The position of secondary uses of materials is also deliberated and broad consent is suggested as a possible way forward.

The objective of Chapter 3 is to debate and reflect on the contentious issue of ownership of human materials, by analysing the national and international position in this regard. I also discuss custodianship as a viable alternative to the ownership model. The concept of benefit sharing in health research is also discussed in light of South Africa's exploitative past and balanced with the idea of public interests and population health that are central to the purpose of biobanks.

Chapter 4 moves on to discuss appropriate privacy and confidentiality safeguards that should be considered in view of the national and international positions regarding protections afforded to personal information.

Chapter 5 provides a comparative analysis of the ethico-legal systems utilised in specific developed countries and another developing sub-Saharan African country, insofar as they relate to biobank research. This is particularly significant, as such analysis will place our current local framework into perspective and substantiate the need for improvement.

Chapter 6 presents an MTA template which I developed as part of this study in an attempt to regulate biobank research in the absence of an explicit ethico-regulatory framework. Direction in terms of the exact provisions that should be contained within such an agreement are elaborated on in detail, taking into consideration the comparative country analysis provided for in the preceding chapter.

Chapter 7 concludes the thesis and contains specific recommendations and answers to the questions which this thesis puts forward. In addition, I present a draft set of Regulations for Human Biobank Research in South Africa, for consideration by the Department of Health. These draft regulations are a culmination of the outcomes of my research, which could be considered as a starting point to standardise biobank research in South Africa.

1.9 Outcomes of the study

The outcomes of this study include:

1. To create a specific ethico-legal framework in the form of a draft set of regulations for biobank research in South Africa. This framework will be presented to the National Department of Health for use towards national policy guidelines and regulations. This framework addresses and incorporates all pertinent ethico-legal issues that the research develops and highlights as considerations. The framework is so designed as to ensure a minimum ethico-legal standard to which all biobanks in the country should be required to comply with; and
2. To develop a generic MTA as part of the framework for inclusion in national regulations.

It is hoped that the outcomes of this thesis will provide the basis that facilitates biobank research whilst at the same time, safeguarding the dignity of individuals and populations at large.

1.10 Research Ethics Committee Review

This study does not involve the participation of human research participants or the use of animals and a waiver of ethics review was applied for and approved.[42]

[42] Please find a copy of the waiver of ethics review certificate, annexed hereto and marked as "**Annexure I**."

Chapter 2

An Informed Consent Model for Biobank Research in South Africa[43]

2.1 Introduction

In the medical research context, the concept of informed consent can be described as the moral, ethical and legal expression of the human right to respect for an individual's autonomy and self-determination. Protecting individual autonomy allows for individuals to decide whether and how their body, body parts and / or associated data will be used in the research process.[44] When an individual consents to a particular research process, he/she justifies the continuance of that process and excludes the basis of *prima facie* wrongfulness or unlawfulness of that particular process taking place.[45]

Classical research ethics focuses on individual consent which can only be obtained after the research has been approved by an REC. However, informed consent with regard to biobank research has become a complicated area of debate as traditional principles can no longer apply. Due to the nature of biobank research, the focus on individual autonomy and informed consent is seriously challenged. As more biobanks are being set up to facilitate wide ranging, population based research, the accuracy of such research results depends upon the size and number of samples collected during the research process.[46] Traditional informed consent which includes re-consent for secondary uses will be extremely burdensome for a researcher to implement. Therefore, there is a move away from the classical research ethics paradigms on informed consent to a format of broad or even blanket consent.[47] Questions arise as to whether consent for biobank research is at all informed and whether this term is even appropriate in the biobank context. In addition, classic consent forms respect

[43] This chapter is based on (in part): Dhai A, Mahomed S. 2013. "Biobank Research: Time for Discussion and Debate." *SAMJ* 103(4) 225- 227.

[44] Cambon-Thomsen A, Rial-Sebbag E & Knoppers BM. 2007. "Trends in ethical and legal frameworks for the use of human biobanks." *European Respiratory Journal* 30(2): 373-82. doi:10.1183/09031936.00165006.

[45] Van Wyk C. 2010. "Consent for Research on Human Participants in South Africa." *Journal of Contemporary Roman-Dutch Law* 73: at 214.

[46] Hallinan D and Friedewald M. 2015. "Open consent, biobanking and data protection law: can open consent be 'informed' under the forthcoming data protection regulation?" *Life Sciences, Society and Policy* 11(1) at 2.

[47] Dhai A & Mahomed S. 2013. "Biobank research: Time for discussion and debate." *SAMJ* 103(4): 225-27. doi:10.7196/samj.6813.

participant autonomy by including a withdrawal clause for the materials that have been collected. However, in the biobank context, it may not always be possible to provide such an assurance to a participant. Clearly, with such extensive networking, sharing of specimens, and transformation of specimens into cell lines, withdrawing of samples will not be as easy as it seems on the consent form. This could be viewed as challenging the concept of autonomy, which, in turn, tests informed consent as a principle within the research process.

In this chapter, I will examine the impact of conventional and biobank research implications on the traditional informed consent model; the South African legislative and ethical framework which currently governs informed consent in the health research context; specific international guidelines that highlight the importance of respect for autonomy and informed consent; and three types of consent models which could best suit biobank research. The focus of this chapter will be informed consent in the context of health research and not in the context of medical treatment. Although the line between treatment and research may not always be clear, according to Van Wyk: "research may involve subordination of at least the immediate interest of the individual participant to the objective of the advancement of generalisable knowledge."[48] Health research involves a more comprehensive information sharing process compared to disclosures by medical professionals to their patients.

2.2 Conventional Research versus Biobank Research

When conventional research is considered, it usually entails an already recognised set of researchers or one researcher for a specific research project; samples from participants are obtained and used in defined ways for research in distinct areas; and informed consent from each participant is obtained for use of his or her sample in specific ways.[49] Biobank research is distinct from conventional research in that brokers or intermediaries who may supply the specimens could obtain the samples but may not be directly involved in the research process. The biobank could be used for a large number of research projects which vary in many scientific areas. Furthermore, future research activities, including research questions and methods which cannot be

[48] Van Wyk C *op cit* (2010) at 220.
[49] *Ibid.*

specified at the time sample collection is considered; and the traditional method of obtaining individual informed consent from each research participant will be impractical to apply, especially when future research activities are considered.[50]

Biobank research introduces a new paradigm which separates the sample collection process, i.e. the informed consent process from the actual research.[51] When unspecified future research, (which may only occur many years after the initial sample collection process takes place) is envisaged, traditional consent models can no longer apply. The complexities that biobank research presents, challenges classical research ethics with regard to maintaining participants' individual autonomy. The following section will outline the current South African legislative and ethical framework with regard to autonomy and informed consent.

2.3 South African Legislative and Ethical Frameworks

2.3.1 Constitution of the Republic of South Africa, 1996

In South Africa, the Constitution of the Republic of South Africa, 1996 is the supreme law of our country. It forms the apex to our legislative framework in that no other law or government action supersedes its provisions.[52] Chapter 2 of the Constitution contains the Bill of Rights, which enumerates the fundamental rights of all persons in the country. According to section 12(2) of the Bill of Rights:[53]

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

[50] *Ibid*.
[51] Rothstein MA. 2005. "Expanding the Ethical Analysis of Biobanks." *The Journal of Law, Medicine & Ethics* 33(1): 89-101. doi:10.1111/j.1748-720x.2005.tb00213.x.
[52] The Constitution of the Republic of South Africa. South African Government. Accessed November 07, 2017. http://www.gov.za/documents/constitution/constitution-republic-south-africa-1996-1.
[53] Chapter 2 of the Constitution of the Republic of South Africa, 1996.

In the health care setting, this translates to the right to informed decision making which includes informed consent and informed refusal.[54] It is relevant to note that the right not to be subjected to medical or scientific experiments without informed consent is a non–derogable right. This means that although there are limitations placed on certain fundamental rights in our Bill of rights, this specific right to informed consent may not be limited, infringed upon or suspended in any way. Although the principle of informed consent is currently enshrined in our Bill of Rights, this doctrine was introduced into our courts as early as 1923. The seminal case of *Stoffberg v Elliot*[55] emphasised that any interference with a person's body that has not been permitted by law or consented to, is a violation of that person's rights.

> In the eyes of the law, every person has certain absolute rights which the law protects. They are not dependent on statute or contract, but they are rights to be respected, and one of the rights is absolute security to the person… Any bodily interference or restraint of man's person which is not justified in law, or excused in law or consented to is a wrong... A man, by entering a hospital, does not submit himself to such surgical treatment as the doctors in attendance upon him may think necessary… he still has the right to say what operation he will submit to, and, unless his consent to an operation is expressly obtained, any operation performed upon him without his consent is an unlawful interference with his right of security and control over his own body, and is a wrong entitling him to damages if he suffers any.[56]

This landmark case signalled the beginning of a move away from paternalistic attitudes towards patient autonomy. In addition to *Stoffberg v Elliot* the right to informed consent has been reiterated in numerous cases thereafter.[57] More recently, *Venter v Roche*,[58] was the first case of its kind in dealing with compensation claims for non-medical related

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[54] Dhai A & McQuoid-Mason DJ. *Bioethics, Human Rights and Health Law: Principles and Practice.* Cape Town: Juta. (2011) at 40. See also: Van Oosten F. F.W. *The Doctrine of Informed Consent in Medical Law.* PhD diss., 1989 at 414: "…the cardinal principle of self-determination still demands that the ultimate and informed decision to undergo or refuse [a medical] intervention should be that of the patient and not that of the doctor." (cited in *Castell v De Greef* 422J- 433A).

[55] 1923 CPD 148.

[56] *Stoffberg v Elliot* 1923 CPD 148. See also: "Contract and consent." Norton Rose Fulbright. Accessed November 07, 2017. http://www.nortonrosefulbright.com/knowledge/publications/44147/contract-and-consent.

[57] For example: *Richter and another v Estate Hammann* 1967 (3) SA 226 (C); *Castell v De Gree*f 1994 (4) SA 408 (C); and *C v Minister of Correctional Services* 1996 4 SA 292 (T) 300.

[58] (12285/08) [2013] WCHC 7 May 2013; and on appeal (A11/2014) 22 October 2014.

injuries in medical trials and the importance of participants understanding the implications of carefully worded informed consent documentation. In *Venter v Roche*, Venter argued that the sponsor (Roche) was obligated to provide him with more than necessary medical expenses. The High Court disagreed, pointing out that what was offered and accepted by the participant (Venter) was adequately described in the consent documentation. Venter accepted the risk of harm as described in the consent documentation, during the consent discussions and accepted the offer of payment of treatment costs, as so described, in the event that harm occurred. Venter's claim was dismissed with costs. Leave to appeal was refused but on petition, the Supreme Court of Appeal granted Venter leave to appeal to a Full Court of the Western Cape High Court, only on the issue of whether or not a tacit agreement was established between himself and Roche.

On 22 October 2014, Bozalek J held that there was no merit in Venter's appeal and the appeal was dismissed. The judgement in this case places a responsibility on regulators (i.e. RECs) reviewing and approving studies, to assess and approve the nature of compensation for research related injuries.[59] In addition, research participants are bound by the terms contained within the informed consent document which has been approved by these regulators. Any amendment thereto would need to be reduced to writing and brought to the attention of the REC in order to be legally binding.[60] These principles have a substantial bearing on RECs reviewing protocols for participation in medical trials. In addition, RECs must ensure that researchers implement an adequate informed consent process that distinguishes between the researchers and sponsors, and the limitation of compensation. Furthermore, informed-consent documents should confirm that the participant is aware that any verbal or other changes to the content of the signed consent document would only be legally binding on the researchers and sponsors if they are reduced to writing and brought to the attention of the REC concerned.

[59] Strode A & Singh PP. 2014. "Compensation for Research-Related Harm: The implications of Venter v Roche Products (Pty) Limited and Others for Research Ethics Committees." *South African Medical Journal* 104(11): 759. doi:10.7196/samj.8596.

[60] Strode A & Singh PP *op cit* (2014) at 761.

The *Venter* case has also shown that delictual claims for research-related injuries will not be successful if the Plaintiff has agreed to limit his or her own rights through signing an informed-consent form that limits compensation. With regard to this, Professor Peter Cleaton–Jones suggests as follows:[61]

> Whatever information on compensation is provided to a potential participant in a clinical trial information sheet, my belief is that it should be on a separate page requiring a signature and preferably combined with questioning to ensure that the potential participant understands it. Perhaps this should be in the front of an informed consent form, which would certainly help RECs reviewing an application, as well as the potential participant.[62]

The decision of this case emphasises the importance of a participant understanding an informed consent document and further understanding the implications of being bound by its content.

2.3.2 National Health Act 61 of 2003

According to the NHA,[63] the rights and duties of health care providers is to ensure that users[64] have full knowledge of: their health status except where this would be contrary to the best interests of the user; the range of diagnostic procedures and treatment options generally available; the benefits, risks, costs and consequences generally associated with each option; and the user's right to refuse health services[65] with an explanation of the implications, risks and obligations of such refusal.[66] Section 6(2) of the NHA indicates that where it is possible, the user must be informed in a language

[61] Chair, Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg, South Africa.

[62] Cleaton-Jones P. 2014."Compensation for research injuries: Thoughts from a human research ethics committee chair." *South African Medical Journal* 104(11): 755-756. doi:10.7196/samj.8939.

[63] 61 of 2003.

[64] Section 1 of the NHA defines a User as: "the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is - (a) below the age contemplated in section 39(4) of the Child Care Act, 1983 (Act No. 74 of 1983), "user" includes the person's parent or guardian or another person authorised by law to act on the firstmentioned person's behalf; or (b) incapable of taking decisions, "user" includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the firstmentioned person's behalf."

[65] Section 1 of the NHA defines Health Service as: "(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution; (b) basic nutrition and basic health care services contemplated in section 28(l)(c) 25 of the Constitution; (c) medical treatment contemplated in section 35(2)(e) of the Constitution; and (d) municipal health services."

[66] Section 6(1).

he or she understands and in a manner which takes into account the user's literacy levels.

Section 7 of the NHA describes consent of the user and indicates that a health service may not be provided to a user without the user's informed consent.[67] This section further specifies that a health care provider must take all reasonable steps to obtain the user's informed consent.[68] Informed consent under section 7 of the NHA is defined as:

> consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.[69]

Section 8(1) of the NHA states that a user has the right to participate in any decision affecting his or her personal health. This is particularly important when research on human participants is considered as certain outcomes of the research may have a bearing on the participant's current or future health. Participation and dissemination of research results to research participants is also outlined in the recently promulgated Regulations relating to Research with Human Participants,[70] which are discussed below, in relation to the informed consent process.

Section 11 of the NHA deals with health services for experimental or research purposes and describes that before any experimental or research health service is provided to a user, a user must be informed that the health service is for experimental or research purposes or part of an experimental or research project.[71] This section further stresses that no health service may be provided to a user for experimental or research purposes unless the user, health care provider responsible for the user's treatment, head of the health establishment and relevant health REC, or any other person to whom such authority has been delegated, has given prior written

[67] Section 7(1).
[68] Section 7(2).
[69] Section 7(3).
[70] *GN* R 719 *GG* 38000 of 19 September 2014.
[71] Section 11(1).

authorisation for provision of the health service in question.[72] It is important to reiterate at this point that the standard of disclosure required for informed consent in respect of participation in research in South African law is different to informed consent for medical treatment. As far as the nature and the scope of information which must be disclosed by common law is concerned, the health care practitioner is obliged to give the patient a general idea in broad terms and in a layperson's language of the nature, scope, consequences, risks, dangers, complications, benefits, disadvantages and prognosis of, as well as the alternatives to, the proposed intervention.[73] More particularly, all serious and typical risks and dangers should be disclosed, but not unusual or remote risks and dangers,[74] unless they are serious or typical, respectively, or if the patient makes enquiries about them.

The test of disclosure is whether the risk or danger inherent in the intervention in question is material, a risk or danger of being material, if in the particular circumstances:

(a) a reasonable patient, if warned of the risk or danger, would be likely to attach significance to it; or
(b) the doctor is or should reasonably be aware that the individual patient, if warned of the risk or danger, would be likely to attach significance to it.[75]

The NHA defines health research as:

> any research which contributes to knowledge of-
>
> (a) the biological, clinical, psychological or social processes in human beings;
> (b) improved methods for the provision of health services;
> (c) human pathology;
> (d) the causes of disease;
> (e) the effects of the environment on the human body;
> (f) the development or new application of pharmaceuticals, medicines; and
> (g) the development of new applications of health technology.[76]

[72] Section 11(2).
[73] Slabbert MN. *Medical law in South Africa*. Netherlands: Wolters Kluwer. (2011) at par. 128.
[74] *Richter v Estate Hammann* 1976 (3) SA 226 (C) 230 at 233.
[75] *Castell v De Greef* 1994 (4) SA 408 (C) at 426.
[76] Section 1.

As the definition of health research under the NHA is so broad, any kind of research involving human beings may be included in its definition. With regard to research or experimentation involving human participants, section 71 of the NHA provides that research or experimentation on a living person may only be conducted in the prescribed manner and with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible or negative consequences of this on his or her health. This amounts to a so-called "full disclosure."[77] It is also evident that future and/or secondary uses of materials from human beings for research purposes can be incorporated into the definition of health research as contemplated by the Act, as health research includes "any research" which contributes to the factors (a) to (g) above. As every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health REC; and as such committee must review all research proposals and protocols and grant approval for health research,[78] approval for future and/or secondary uses of human materials for research purposes must also be obtained from a health REC. Section 16(2) of the NHA weakens this requirement[79] as no authorisation by the user, head of the health establishment or health REC is required, where research reflects or obtains no information as to the user's identity. However, in a situation where conflicting statements are made, the higher standard is applied. This requirement challenges informed consent with regard to biobank research where the objects of future research or experimentation and therefore any possible consequences on the participant's health, may be unknown at the time the initial research is contemplated.

[77] Carstens PA & Pearmain D. *Foundational principles of South African medical law*. Durban: Lexis Nexis. (2007) at 894-895.

[78] Sections 73(1)&(2).

[79] According to section 16(2): "if the study, teaching or research…reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated…" (ie: of the user, head of the health establishment and the HREC).

2.3.3 Regulations relating to Research with Human Participants[80]

The recently promulgated Regulations relating to Research with Human Participants provide a list of what participants should be informed of during the research process. The Regulations state that research participants or their legally authorised representatives must be informed of the purpose, methods, and procedures including possible randomisation; alternatives to participation; potential harms and risks of harm; expected benefits of the research; the freedom to choose to participate or not, or withdraw from the process; the ways in which confidentiality and privacy will be maintained; details of the contact person in case of a research related injury; reimbursement and/ or incentives for participation; sponsor information; potential conflicts of interest; information about approval from the health REC or Medicines Control Council; information on insurance in the event of research related injury for more than minimal risk research; and the availability of beneficial products or interventions post research.[81]

This list is quite comprehensive and supports the notion that informed consent is an on-going information sharing process rather than a process that ceases once participant samples have been obtained. The Regulations further provide protection for vulnerable persons[82] involved in research and stipulate that such research must be evaluated with caution and carried out under certain circumstances only. These Regulations further provide that one of the obligations of a researcher is to disseminate research results, whether negative or positive, to research stakeholders, in a timely and competent manner including to participants and participating communities as far as possible.[83] This ensures that participants are kept as close to the research process as possible and further supports the on-going nature of the informed consent process which can at times be disregarded by researchers. Therefore, it is an established principle that informed consent should not be a "once off" process. Though, the

[80] *GN* R 719 *GG* 38000 of 19 September 2014.
[81] Regulation 5.
[82] The Regulations, in their Definitions section, define vulnerable persons as: "those persons at increased risk of research-related harm, or who are limited in their freedom to make choices, or relatively incapable of protecting their own interests."
[83] Regulation 3.

practicalities of this on-going process may pose difficulties when biobank research is contemplated.

2.3.4 Regulations relating to the Use of Human Biological Material[84]

Section 55 of the NHA states that a person may not remove tissue, blood, a blood product or gametes from the body of another living person, unless it is done with the written consent of the person from whom the tissue is removed, in the prescribed manner and in accordance with the prescribed conditions.[85] The Regulations relating to the use of Human Biological Material provides that a competent person may not remove any biological material from the body of another living person for the purpose of genetic testing, genetic training, genetic health research or therapeutics unless it is done:

1. with the written informed consent of the person from which such biological material shall be removed;
2. with the written informed consent of a child over the age of twelve years provided that child has sufficient maturity and the mental capacity to understand the benefits, risks, social implications of the procedure (should the child not possess sufficient maturity or understanding, the written informed consent of the parent or guardian will be necessary);
3. with the written informed consent of a parent, guardian or care giver where the child is younger than twelve years;
4. consent by the head of a health establishment in the case of an emergency;
5. consent by the Minister, if the parent, guardian or care giver of the child unreasonably refuses or is incapable of giving consent, cannot be readily traced or is deceased; or
6. with the written informed consent of a mentally ill person if that person is capable of giving consent; or a curator, spouse, next of kin, a parent, guardian, major child, brother or sister, partner or associate, if such mentally ill person is incapable of giving consent; and the head of a health

[84] *GN* R 177 *GG* 35099 of March 2012.
[85] Sections 55(a) and (b).

establishment in the case of an emergency.[86]

The Regulations also allow for the removal of biological materials from deceased persons under certain prescribed conditions for the purposes of genetic testing, health research and therapeutics. Where no consent was given by the deceased before his or her death for the use of his or her biological material, then the organisation or institution or person concerned must take steps to locate the spouse, partner, major child, parent, guardian, major brother or major sister of a deceased person, in the specific order mentioned, in order to obtain consent.[87] Therefore, it has been established that in South Africa, the doctrine of traditional informed consent applies in project specific cases.

Informed consent relating to participation in specific research projects should be distinguished from consent relating to future and/or secondary uses of human biological material, which is an issue that is often overlooked. Despite the existence of international research ethics documents governing the future use of human biological material,[88] as Nienaber[89] points out, South Africa's framework does not adequately address informed consent for the future use of human biological material. However, the second edition of the South African ethical guidelines: Ethics in Health Research, Principles, Structures and Processes[90] published in 2015, is the first national ethics document which outlines a consent process for biorepository research. It is also the first national ethical document that provides a section under "special topics" dedicated to biobanks or repositories, informed consent and secondary uses of materials, which I will discuss in some detail hereunder.

[86] *GN* R 177 *GG* 35099, Regulation 3(1)(a)-(c).

[87] *GN* R 177 *GG* 35099, Regulation 4(1).

[88] Eg: World Health Organisation's Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research (2003); Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (1997); the United Nations Educational, Scientific and Cultural Organization's International Declaration on Human Genetic Data (2003); and the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997); Treaty Series No 195.

[89] Nienaber A. 2011. "Consent to and Authorisation of the Export and Use of Human Biological Specimens for Future Research – Perspectives from Three African Countries." *Xliv Cilsa*, no. 2006: 225–54.

[90] National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Guidelines) *Second Edition.*

2.3.5 Department of Health, National Ethics Guidelines: Ethics in Health Research - Principles, Structures and Processes

The NHREC was established in accordance with section 69(1) of the NHA. One of the responsibilities of the NHREC is to determine guidelines for the functioning of health research ethics committees, in order to facilitate best practice.[91] Accordingly, the first edition of the Department of Health, National Ethics Guidelines were published in 2004 and the second edition was published in 2015. The second edition of the Guidelines (which has quasi-legal standing in the country) is the only document which attempts to define and regulate biobank research in the country. The Guidelines use the term "biobank" and "repository" interchangeably. In accordance with the Guidelines, a repository is defined as:

> A collection, storage and distribution system for human biological materials[92] for research purposes including blood, urine, faeces, bone marrow, cell aspirates, diagnostic specimens, pathology specimens and so on. Usually demographic and medical information about the donors is included in the repository as are codes that link the material to the donors.[93]

Regarding REC oversight,[94] the Guidelines stipulate that institutions and researchers that maintain repositories (biobanks or tissue banks) must have appropriate facilities, equipment, policies and procedures to store human biological materials and data safely and in compliance with accepted standards.[95] It therefore appears that the Guidelines infer that repositories could also include tissue banks.[96] As the Guidelines do not offer an alternate definition for a tissue bank, this definition is drawn from the Regulations relating to Tissue Banks[97] which define a tissue bank as:

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[91] Section 72(6)(a) of the NHA and National Guidelines *op cit* (2015) at 9.

[92] According to the National Guidelines Human Biological Material is defined as: "materials including blood and blood products, DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors." at 76.

[93] Guideline 3.5.2.1 at 50.

[94] The objectives of the thesis do not include making a comparison between REC oversight of different countries.

[95] Guideline 3.5.2.2 at 50.

[96] *Ibid*.

[97] *GN* R 182 *GG* 35099 of 2 March 2012.

> an organisation, institution or *person* that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals *for transplantation purposes* and is registered in terms of regulation 3 of these regulations. (*my emphasis*)

As pointed out in section 1.1.3 of Chapter 1, it is evident that the definition of a tissue bank is very limited and quite different from the definition of a repository as found within the guideline document. A tissue bank could even include a person and is limited to transplantation purposes only. It therefore does not make practical sense to equate a repository to a tissue bank in our South African situation as the scope of a tissue bank is quite limited. In addition, a tissue bank will require different requirements for regulation than a biobank.

The Guidelines do provide for appropriate safeguards, including physical, administrative and technical, to protect against unauthorised handling of materials or data and require that repositories be approved by an REC. However, it is not mandatory for institutional repositories created, maintained and used for present or future research purposes, to have prior institutional REC approval. Only new repositories require REC approval. The Guidelines also indicate that an existing research database[98] or non-research database may be converted into a repository and that RECs should establish procedures to guide this process and to guide the use of the repository.[99] Therefore, in accordance with the Guidelines, a biobank or tissue bank may fall under the category of being termed a repository. Furthermore, only new repositories require REC approval and an existing research database or non-research database may also be converted into a repository. As RECs are required to establish procedures to guide this process and to guide the use of the repository, an REC would be responsible for oversight of the biobank, or tissue bank and/or database (should it be converted into a repository). Therefore, a biobank, tissue bank and database could all be repositories as defined within the Guidelines. There are obvious differences between the definitions of a tissue bank, database and repository. Therefore, on reading the Guidelines, it becomes quite confusing to establish exactly how the Guidelines actually define a biobank.

[98] The National Guidelines define a Data base as: "a collection of information including images (data) arranged to facilitate swift search and retrieval. It may be electronic or paper-based." at 51.
[99] Guideline 3.5.2.2. at 50.

With regard to informed consent, the Guidelines stipulate that a consent document for donors should clearly explain: the purpose and nature of a repository, including specifics for which consent is being sought; how a repository works and the types of research it supports; the conditions and requirements under which data or material will be shared with other researchers; how privacy and confidentiality interests will be protected; the nature and extent of specific risks of harm related to use and storage of material or data, especially if identifiers are retained; in the case of genetic or genomic research, information about the implications of genetic testing (e.g. paternity determinations, insurance risks, reproduction decisions) and associated confidentiality risks. The informed consent document should also explain potential benefits (if any); where applicable, that the material may be used for future research not yet identified or shared with or transferred to other institutions; that donors have the freedom to withdraw consent at any time and to request withdrawal of data and that unused identifiable material will be destroyed if it is possible; information about the length of storage time; when the current consent to use material or data will expire; information about possible secondary uses of stored material; information about the possible creation of an immortalised cell line based on the specimen; that the REC may approve a waiver of consent for secondary uses of material or data where no more than a minimal risk[100] of harm is likely and the donor's rights and welfare interests are unlikely to be adversely affected and the research cannot be conducted if the waiver is not approved.[101] Therefore, the extent of information required to be included in the informed consent process is comprehensive and promotes the protection of research participants.

The guideline document also describes secondary uses of materials or data as "use in research of materials or data originally collected for other purposes."[102] It is the first document that attempts to regulate, on national level, the secondary uses of materials. It does not recommend a blanket or unrestricted consent for secondary uses and states that with unrestricted consent, it is difficult to implement fundamental ethical

[100] According to the National Guidelines a Minimal risk is: "where probability and magnitude of possible harms implied by participation are no greater than those posed by daily life in a stable society or routine medical, dental, educational or psychological tests or examinations." at 78.
[101] National Guidelines *op cit* (2015) 3.5.2.3 at 52.
[102] National Guidelines *op cit* (2015) 3.3.7 at 43.

principles especially that of respect for persons.[103] The Guidelines also indicate that RECs should carefully deliberate future use of materials as biological materials cannot be completely anonymised. According to the Guidelines, the presence of hereditary elements implies that any sample can be re-identified which has implications for the consent process insofar as participants should understand clearly what is being requested when secondary uses are considered.[104] This is particularly important when deciding upon privacy and confidentiality safeguards which will be discussed in Chapter 4 of this thesis. However, the Guidelines also state that research which relies exclusively on secondary use of anonymous information or anonymous human biological materials usually does not require formal ethics review, provided that no identifiable information is generated.[105] This appears somewhat inconsistent with the acknowledgement that biological materials cannot be completely anonymised.[106] According to the Guidelines, broad consent is established when:

> the donor donates materials with permission to use them for a broad range of future studies, subject only to further prior ethics review and approval.[107]

However, as the Guidelines endorse the H3Africa initiative[108] and as they have incorporated the initiative's objectives and vision widely throughout the document, the Guidelines follow H3Africa's recommendation that consent should be:

> broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health. The consent processes need to be appropriate for the cultural contexts in which the research takes place and tailored accordingly.[109]

A specific type of consent for biobank research is not recommended[110] *per se* but the Guidelines do indicate that blanket or unrestricted consent should not be implemented.

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[103] National Guidelines *op cit* (2015) 3.3.6 at 42.

[104] *Ibid.*

[105] National Guidelines *op cit* (2015) 1.1.10 at 8.

[106] For example, should a sample contain DNA, it is possible to re-identify that sample even though it is anonymised or de-identified.

[107] National Guidelines *op cit* (2015) 3.3.1 at 41.

[108] Human Heredity and Health in Africa (H3Africa) Initiative. Accessed November 08, 2017. http://h3africa.org/.

[109] National Guidelines *op cit* (2015) at 42.

[110] The National Guidelines outline three different types of consent: "i. Narrow (restrictive) consent: the donor permits use of the biological specimen for single use only; no storage of leftover specimen; and no sharing of data or specimen. This form necessitates new consent if further use is desirable. ii. Tiered

The following is recommended for research purposes, in the absence of broad consent to future use of material or data, (including images):

1. Expedited review is required for the use of existing or archived material collected for clinical or diagnostic purposes, including waste and surplus samples. If subsequent use was foreseen and if it falls within the scope of the current proposal then no new consent is required.
2. If the current proposal is different in terms of its scope, new consent may be required.
3. If the samples are anonymous and the results of the research would not place any individual, family or community at social, psychological, legal or economic risk of harm, then new consent is not required.
4. If the link to identifiers exists but is not provided to the research team and the results of research will not place any individual, family or community at social, psychological, legal or economic risk of harm, then new consent is not required.
5. The person who holds the code or link should sign an explicit written agreement not to release the identifiers to the research team. This agreement should accompany submission to the REC.
6. If the samples can be linked to identifiers, the REC must decide on a case-by-case basis whether expedited or full review is necessary.[111]

Therefore, the Guidelines suggest that where samples are anonymous or if links to identifiers exist but are not provided to the research team and the results of the research does not create the risk of harms, then no new consent is required for secondary uses. Furthermore, if subsequent use was foreseen and if it falls within the scope of the current proposal then no new consent is required. However, if the current proposal is different in terms of its scope, new consent *may* be required (*my emphasis*). This does not create a firm position where the scope of the proposal

consent: the donor provides consent for the primary study and chooses whether to permit storage for future use, sample and data sharing. iii. Broad consent: the donor permits use of the specimen for current research, for storage and possible future research purposes, even though the precise nature of future research may be unclear at present. The nature of the further usage should be described as fully as possible and should stipulate that further prior ethics review of the new study is necessary. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent." at 43.

[111] National Guidelines *op cit* (2015) 3.3.7 at 44.

changes. In that situation, REC approval and a new consent (if possible) should be mandatory. Should it be impossible or impracticable to obtain a new consent, the REC should then make a considered determination in that regard. Although not strictly pertinent to biobank research *per se*, where materials from human beings are retained for research purposes over long periods of time, it is important to note that certain sections of the Guidelines have somewhat weakened protections for human participants. For example, section 1.1.9 stipulates that:

> Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review, provided that
>
> - the researcher does not interact directly with individuals or groups.
> - the researcher does not stage any intervention.
> - the individuals or groups do not have a reasonable expectation of privacy.
> - dissemination of research findings does not identify individuals or groups.

This conflicts with the requirements for health research under the NHA where ethics review and approval is required for any health research[112] conducted by an institution, health agency and health establishment.[113]

The above legislation and guidelines set out the principles for informed consent for health research in South Africa. The second edition of the Department of Health, National Ethics Guidelines touches on consent principles specific to biobank or repository research, in particular consent for secondary uses of materials. I submit that the rules around informed consent and secondary uses require to be much firmer. To place this submission in context, I will now analyse certain pertinent international guidelines that outline principles for informed consent specific to biobank research.

[112] As defined in chapter 1.
[113] Section 73 of the NHA.

2.4 International Guidelines

2.4.1 The Organisation for Economic Co-operation and Development on Human Biobanks and Genetic Research Databases (OECD guidelines)[114]

The OECD guidelines, to which South Africa is subscribed, aim to provide guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases which are structured resources that can be used for the purpose of genetic research and which include: (a) human biological materials and/or information generated from the analysis of the same; and (b) extensive associated information. This Guideline was adopted by the OECD Council on 22 October 2009 and is intended to be evolutionary in nature.[115] This set of Guidelines is very comprehensive and outlines instances of informed consent for biobank and genetic database research. It defines informed consent as:

> A process by which information concerning the intended research is provided to the participant or participant's substitute decision-maker with an opportunity for them to ask questions, after which specific approval is documented.[116]

In particular, it provides for cases of consent for future or secondary uses. Under governance, management and oversight, the Guidelines stipulate that a review process should be in place for instances where the human biological materials or data are to be used in a manner not anticipated in the original informed consent process. This includes cases where uses deviate from the original consent; where informed consent may not have been obtained at the time of collection; for determining when to seek re-consent; and for uses where consent was obtained using a broader or layered format for uses unspecified at the time of collection, especially in the case of large scale genetic epidemiology studies.[117]

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[114] OECD Guidelines on Human Biobanks and Genetic Research Databases (OECD Guidelines) (2009).
[115] *Ibid*.
[116] OECD Guideline glossary at 46.
[117] Point 3.1 of the Guideline at 7.

In its terms of participation, the Guidelines outline that prior, free informed consent should be obtained by each participant. However, the biobank and database may provide for obtaining consent or authorisation from an appropriate substitute decision maker, or for a waiver of consent from an REC or appropriate authority.[118] The Guidelines further stipulate that special regard must be had regarding participation of vulnerable populations or groups and that their involvement should be subject to protective conditions in accordance with applicable law and ethical principles.[119] The operators of the biobank or database should also have a clearly articulated policy on whether participants may be re-contacted; the situations for which re-contact will be permitted; and the conditions that will govern re-contact.[120] Information should be anonymised or coded, but, the operators of the biobank or database should disclose to participants, insofar as possible, the exceptional conditions under which researchers may be provided access to materials that are not coded or anonymised.[121]

Participants must be provided with information on who their materials will be supplied to; and must be informed of their right to withdraw together with the implications thereof.[122] Of special consideration, participants should be provided with information about commercial products that may arise from the research**,** including human biological materials, data derived from the analysis of samples, data or other information provided by or about the participant and information on the benefits, if any, the participant may receive.[123]

Participants should be informed of the risks and benefits of participation in order to realistically assess the implications of their participation. The informed consent process should further cover the materials to be collected, data anticipated to be derived from the analysis of the samples, the records to be accessed, intended uses, storage, and duration of storage.[124] Importantly, the Guidelines also specify that where subsequent use of materials is envisaged, which are inconsistent with the original

[118] Point 4.B at 8.
[119] Point 4.C at 8.
[120] Point 4.D at 8.
[121] Point 4.E at 8.
[122] Points 4.F&4.G at 9.
[123] Point 4.H at 9.
[124] Point 4.4 at 9.

consent, a new consent should be obtained from the participant or appropriate substitute decision maker, or a waiver of consent obtained from an REC or appropriate authority in accordance with applicable law and ethical principles pertaining to the protection of human participants.[125] Furthermore, operators of the biobank or database could consider obtaining consent that permits material and /or data to be used to address unforeseen research questions. In these instances, participants should be fully informed of the extent of this consent and additional safeguards should be put in place to ensure participant protection.[126]

In addition, clearly articulated policy on feedback must be established and the nature of feedback (if any) that will be provided to the participant.[127] The biobank or database should have in place policies and procedures for ensuring that any re-contacting is not unduly burdensome for participants and is carried out by representatives or designees trained in dealing with sensitive issues and who are impartial in regard to the outcome of the research.[128] The Guidelines stress the importance of developing communication strategies which should take the different needs of participants into consideration. Consideration should also be provided for employing different formats and modes for providing information to participants. While the goal of the informed consent process should be to provide as much information as is relevant, the consent document should remain straightforward, readable and accessible.[129]

The Guideline is very specific with regard to the protection of materials and outlines the informed consent process in detail. It provides that informed consent must be obtained from a participant, however recognises that there are instances where this may be impractical to achieve especially in cases of secondary and future use of the material, and allows for a waiver of consent under certain circumstances. The Guideline also emphasises the governance, management and oversight roles of RECs in ensuring that the best method of informed consent is adopted and that participants are afforded substantial protections.

[125] Point 4.5 at 9 – 10.
[126] Point 4.6 at 10.
[127] Point 4.9 at 10.
[128] Point 4.10 at 10.
[129] Point 39 at 31.

2.4.2 World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects[130]

The World Medical Association (WMA) is an independent confederation of national medical associations from 112 countries (including South Africa) and represents more than 9 million physicians.[131] The Declaration of Helsinki, to which South Africa subscribes,[132] was first adopted at the 1964 WMA General Assembly in Helsinki and has undergone a number of amendments since its inception, the latest of which took place in 2013.[133] Its purpose is to provide guidance to physicians engaged in clinical research and its main focus is the protection of the research subject.[134] The guidelines to the Declaration of Helsinki are by far the most cited research ethics document in Central and West Africa.[135] The Declaration makes it very clear that "while the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects."[136] It unequivocally states that protecting the wellbeing of vulnerable research participants is essential. The Declaration is thus primarily concerned with protecting those involved in research and promoting ethical research and further states that "no national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration."[137]

The Declaration is very specific with regard to informed consent for participants involved in medical research and it is on these principles that our current legislative and ethical guidelines are based. Of importance, section 32 of the Declaration was

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[130] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

[131] Dhai A. 2016. "The WMA Declaration of Taipei: Human databases and biobanks for the common good." *SAJBL* 9(2): 50-51.

[132] National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Guidelines) *Second Edition.*

[133] *Ibid.*

[134] Williams JR. 2008. *"*The Declaration of Helsinki and public health*" Bulletin of the World Health Organisation* 86(8): 650-652.

[135] Dhai A & McQuoid-Mason DJ *op cit* (2011) at 26.

[136] Guideline 8.

[137] Guideline 10.

recently inserted to accommodate consent specific to biobank research. It reads as follows:

> For medical research using identifiable human material or data, such as research on material or data contained in *biobanks or similar repositories*, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee. (*my emphasis*)[138]

Therefore, section 32 of the Declaration currently stipulates that informed consent must be obtained for the collection, storage or reuse of identifiable human biological material or data contained in biobanks or similar repositories for medical research. The Declaration also recognises that traditional informed consent from each individual participant may be impossible or impracticable to obtain and in these situations the future and/or secondary research may be carried out after an REC has considered and approved the research. This move away from traditional informed consent is also emphasised in the WMA Declaration of Taipei and CIOMS guidelines which will be discussed below.

2.4.3 The World Medical Association Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (Declaration of Taipei)[139]

The Declaration of Taipei, which lays its foundation on the Declaration of Helsinki, was approved by the WMA in October 2016. The intent of the Declaration of Taipei is to provide regulation in respect of the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In accordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.[140] However, during the time of writing this thesis, the draft

[138] Section 32.

[139] WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

[140] Paragraph 3.

Declaration of Taipei and the subsequent finalised Declaration became available for analysis. I will therefore begin my analysis by outlining the pertinent aspects of the draft Declaration with respect to informed consent and highlight the differences between the draft and final declaration in respect of informed consent. The draft Declaration of Taipei[141] provided that:

> Informed consent, although not perfect, is the strongest instrument for protecting personal autonomy, and with it self-determination and dignity. It is the primary means for all potential research subjects to express their will and/or preferences. We consider it a crucial instrument for protection and respect.[142]

In contrast to the Declaration of Helsinki, the draft Declaration aimed to address any use of health databases and biobanks and was not restricted to research. The draft Declaration pointed out that the major risk scenarios in relation to health data and biobanks do not result from science *per se*, but from the commercial, administrative or political use of such data. Limiting the Declaration to research only would have not allowed for consideration of the imminent risk of abuse from outside the field of medicine e.g. commercialisation, cost-cutting and potential political abuse. It also acknowledged that the "one – by one" approach which has been the traditional method of obtaining informed consent must be retained because of immediate impacts that could result to participants. Yet, unlike physical experiments or research which requires direct contact with participants, biobanks allow for the frequent use of data sets. The draft Declaration recognised that if gaining consent from donors of the data or specimens were to be a *conditio sine qua non* (an absolute condition) for their use, it could entail multiple problems or even be prohibitive as it may no longer be possible to contact the donors.

Furthermore, the draft Declaration conceded that a high frequency of requests for use from individual participants could become burdensome.[143] It further recognised that in

[141] A draft from the Working Group intended for open consultation after acceptance of the executive committee of the WMA. Accessed 04 July, 2015. http://www.wma.net/en/20activities/10ethics/15hdpublicconsult/2015-Draft-policy-HDB_BB.pdf. Please note that as the finalised Declaration was published in 2016, the draft Declaration is no longer accessible online. Therefore, this internet link is no longer functional.

[142] Page 1 of the Foreword.

[143] *Ibid.*

the case of biobank research, the possibility of consent that accepts the use of the data or specimen on more than one occasion should be considered (i.e.: broad consent) and that the potential for harm when using only data or specimens compared to physical experimentation, is often minimal. It was on this premise that the draft Declaration was developed. It advised that a balanced approach be adopted by requesting broad consent from donors of data or specimens "indicating their preparedness to share or donate their data or material for later use, which at the time of donation or sharing cannot be definitely described."[144] This broad consent would be conditional upon a governance process which can partly substitute individual informed consent or ensure that informed consent will be obtained at a later date should this be deemed necessary by an REC.

The draft Declaration clearly outlined that it was only relevant to health data bases and biobanks that contain identifiable data and biological material. Under a section titled "Ethical Principles" the draft Declaration emphasised that individuals must be given an opportunity to decide whether their identifiable information will or will not be included in a health database or their biological material in a biobank. The purpose, nature of the data or materials to be collected and information on who will have access to the database or biobank must be included in the consent process.[145] The draft Declaration further outlined that individuals have the right to solicit and be provided with information about their data and its use, as well as request necessary corrections of mistakes or omissions. In addition, individuals have the right to (at any time and without reprisal) withdraw consent for their identifiable information.[146] Of importance, section 18 dealt directly with future and secondary uses of data or materials and stated that:

> If Health Databases and Biobanks are established to allow for multiple studies and if, during the consent process, *all principle information about future use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, and if all use is explicitly approved by a dedicated, independent ethics committee, then conditional broad consent is acceptable.* In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable. (*my emphasis*)

[144] Page 1 of the Foreword.
[145] Section 15.
[146] Sections 16&17.

This section highlighted the fact that broad consent is acceptable if the following conditions are met during the consent process: all principle information about future use is provided; all relevant safeguards are secured; the use of health data or biological material is transparent; and if all use is explicitly approved by a dedicated, independent ethics committee. Of note, broad consent for future, yet undefined uses was not provided for within this section. However, section 32 of the Declaration of Helsinki recognises that where it is impossible or impracticable to obtain informed consent for identifiable material for biobank or similar repository research, the research may be carried out after an REC has considered and approved the research. Therefore, while the draft Declaration supported the notion of conditional broad consent, it acknowledged the difficulties of obtaining re-consent in certain circumstances for undefined future research and provided for the consideration and approval of an REC in these circumstances. This provision is echoed in section 32 of the Declaration of Helsinki. Furthermore, the draft Declaration specifically prohibited blanket or open consent for future use of health data or biological material not envisaged at the time of collection and stated that this type of consent would be ethically unacceptable.

Section 19 provided for consent to be waived to protect public health in the event of a clearly identified and immediate threat where anonymous data would not suffice. A dedicated REC should confirm that each case is justifiable. The role of ethics committees was emphasised in the draft Declaration as dedicated independent ethics committees must approve the establishment of all health databases and biobanks, approve all use of data and human material and decide on the type of consent necessary. The committee must also have the right to monitor ongoing activities.[147]

Finally, the last section of the draft Declaration urged relevant authorities to formulate policies that protect health data and human material on the basis of the principles set out in the Declaration. It is important to mention here that the University of the Witwatersrand, Johannesburg, has taken the lead in South Africa with regard to policy development specific to biobank research and has an already developed, fully functioning Biobanks Ethics Committee. I will discuss their policies and functions in

[147] Sections 20&21.

Chapter 6. Of significance and with regard to informed consent for future uses, it is also pertinent to note that the recently promulgated Protection of Personal Information Act[148] has not placed more stringent requirements on biobanks than the NHA or Declaration of Helsinki. However, as the finalised Declaration of Taipei was published in 2016, I shall now turn to analyse and compare its contents with that of the draft Declaration.

The finalised Declaration of Taipei is a toned down version of the draft Declaration. Its requirements are not as stringent as those contained in the draft Declaration. It goes on to outline the requirements for a valid consent, should the materials be collected and stored in a health database or a biobank for multiple or indefinite uses. In this regard the consent is only valid if individuals are informed of:

- The purpose of the Health Database or Biobank;
- The risks and burdens associated with collection, storage and use of data and material;
- The nature of the data or material to be collected;
- The procedures for return of results including incidental findings;
- The rules of access to the Health Database or Biobank;
- How privacy is protected;
- The governance arrangements as stipulated in paragraph 21 [of the Declaration];
- That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent;
- Their fundamental rights and safeguards established in this Declaration; and
- When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.

Unlike the draft Declaration, the finalised version does not openly promote the use of broad consent. Neither does it condemn the use of blanket or open consent. Yet, as there are strict requirements for consent for secondary uses, one may infer that blanket or open consent will not be acceptable in accordance with the finalised Declaration. Significantly, the Declaration of Taipei has made progressive steps towards effectively

[148] 4 of 2013.

interpreting the nature of biobank research. It has done this by recognising that withdrawal of consent may not always be possible in the case of non–identifiable materials. In addition, the aforementioned requirement as well as the disclosure of commercial uses and benefit sharing within an informed consent displays fairness to participants, highlighting an element of justice when biobank research is considered. The Declaration goes on to state that in the event of a clearly identified, serious and immediate threat, where anonymous data will not suffice, the requirements for consent may be waived to protect the health of the population. In this instance an independent ethics committee should confirm that each exceptional case is justifiable.[149]

Ethical oversight is emphasised throughout the finalised Declaration of Taipei. Apart from an independent ethics committee approving the establishment of Health Databases and Biobanks, the ethics committee must also approve the use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use, or if other measures have to be taken to protect the donor.[150]

Another international guideline which has been significantly reworked and which is relevant for discussion is the CIOMS guidelines.

[149] Paragraph 16.
[150] Paragraph 19.

2.4.4 The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation[151] (CIOMS guidelines)

The Council for International Organisations and Medical Sciences (CIOMS), of which South Africa is a member,[152] was formed in 1949 jointly by the World Health Organisation (WHO) and the United Nations Scientific and Cultural Organisation (UNESCO). The goals of CIOMS are to facilitate and promote international activities in the field of biomedical sciences, in collaboration with the United Nations and the WHO. To these ends, CIOMS has undertaken vital work in the areas of bioethics, international health policy (including consideration of social justice and individual dignity in relation to health policy), and drug development (safety, pharmacogenetics, reporting of adverse reactions, and the ethics of drug promotion).[153] The aim of the guidelines is to set out how universal ethical principles should be applied, with particular attention to conducting research in low resource settings. The fourth version of the guideline was published in 2016.[154] The guidelines have broadened the scope of "health –related research to include:

> …activities designed to develop or contribute to generalizable health knowledge within the more classic realm of research with humans, such as observational research, clinical trials, biobanking and epidemiological studies. Generalizable health knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based related to health, which can be corroborated by accepted scientific methods of observation and inference.[155]

[151] The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) Geneva 2016. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/.

[152] CIOMS Members, Council for International Organisations for Medical Sciences. Accessed December 07, 2017. https://cioms.ch/cioms-members/.

[153] Macrae DJ. 2007. "The Council for International Organizations and Medical Sciences (CIOMS) Guidelines on Ethics of Clinical Trials." *Proceedings of the American Thoracic Society* 4(2): 176-79 at 177.

[154] CIOMS Guidelines. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/.

[155] Page xii.

The latest version of the CIOMS guidelines were published in 2016. They contain a dedicated guideline for the collection, storage and use of biological materials and related data.[156] Guideline 11 outlines that the default position regarding informed consent should be specific informed consent when samples are collected for a particular purpose. However, the CIOMS guidelines endorse broad consent for unspecified future use. It goes on further to state that the ethical acceptability of broad informed consent relies on proper governance.[157] In a commentary to Guideline 11, the guidelines state that:

> Broad informed consent encompasses the range of future uses in research for which consent is given. Broad informed consent is not blanket consent that would allow future use of bodily material without any restriction. On the contrary, broad informed consent places certain limitations on the future use of bodily materials. Broad informed consent forms should specify: the purpose of the biobank; the conditions and duration of storage; the rules of access to the biobank; the ways in which the donor can contact the biobank custodian and remain informed about future use; the foreseeable uses of the materials, 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. The research ethics committee must ensure that the proposed collections, the storage protocol, and the consent procedure meet these specifications.[158]

The CIOMS guidelines therefore recognise that since the precise nature of the research is typically unknown, it is impossible to obtain specific informed consent at the time the material is collected. Therefore, it endorses broad informed consent for future use as an acceptable alternative to specific informed consent. Re-consent becomes necessary when the proposed use of the materials falls outside the scope of the initial protocol.[159] The CIOMS guidelines provides for a waiver of individual informed consent in the following circumstances:

1) the research would not be feasible or practicable to carry out without the waiver;

[156] Guideline 11 at 41.
[157] *Ibid* at 41.
[158] Commentary on Guideline 11 at 43.
[159] *Ibid*.

2) the research has important social value; and
3) the research poses no more than minimal risks to participants or to the group to which the participant belongs.[160]

In my opinion, the above definition of broad consent encapsulates the principles succinctly and precisely. It is becoming evident that we must move away from the traditional model of obtaining informed consent from each individual research participant for biobank research as this would pose difficulties especially when secondary and future uses are considered. Most international guidelines are specific that the broad consent model should be implemented even though different types of consent have been proposed as alternatives. However, the type of consent that would best suit the South African/African context, remains an open question. I will now briefly discuss three predominant consent models namely: blanket/open, dynamic and broad consent in order to identify their strengths and weaknesses and advocate the most appropriate model of consent for the African setting, in my opinion.

2.5 Consent models

2.5.1 Blanket /open consent

The traditional informed consent model which requires consent by each individual participant and re-consent in the event of future and secondary uses, will be most burdensome to apply to the type of wide ranging research that includes extensive networking, which biobanks facilitate. These new research possibilities place strain on the traditional, accepted methods of how informed consent should be obtained. Blanket /open consent has a long history[161] during which time multiple definitions have been proposed. Yet, there are certain common features within the various definitions which characterise blanket/open consent and differentiate it from other forms of consent.[162]

With regard to blanket /open consent: the research participant is only required to provide his or her consent once during the initial stages of the research. Unlike

[160] Guideline 11 at 41.
[161] Chadwick R & Kåre B. 2001. "Solidarity and Equity: new ethical frameworks for genetic research." *Nature Reviews Genetics* 2(4): 318-21. doi:10.1038/35066094.
[162] Hallinan D & Friedewald M *op cit* (2015) at 36.

traditional informed consent, the participant is not required to provide consent for a specific research project or to an area of research. The participant provides a once off consent for all future and secondary uses for projects or research areas, including undefined areas of research. Third party transfers and recipients of material are unspecified and the participant plays no role in deciding how their material will be used.[163] According to Hallinan & Friedewald, in Western societies, blanket/open consent is the most prominent type of consent model used for biobank projects and it is not difficult to see why.[164] This type of consent places no limitations on the scope and possibilities of research and the uses of samples. As a once off process, it is a fairly easy method of obtaining consent for future and/or secondary uses of materials as it requires minimal organisational and administrative effort. In societies where literacy levels are high, citizens most probably understand the function and purpose of a biobank, participant interaction with researchers is not based on community approval, and participants may retain no ties to their materials, blanket/open consent could be an appropriate consent model to adopt.

However, in the South African/African context, this type of consent could become legally and ethically problematic considering the potential exploitation of vulnerable communities that may result if it is adopted. Blanket/open consent asks participants for permission to use their samples as the researcher sees fit. It gives the participant very little to no control over how their material is used. Furthermore, it is not currently acceptable or provided for in the South African ethico-legal framework. As future or secondary uses of materials from human beings for research purposes are incorporated into the definition of health research as contemplated by the NHA, and as a REC must review all research proposals and protocols and grant approval for all health research,[165] approval for future or secondary uses of human materials for research purposes must be obtained from a heath REC. Therefore, this requirement will not allow for the adoption of blanket consent as an REC must act as an intervener when secondary uses are contemplated. In addition, it must be highlighted that a different dynamic of community involvement exists in the research setting in many African countries, unlike the individualistic approach supported in Western societies.

[163] *Ibid*.
[164] *Ibid*.
[165] Sections 73 (1) &(2) of the NHA.

A study in Ghana[166] stresses the importance of the role that community leaders play during the consent process. Only when relevant community leaders have discussed a proposed study with researchers and given permission for the study to commence, may researchers invite individuals in the community to participate. It is not uncommon though, that some participants may refuse to consent even after community leaders have approved participation. Furthermore, certain communities retain ties to their body parts even after their samples have been obtained and utilised for research purposes.

In my opinion, blanket/open consent is not a feasible method of consent in societies where most research participants have low literacy levels; retain ties to their biological materials; require the participation of community leaders in the consent process; and do not adequately understand the concept, purpose and function of a biobank.

2.5.2 Dynamic consent

Another model to consider is dynamic consent. This model is a unique concept which uses modern communication strategies to inform, involve, offer choices and obtain consent for every research project based on biobank resources.[167] It employs features of modern technologies in an attempt to solve the problem of the lack of "real time" specific information about individual research projects. At first glance, dynamic consent seems appealing. It emphasises continuous re-contact with donors to the biobank, providing them with "real time" information on specific research projects, enabling participants to easily provide or revoke consent. Contrasted with blanket/open consent, dynamic consent involves more specific consents with active opt-in requirements for each research project[168] and requires participants to make an informed consent for both primary and secondary uses of their materials. This consent model attempts to keep participants better informed by continuously sending out updated information about specific research projects via SMS's, emails or websites.

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[166] Tindana PO, Kass N & Akweongo P. 2006. "The informed consent process in a rural African setting: A case study of the Kassena-Nankana district of Northern Ghana." *IRB Ethics and Human Research*. 28(3): 1-6.

[167] Steinsbekk KS, Myskja BK & Solberg B. 2013. "Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?" *European Journal of Human Genetics* 21(9): 897-902 at 897. doi:10.1038/ejhg.2012.282.

[168] *Ibid*.

The UK biobank and Norwegian Mother Child Cohort study which utilises broad consent (which I will discuss in paragraph 2.4.3 below) keeps their donors and other interested parties regularly informed by updating their web pages and sending out newsletters annually.[169] Therefore, the information strategies proposed in the dynamic consent model may be seen as an alternative route of distributing information and not something necessarily new. Proponents of dynamic consent claim that:

> In this model, consent is not a mere communication exercise but a bidirectional, ongoing, interactive process between patients [research participants] and researchers.[170]

This model aims to gain the trust of research participants by keeping them continuously involved in the research process. However, it is submitted that being repeatedly asked for consent may become confusing and a burden to participants. It may have the effect of discouraging rather than encouraging participation. Although, perhaps in certain instances, participants may appreciate the closer, more engaged relationship. Dynamic consent also transfers ethical responsibilities from ethics committees to participants in addition to giving participants direct control over their samples. This means that ethics oversight for secondary or future research would be weakened.[171] Furthermore, this model aims to enable the return of research results to participants in an easier more tailored manner. Nevertheless, this may shift the focus of the intent of participants and make the return of individual research results the primary motivation for participation.[172]

It is important that an improvement on information strategies should be addressed. If we consider the South African/African situation, dynamic consent could be seen as a progressive method of keeping participants updated. The shift of responsibility from RECs to participants is challenging, especially when communities with low levels of literacy are considered. In addition, it is not unheard of that participants may live in

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[169] UK Biobank Newsletter 2014 Comments. Accessed November 08, 2017. http://www.ukbiobank.ac.uk/newsletter/; and Norwegian Mother and Child Cohort Study (MoBa). Norwegian Institute of Public Health. Accessed November 08, 2017. https://www.fhi.no/en/studies/moba/.

[170] Kanelloupoulou NK, Kaye J, Whitley E, Creese S, Lund D & Hughes K. 2011. "Dynamic consent– a solution to a perennial problem?" *BMJ Recent Rapid Responses.*

[171] Steinsbekk KS, Myskja BK & Solberg B *op cit* (2013) at 901.

[172] *Ibid* at 901.

areas with no cell phone reception or signal for internet connection. Furthermore, not all participants may be computer/ technologically literate. It also appears to be slightly flippant that participants receive highly personal and in some instances perhaps life changing information over an SMS or email. Confusion and panic may also result if the contents of the communication are misinterpreted. I do not believe that this model would best suit the current South African situation. A study conducted in Ethopia rightly cautions against "borrowing" consent models from developed countries and blindly applying them to societies where basic functioning systems are very different.[173] I will now discuss the broad consent model which I believe, if implemented correctly, could be a possible solution for biobank research in South Africa.

2.5.3 Broad consent

Broad consent should not be confused with blanket or open consent. Adopting this model means that participants will consent to a framework for future research of certain types.[174] This framework includes ethical review of each specific research project by an independent ethics committee and the implementation of strategies to regularly update the participant, as well as the provision of ongoing withdrawal opportunities. Should anything in the research framework change, the participant should re-consent. However, should it be impossible or impracticable to re-consent, the participant and the REC should make a considered determination in this regard. It is on this premise that broad consent still aims to offer informed consent to research participants.[175] The notion of broad consent being an informed consent model is opposed by some scholars[176] with specific regard to unspecified, future research

[173] Tekola F, Bull SK, Farsides B, Newport MJ et al. 2009. "Tailoring Consent to Context: Designing an Appropriate Consent Process for a Biomedical Study in a Low Income Setting." *PLoS Neglected Tropical Diseases* 3(7) at 2. doi:10.1371/journal.pntd.0000482.

[174] Steinsbekk KS, Myskja BK & Solberg B *op cit* (2013) at 879; Kaye J, Stranger M (eds.): *Principles and Practise in Biobank Governance*. Burlington: Aschgate Publishing Company 2009. 79-92; Steinsbekk KS, Solberg B. 2011. "Biobanks – when is re-consent necessary?" *Public Health Ethics* 4: 236–50; Helgesson G. 2012. "In defense of broad consent." *Camb Q Healthc Ethics* 21: 40–50; and Hansson MG, Dillner J, Bartram CR, Carlson JA, Helgesson G. 2006. "Should donors be allowed to give broad consent to future biobank research?" *Lancet Oncol* 7: 266–69.

[175] Steinsbekk KS, Myskja BK & Solberg B *op cit* (2013) at 879; and Steinsbekk KS & Solberg B. 2011. "Biobanks – when is re-consent necessary?" *Public Health Ethics* 4: 236–250.

[176] Steinsbekk KS, Myskja BK & Solberg B *op cit* (2013) at 879.

projects that are sometimes unforeseen at the time the initial research is contemplated.

Some objectors of this model go as far as labelling "informed broad consent" in biobank research a contradiction of terms.[177] In addition, some opposing this model claim that broad consent "… hinders donors from exercising fundamental rights and freedoms."[178] This model challenges the participant's right to autonomy as the fundamental principles of informed consent are tested with regard to unknown, future and/or secondary uses. Sheehan,[179] Steinsbekk[180] and Solberg[181] argue that many ordinary decisions are made by people, which are properly informed decisions even though they may not have all the specifics at the time the decision was made. They argue therefore, that these decisions are still "perfectly acceptable and autonomous" in most people's minds. However, inasmuch as the views of critics must be respected, an appropriate model for consent specific to biobank research will have to be developed and efficiently implemented in order to protect participants and encourage ethical research.

It is apparent that traditional informed consent models simply cannot work when future and/ or secondary uses of materials or data are contemplated for research purposes. Issues may arise where participants cannot be contacted or reached for re-consent. The answer here should not lie in discontinuing research, but rather in achieving a balance between participant protections and the progressive nature of research. The Declaration of Helsinki, OECD guidelines, CIOMS guidelines and the second edition of the Department of Health, National Ethics Guidelines (as discussed in sections 2.3 and 2.4) all promote the model of broad consent specific to biobank

[177] Caulfield T, Upshur R & Daar A. 2003. "DNA databanks and consent: a suggested policy option involving an authorization model." *BMC Med Ethics* 4: 1; Arnason G. *Blood and Data: Ethical, Legal, and Social Aspects of Human Genetic Databases*. Arnason G, Nordal S & Arnason V (eds) Haskolautgafan (2004); Hofmann B. 2009. "Broadening consent and diluting ethics?" *J Med Ethics* 35:125–129; and Hofmann B, Solbakk JH & Holm S: *Consent to biobank research: one size fits all?* in Solbakk JH, Holm S & Hofmann B (eds): *The Ethics of Research Biobanking.* Heidelberg: Springer 2009 at 3-23.

[178] Karlsen JR, Solbakk JH & Holm S 2011. "Ethical endgames: broad consent for narrow interests; open consent for closed minds." *Camb Q Healthc Ethics* 20: 572–583.

[179] Sheehan M. 2011. "Broad consent is informed consent." *BMJ* 343.

[180] Steinsbekk KS & Solberg B. 2011. "Biobanks – when is re-consent necessary?" *Public Health Ethics* 4: 236–250

[181] *Ibid*.

research where future and/or secondary uses of materials are unspecified and unforeseen during the initial research stages.

Participants must be made aware at the initial consent stages that in certain exceptional situations, where it becomes impossible or impracticable for re-consent to be obtained, an REC will consider, review and approve the research and ensure protection of the participants' interests. In the same way, participants must also be made aware that withdrawal from the study may not always be possible. In this way, the ethics committee provides a safeguard to the interests of the participant, researcher and research project.

In my opinion, there should be a move away from a rigid application of a traditional model that will only prove to become arduous to both participants and researchers. Furthermore, instead of complete focus on a participant being informed at every turn, the emphasis should lie in ensuring participant protections, which a competent REC can achieve by continuously being involved in the process. A model of broad consent combined with skilled and regular ethics review, together with active information sharing in a language and at a level which all participants understand, is a preferred solution.

2.6 Conclusion

The history of exploitation with regard to research abuses in Africa, is a reality.[182] For example, during the early 1990s in Zimbabwe, Dr Richard Gladwell McGown, a British anaesthetist was arrested after having conducted dangerous human experiments on five hundred patients, without their knowledge or the approval of any relevant authorities at the time. Dr McGown was charged with murder as allegedly, up to six of the patients died from the experiments he carried out.[183] More recently, in 2001, Pfizer was sued by thirty families in Nigeria over trials of an antibiotic (Trovan) that was intended to treat meningitis. Investigations revealed that the antibiotic was tested

[182] Ndebele P, Mwaluko G, Kruger M, Ouwe O, Oukem-Boyer M & Zimba M. *History of Research Ethics Review in Africa* Chapter 2 at 4, in Kruger M, Ndebele P & Horn L (eds) *Research Ethics in Africa, a Resource for Research Ethics Committees*. *African SUN MeDIA* 2014.

[183] *Ibid*.

on nearly two hundred children without adequate informed consent from the families or approval by a local ethics committee. Questions around the standard of care which the researcher's failed to adequately exercise, also arose. Eleven children died, while some survivors suffered permanent brain damage and paralysis. An out of court settlement was reached, with Pfizer having to pay substantial compensation to the families concerned.

The abuses inflicted on developing world research participants, at the hands of the developed world, has played a significant role in shaping present day protections, norms, standards and requirements, specifically with regard to traditional informed consent. However, the move away from traditional informed consent to a model of broad consent appears to be the most practical solution for biobank research. International guidelines have adopted this model under certain conditions which include review and approval by a competent ethics committee for future and/or secondary uses where consent is impossible or unfeasible to obtain.

Nonetheless, how can a model of consent be effectively contemplated when the position of ownership of the actual materials remains a vague concept in our law? Should a participant relinquish ownership rights to his/her materials, the debate around informed consent, especially with regard to secondary uses, would fall flat. It would then be up to the institution/biobank to determine the uses of the materials, regardless of the participant's consent. In addition, should any benefits accrue to the participant or local researcher/institute if in fact no ownership rights exist? In the next chapter I will debate and reflect on the contentious position of ownership in human materials by analysing the national and international position in this regard. I will also provide a suitable alternative to the ownership model and justify the concept of equitably sharing in the benefits of health research, in an attempt to forge a way forward based on the principles of justice and public interests.

Chapter 3

Ownership of Human Materials & the Concept of Benefit Sharing[184]

3.1 Introduction

The issue of ownership in human tissues is riddled with complexities and there are no clear, defined rules in South African law. The ownership of tissue samples donated for medical research is an on-going subject of dispute. Some advocates assert that patients have on-going ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample.[185] Researchers argue that giving patients' property rights in their samples will turn the human body and body parts into a commodity and bring research to a halt.[186]

Participants may also then lay claim to any subsequent commercial benefits or intellectual property benefits that arise as a result of the use of their tissues. There is a significant potential for a conflict of rights in the arena of intellectual property where an inventor of a new drug or similar health care invention wishes to commercially exploit the intellectual property rights in that invention.[187] One thing is certain: the creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, accepted answers. When these questions have arisen in litigation, the courts have struggled to adapt the tradition and precedent of the law to the challenges arising from the biotechnology era.[188] Currently, in South Africa the sale or trade in human tissues is prohibited.[189] This internationally recognised principle should not be confused with the subsequent commercialisation

[184] This chapter is based on (in part): Mahomed S, Slabbert MN, Pepper MS. 2013. "The legal position on the classification of human tissue in South Africa – Can tissues be owned?" *SAJBL* 6(1): 16 – 20. Two outcomes of this chapter are: Mahomed S, Sanne I. 2015. "Benefit Sharing in health research." *SAJBL* 8(2):60; and Mahomed S, Slabbert MN & Pepper MS. 2017. "Ownership and human tissue - the legal conundrum: A response to Jordaan's critique." *SAMJ* 107(3):196.

[185] Gibson SF. 2008. "The Washington University v Catalona: Determining ownership of genetic samples." (48) *Jurimetrics J* 167-191.

[186] *Ibid*.

[187] Carstens PA & Pearmain D. *Foundational principles of South African medical law*. Durban: Lexis Nexis. (2007) at 173.

[188] Mahomed S, Slabbert MN, Pepper MS. 2013. "The legal position on the classification of human tissue in South Africa – Can tissues be owned?" *SAJBL* 6(1): 16 – 20.

[189] Section 60(4) of the NHA.

of intellectual property emanating through the course of the research process, which is permitted. There are abundant examples in law, showing the law's uneasiness in making sense of the human body in the context of ownership and property, as the notion of owning oneself (and one's tissues) implies that persons are able to objectify themselves, and in the process become susceptible to objectification by others. The question of the human body as property involves complex legal, ethical and philosophical dimensions. In this chapter, I will provide the current position in relation to the classification of human materials with regard to the South African and international ethico-legal context. I will also propose an alternative model to ownership, which I believe best suits biobank research. I will further discuss the importance of benefit sharing when health research, which involves participants, is conducted.

3.2 The Traditional Classification of the Human Body and the Common Law Understanding of Ownership

The human body and its parts are traditionally classified as *res extra commercium* (a thing outside the commercial sphere). Separated bodily materials present another problematical category, as the law has traditionally regarded separated bodily materials as *res nullius,* belonging to no one, until brought under the control the first person who obtains possession of the separated human tissue.[190] The universal legal prohibition on the sale or trade of human tissue, embodied globally and various statutory regulations of the use of human tissue are equally ambiguous, as these statutory prohibitions inconsistently reinforce a construction of the human body as a commodity (property), subject to regulation.[191]

This prompts the question as to how, in view of the common law position that no man is *dominus membrorum suorum* (master of his own bodily members) and the universal notion that the human body is *res extra commercium*[192] (a thing outside the commercial sphere), the ethico-legal framework in South Africa addresses the issue

[190] Slabbert MN. 2008. "Human bodies in law: Arbitrary discursive constructions?" *Stellenbosch Law Review* 19(1): 71-100.

[191] *Ibid*.

[192] Beier K, Schnorrer S & Hoppe N. Lenk C (eds). *The Ethical and Legal Regulation of Human Tissue and Biobank Research in Europe*. *Proceedings of the Tiss.EU Project*. erschienen im Universitätsverlag Göttingen (2011) at 20.

of human materials as property, and if so, what the consequences of this classification are. What rights do individuals have over their own materials, how do these rights impact intellectual property claims and could benefit sharing be one mechanism by which an equilibrium between these factors are reached?

The common-law description of ownership is found in South African case law where ownership is defined in various decisions as:

> the most complete real right which gives the owner the most complete and absolute entitlements to a thing. Even so, it is a right which can be limited by objective law and by the rights of others (limited real rights or creditor's rights).[193]

Furthermore, a "thing" is defined as:

> In terms of characteristics, as corporeal or tangible object external to persons and which is, as an independent entity, subject to juridical control by a legal subject, to whom it is useful and of value.[194]

Ownership is a real right that is often defined on the basis of entitlements. The following entitlements are usually distinguished: control; use; encumber (the entitlement to grant limited real rights in respect of a thing); alienate/ transfer; and vindicate (the unique entitlement of the owner to claim the thing from another person).[195] Should a biobank procure ownership of an individual's material, it would obtain a real right and ultimate control over that material. In other words, there would be no requirement to inform the research participant of any subsequent uses of the material or even update the participant as to progress of the research process (where possible) as required by the Regulations relating to research with Human Participants.[196] Regulation 3(e) of these Regulations further obligates researchers to disseminate research results not only to stakeholders but also to participants and participating communities in as far as possible. If a research institution or biobank

[193] Van der Walt AJ & Pienaar GJ. *Introduction to the Law of Property* (5th edition): Juta (2006) 39-47.
[194] *Ibid*.
[195] *Ibid*.
[196] *GN* R 719 *GG* 38000 of 19 September 2014.

legally owns the participant's materials, then how far could this right extend and would such responsibility be taken earnestly?

Should legal ownership pass to a biobank once the materials have been obtained from the participant, the biobank would have ultimate control over the use of the materials. This could result in unscrupulous individuals utilising materials of vulnerable individuals to advance the purposes of their research, without consideration of the individuals from which the materials were sought. Furthermore, should the research institutions "own" materials by a transfer of ownership rights from the research subject to the specific institution/biobank, any future uses of the materials may occur without the research subject's consent. The most commonly accepted view is that once a person donates biological materials to a researcher or institution, that person relinquishes any property claims to the materials,[197] yet, this is contradicted by the continuing rights and interests that the donor of the biological materials has regarding uses and secondary uses in his/her materials. In the case of *Greenberg v Miami Children's Hospital Research Institute*[198] it was held that a research product developed from human tissue is factually and legally distinct from the original excised tissue, such that a tissue specimen becomes the property of the researcher and thus prevents the donor from asserting rights in the resulting patent or commercial product.[199] In this scenario, since ownership rights have been transferred to the institution, any proceeds generated from a therapy produced using the individual's tissues (directly or indirectly), may never benefit the individual in question. Moreover, it does not seem practical to allow a situation in which research participants hold legal ownership rights in their tissues. Situations could then arise where payment is demanded for any subsequent profitable discoveries that result from the research, or participants may lay claim to other revenue streams deriving from the tissue. Participants may also participate in the research in the hopes of attaining a financial reward following a possible discovery. This will cause an ethical challenge with regard to the intention of the participant and whether his/her informed consent has not been swayed in the hopes of receiving a monetary reward. However, without the tissue from the research participant, no

[197] Kristin E & Schleiter JD. 2009. "Donors Retain No Rights to Donated Tissue." *American Medical Association Journal of Ethics* 11(8): 621-625.
[198] 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
[199] Hakimian R & Korn D. 2004. "Ownership and use of tissue specimens for research." *Journal of the American Medical Association* 292(20):2500-5.

scientific progress can take place. Achieving a balance in the form of benefit sharing could be one method implemented in an attempt to cater for the conflicting positions regarding ownership. In addition, moving away from the ownership model altogether may change the way materials are perceived during the research process. I will now provide an analysis of relevant South African legislation that should be considered when ownership and intellectual property rights of human materials are contemplated.

3.3 South African legislative framework

3.3.1 The Intellectual Property Rights for Publically Financed Research and Development Act 51 of 2008 (IPR Act)

The IPR Act was promulgated on 22 December 2008. Its operation commenced on 2 August 2010. The objects of the Act as defined in Section 2(1) include:

> Making provision that intellectual property[200] emanating from publicly financed research and development is identified, protected, utilised and commercialised[201] for the benefit of the people of South Africa, whether it be for a social, economic, military or any other benefit.

Section 2(2) of the IPR Act also stipulates that a recipient protects intellectual property emanating from publically financed research and development[202] from appropriation and ensures that it is available to the people of the Republic.[203] It is worth noting that the Act and its overriding objectives are not unique to South Africa. According to information published on the National Intellectual Property Management Office's (NIPMO) website, the IPR Act is based on the United States Patent and Trademark Laws Amendments of 1980, commonly referred to as the Bayh-Dole Act. Similar legislation has been enacted in Germany, Taiwan, Korea and Brazil, and systems

[200] Section 1 of the IPR Act defines Intellectual Property as: "…any creation of the mind that is capable of being protected by law from use by any other person, whether in terms of South African law or foreign intellectual property law, and includes any rights in such creation, but excludes copyrighted works such as a thesis, dissertation, article, handbook or any other publication which, in the ordinary course of business is associated with conventional academic work.

[201] Section 1 of the IPR Act defines Commercialise as: "…the process by which intellectual property emanating from publically financed research and development is or may be adapted or used for any purpose that may provide any benefit to society or commercial use on reasonable terms."

[202] Section 1 of the IPR Act defines Publically Financed Research and Development as: "…research and development undertaken using any funds allocated by a funding agency but excludes funds allocated for scholarships and bursaries." A Funding Agency is defined as: "…the State or an organ of state or a state agency that funds research and development."

[203] Section 2(2)(b) of the IPR Act.

have been put in place to achieve the same goals in Switzerland, the United Kingdom and Turkey.[204]

Research and development (R&D) is not defined in the IPR Act, but it is defined in the Regulations by making reference to the Frascati Manual.[205] Briefly, R&D is said to comprise of basic research, applied research, and experimental research.[206] Specialised health care carried out for research purposes in a university or hospital should be regarded as R&D. Further, data collected, processed and interpreted as part of the R&D process should be regarded as R&D. Data which is collected or processed for social sciences which is for the purpose of scientific research should also be regarded as such.[207] For purposes of this Act, the activities of biobank research will fall under the definition of specialised health care. Further, the collection, processing and interpretation of data is an integral part of biobank research and would be determined as research and development in accordance with the IPR Act.

The IPR Act provides for three scenarios regarding ownership of intellectual property namely; ownership of intellectual property from publicly financed R&D; co-ownership of intellectual property between institutions and private organisations; and ownership of intellectual property by a private organisation.[208]

Section 4(1) of the IPR Act provides that any intellectual property emanating from R&D conducted using any public funds shall be owned by the recipient[209] of the public funds. Therefore, should R&D emanate from a biobank/institution through the use of public funds and should a private entity or organisation not pay for the R&D on a full cost basis, the R&D would be retained by the biobank/institution. Such biobank/institution would not have the latitude to negotiate with the private entity or

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[204] Parliamentary Monitoring Group. Accessed November 09, 2017. https://pmg.org.za/bills/.

[205] OECD *Frascati Manual 2002: Proposed Standard Practice for Surveys on Research and Experimental Development*, OECD Publishing, Paris. Paragraph 3.1.4 of Regulation number 35978 Accessed November 09, 2017. http://dx.doi.org/10.1787/9789264199040-en.

[206] *Ibid.*

[207] Magagula D, Opinion by Norton Rose Fulbright 2014. "Legal Opinion on the Interpretation and Applicability of the Intellectual Property Rights from Publically Financed Research and Development Act, 2008 and its Regulations to the Research and Development activities undertaken by Wits Health Consortium (Pty) Ltd." at 7-8.

[208] Sections 4 & 15 of the IPR Act.

[209] According to section 1 of the IPR Act, a Recipient is defined as: "… any person, juristic or non-juristic that undertakes research and development using funding from a funding agency and includes an institution."

organisation regarding the ownership of intellectual property. However, should the biobank/institution wish to relinquish ownership of the intellectual property, it would have to do so in consultation with NIPMO.[210] Furthermore, should the private entity or organisation be a foreign entity and if the R&D activities will be conducted offshore, the biobank/institution will be required to inform NIPMO prior to concluding such agreement.[211] The biobank/ institution will also have to satisfy NIPMO that there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and that the Republic will benefit from the offshore activities.[212] This is of considerable relevance when the transfer of materials is contemplated for biobank research purposes.

Notwithstanding the provisions of section 4(1) of the Act as summarised above, section 15(2) stipulates that any private entity or organisation may become co-owner of the intellectual property emanating from publically financed R&D, where the private entity or organisation collaborating in the R&D does not pay for the R&D on a full cost basis, if:

(i) There was a contribution of resources, such as the private organisation providing the background intellectual property;
(ii) The institution and the private organisation collaborated in the creation of the intellectual property;
(iii) Appropriate arrangements for benefit sharing with intellectual property creators at the institution have been made; and
(iv) The institution and the private entity conclude an agreement for the commercialisation of the intellectual property.

The default position created by the IPR Act is for ownership of all intellectual property derived from R&D, where any public funds were used, to be retained by the institution, except when all the criteria above are met.

Section 15(4)(a) of the IPR Act provides that:

[210] Section 4(2) of the IPR Act.
[211] Section 12(1) of the IPR Act.
[212] Section 12(2) of the IPR Act.

> Any research and development undertaken at an institution and funded by a private entity organisation on a full cost[213] basis shall not be deemed to be publically financed research and development and the provisions of this Act shall not apply thereto.

In this situation the institution/ biobank and private entity would be free to negotiate with regard to ownership of the intellectual property i.e.:

(i) The private organisation can elect to retain ownership of the intellectual property with the institution using the intellectual property under licence; or
(ii) The intellectual property can be co-owned by the institution and the private organisation; or
(iii) The institution can retain the ownership of the intellectual property with the private organisation using the intellectual property under licence.

According to section 15(5), a private entity or organisation includes a private sector company, a public entity, an international research organisation, an educational institution or an international funding or donor organisation. Therefore, where a sponsor funds the R&D at full cost, then the sponsor and the South African institute/ biobank have the power to negotiate with regard to the ownership of the resultant intellectual property. This is due to the fact that the transaction will not be deemed as R&D conducted using public funds. Consequently, the provisions of the IPR Act shall not apply to this type of transaction. Therefore, the application of the IPR Act extends only to publically funded R&D.

As considered above, the objectives of the Act include utilising and commercialising intellectual property emanating from publically financed R&D for the benefit of the people of South Africa. Section 5 of the IPR Act places certain obligations on any person, juristic or non-juristic (including an institution) that undertakes research and development using funding from a funding agency (i.e. a recipient). One of the obligations of the recipient is to (in the case of an institution) manage revenues due to it from intellectual property transactions and the commercialisation thereof, including

[213] According to section 15(4)(b) of the IPR Act, Full Cost is defined as: "… the full cost of undertaking the research and development as determined in accordance with international financial reporting standards, and includes all applicable direct and indirect costs as may be prescribed."

managing benefit sharing arrangements with intellectual property creators at the institution.[214] A further obligation placed on the recipient in respect of an institution is to put in place mechanisms to annually assess, record and report to NIPMO on the benefits for society of publicly financed research conducted in that institution. These requirements attempt to ensure that benefit sharing takes place with intellectual property creators at the institution and that societal benefits are annually assessed, recorded and reported in respect of publically financed research.

The Act goes further in terms of the rights of intellectual property creators in institutions and grants intellectual property creators and their heirs a specific right to a portion of the revenues that accrue to the institution from their intellectual property.[215] According to section 10(2) of the Act, intellectual property creators at an institution and their heirs are entitled to the following benefit-sharing:

> (a) at least 20 per cent of the revenues accruing to the institution from such intellectual property for the first one million rand of revenues, or such higher amount as the Minister may prescribe; and
> (b) thereafter, at least 30 per cent of the nett revenues accruing to the institution from such intellectual property.[216]

The balance of the revenues generated by the intellectual property may be distributed by the recipient as it deems fit, however, the recipient must apportion part of it for funding (amongst other things) more research and development.[217] Although the Act touches on benefit sharing arrangements of intellectual property creators and their heirs, it is silent on benefit-sharing arrangements with the communities from which the data may have originated. It does promote the notion that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of South Africa. Nevertheless, the implementation of its objectives remain to be tested.

[214] Section 5(1)(f) of the IPR Act.
[215] Section 10(1) of the IPR Act.
[216] Section 10(2)(a)&(b) of the IPR Act.
[217] Section 10(5) of the IPR Act.

3.3.2 The Patents Act 57 of 1978 (PA)

Another piece of legislation which has a bearing on intellectual property rights with regard to biobank research and subsequent inventions, is the Patents Act (PA). The concept of patents with regard to health care research and development is problematic. If the creation is vital for saving a life or curing a disease, this can contribute greatly to the tensions between the right to accessing that health care on the one hand, and the right of a patent holder to exploit the creation on the other.[218]

A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem.[219] According to section 25(1) of the PA, a patent may be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. In accordance with international case law, it is generally agreed (and particularly relevant in the field of biotechnology) that a patent should not be granted merely because the applicant has been involved in a costly and protracted effort.[220] If the objective is known and sufficient of the theory and practice, for the applicant to know in which direction he/she is going, without there being an original step, then an invention is likely regarded as being obvious.

The Companies and Intellectual Property Registry Office (CIPRO) is the custodian of all patent applications that are filed within the Republic of South Africa. A provisional specification affords temporary protection for twelve months and can be extended for three months. It can form the basis for a complete patent application and for foreign patent applications. Once the invention has been fully developed and tested, a fresh patent application, with complete specification, is filed.[221]

It is important not to confuse a patent, which is ultimately the end result that the developed research may produce, with ownership of the actual sample itself. In the biotechnology industry, there has been an increase in patents on a variety of inputs

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[218] Carstens PA & Pearmain D *op cit* (2007) at 173.

[219] Companies and Intellectual Property Registration Office. Accessed November 09, 2017. http://www.cipro.co.za/products_services/patents.asp.

[220] Gibson J (ed) *Patenting Lives: Life Patents, Culture and Development* Routledge (2016) at 13.

[221] Pouris A & Pouris A. 2011. "Patents and economic development in South Africa. Managing intellectual property rights" *South African Journal of Science* 107 (11/12).

into the process of discovering drugs or other medical therapies or methods of diagnosing disease.[222] However, a registered patent in accordance with the PA is only protected within South Africa. A study showed that during the 1996-2006 period, South African universities and their academics applied for 280 patents at CIPRO. Yet, only 58 of the 280 patents were protected abroad.[223] Even though certain inventions may only require protection in the local market, it can be argued that international protection of approximately 20% of academic patents is relatively low. South African inventors are not able to protect their inventions abroad, in addition, they also run the danger of disclosing their inventions to foreigners by patenting only locally.[224] With regard to biobank research, the sharing/ negotiation of intellectual property raises further issues. The IPR Act attempts to provide for more effective utilisation of intellectual property emanating from publicly financed research and development. While the IPR Act establishes NIPMO and the Intellectual Property Fund, it is silent on issues related to CIPRO's activities. Furthermore, the sharing of benefits (ether monetary or non-monetary) between the recipient biobank/ institution and the providing biobank/ institution and/or the research participants/ communities involved, is not adequately addressed in South African law.

The latest version of the Department of Health, National Ethics Guidelines[225] (which has quasi-legal standing in the country), does not firmly address issues of ownership or resultant intellectual property rights but rather points to pieces of legislation and international guidelines that may provide guidance.[226] However, the Health Professions Council of South Africa (HPCSA) Guidelines on Over servicing, Perverse Incentives and Related Matters[227] address forms of inducement which may be considered unacceptable and I will briefly discuss its content below.

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[222] *Ibid.*

[223] *Ibid.*

[224] *Ibid.*

[225] National Guidelines *op cit* (2015).

[226] National Guidelines *op cit* (2015) at 48 states that: "Current legislation that governs intellectual property relating to traditional knowledge and genetic material includes: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, which advances Articles 15 & 8(j) of the Convention on Biological Diversity; The National Environmental Management: Biodiversity Act 10 of 2004 and its Regulations; The Patents Act 57 of 1978; The Department of Trade & Industry's policies on Intellectual Property including the Intellectual Property Amendment Bill 2008."

[227] HPCSA "Guidelines for Good Practice in Health Care Professions: Guidelines on Over servicing, Perverse Incentives and Related Matters" September 2016 Booklet 11. (Guidelines on Over servicing, Perverse Incentives and Related Matters).

3.3.3 Guidelines on Over servicing, Perverse Incentives and Related Matters

In these guidelines, the HPCSA seeks to identify incentive schemes and forms of inducement that it finds unacceptable.[228] The list provided in these guidelines is not exhaustive. In accordance with this guideline an improper financial gain or other valuable consideration is defined as:

> money, or any other form of compensation, payment, reward or benefit which is not legally due or which is given on the understanding, whether express, implied or tacit, that the recipient will engage or refrain from engaging in certain behaviour in a manner which is either:
>
> (i) Illegal; and/or
> (ii) Contrary to ethical or professional rules; and/or
> (iii) Which, in the opinion of the HPCSA, may adversely affect the interests of a patient or group of patients.
>
> In order to procure some direct or indirect advantage, benefit, reward or payment for the person offering or giving the said money, compensation, payment, reward or benefit, and "perverse incentive" has the same meaning.[229]

The guidelines also clearly stipulate that healthcare practitioners[230] shall not charge a fee or receive any financial gain or other valuable consideration for referring patients to other health professionals or for participation in drug trials or other research trials of a similar nature.[231] Therefore, any exchange of money for an improper financial gain is considered unethical and in breach of the HPCSA guidelines.

Furthermore, the guidelines stipulate that healthcare practitioners shall not:

> provide a service or perform or direct certain procedures to be performed on a patient that are neither indicated nor scientific or have been shown to be ineffective, harmful or inappropriate through evidence-based review.[232]

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[228] Guidelines on Over servicing, Perverse Incentives and Related Matters at 3.
[229] Guidelines on Over servicing, Perverse Incentives and Related Matters 3-4.
[230] In terms of clause 2.6 the Guideline, a Healthcare Practitioner is defined as: "any person registered with the HPCSA." at 3.
[231] Guidelines on Over servicing, Perverse Incentives and Related Matters 8.
[232] Guidelines on Over servicing, Perverse Incentives and Related Matters 5.

Therefore, any unscrupulous behaviour by healthcare practitioners shall not be tolerated. Although ethical guidelines may not constitute legal rules *per se*, a breach of these guidelines may point to unprofessional conduct or possible negligence, which may have legal consequences. These guidelines also illustrate the professional standards to which health practitioners are bound. However, as indicated previously, The Department of Health, National Ethics Guidelines do not address actual issues of ownership of materials or the resultant intellectual property which may be a consequence of the research process. One should bear in mind the above precautions when third party agreements are entered into stipulating the sharing of benefits. The agreement should not be construed as an incentive for the research to take place.

3.3.4 NHA Regulations Relating to the Artificial Fertilisation of Persons

The NHA Regulations Relating to the Artificial Fertilisation of Persons[233] attempts to provide clarity on the issue of ownership and states:

> Before artificial fertilisation, the ownership of a gamete donated for the purpose of artificial fertilisation is vested (in the case of a male gamete donor) but –
>
> (i) before receipt of such gamete by the authorised institution to effect artificial fertilisation, by the authorised institution which removed or withdrew the gamete; and
>
> (ii) after receipt of such gamete by the authorised institution that intends to effect artificial fertilisation, in that institution. (emphasised)
>
> After artificial fertilisation, the ownership of a zygote or embryo effected by donation of male and female gametes is vested –
>
> (i) "in the case of a male gamete donor, in the recipient; and
>
> (ii) in the case of a female donor, in the recipient.[234] (emphasised)

[233] Regulation 18 of the Regulations Relating to the Artificial Fertilisation of Persons Notice 175 in *Government Gazette* 35099 of 2 March 2012.

[234] *Ibid.*

Therefore, it appears that whoever is in possession of the material would be the owner of the material. However, this is limited to the purposes of artificial fertilisation as per the regulations. In addition, an embryo is defined in the NHA as "…a human offspring in the first eight weeks from conception" and in the Regulations Relating to the Import and Export of Human Tissue, Blood, Blood products, Cultured cells, Stem cells, Embryos, Foetal tissue, Zygotes and Gametes[235] as "…a human offspring in the first eight weeks of conception". Despite these definitions (the latter of which is conceptually confusing i.e. "of conception"), current legislation does not provide any guidance on whether an embryo may fulfil the requirements to be categorised as property.[236] Therefore, the exact characterisation of an embryo (which also falls into the definition of human biological materials)[237] in South African law also remains unknown and will have to be dealt with on a case by case basis taking into consideration all relevant factors. Even though South African law is unclear in this regard, this does not mean that the law does not offer any protections.[238] It is submitted that with regard to biobank research, the use of the word "ownership" in itself is problematical and that it should be substituted perhaps with either "proprietary rights" or "custodianship," which denotes something quite different from the legal understanding of ownership. These concepts will be deliberated below.

[235] Regulation 1 of the Regulations Relating to the Import and Export of Human Tissue, Blood, Blood products, Cultured cells, Stem cells, Embryos, Foetal tissue, Zygotes and Gametes Notice 181 in *Government Gazette* 35099 of 2 March 2012.

[236] The South African legislative uncertainty in this regard, may be compared to certain foreign jurisdictions where there is a recognition of property rights in embryos (implicitly or explicitly) by specific courts in the United States, also in respect of stored gametes in the United States, Australia and the United Kingdom eg: *York v Jones* 717 F. Supp 421 (ED Va, 1989); *Frisina v Women and Infants Hospital* LEXIS 7;3 (RI Superior Court, 2002); *Jeter v Mayo Clinic Arizona* 121 P 3d 1256 (Ariz Ct App, 2005); *Dahl v Angle* 222 Ore App 572 (Or Ct App, 2008); *Hecht v Superior Court of Los Angeles County*, 20 Cal Rptr 2d 275 (Cal Ct App, 1993); *Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 118; *Jocelyn Edwards; Re the estate of Edwards* [2011] NSWSC 478; Re Section 22 of the Human Tissue and Transplant Act 1982 (WA); Ex parte C [2013] WASC 3; *Yearworth v North Bristol NHS Trust* [2009] 3 WLR 118.

[237] Regulation 1 of the Regulations Relating to the Use of Human Biological Material Notice 177 in *Government Gazette* 35099 of 2 March 2012.

[238] For example: the rule of *nasciturus* fiction: "refers to the legal principle in which foetuses if subsequently born alive, will acquire all of the rights of born children whenever this is to its advantage." See: Smit VT "Everyone has the right to life – Fact or a nasciturus fiction?" *De Rebus*. March 20, 2017. Accessed November 09, 2017. http://www.derebus.org.za/everyone-has-the-right-to-life-fact-or-a-nasciturus-fiction/.

3.4 Proprietary rights and Custodianship

Proprietary information is information that is not public knowledge. The recipient of such information is therefore generally duty bound from making unauthorised use of such information. If human materials are afforded a proprietary interest, they would be protected from unauthorised use. The holder of the proprietary right (i.e. the research subject) would have to consent to any use of their materials in the research phase and any subsequent future use thereof. Argument may be made that considering a research participant has to provide informed consent for a variety of conditions of use of their materials,[239] their proprietary interest in their materials does not discontinue once their samples have been procured. Providing a participant with a proprietary interest would also ensure that the proceeds or any benefits of any therapy developed from the materials may be distributed, in part, to the participant. A mandatory agreement (e.g.: an MTA) stipulating the terms and conditions of such distribution should be required.

It is submitted that when human materials are obtained from research participants and transferred to one or more institutions/ biobanks for research purposes, that institution/ biobank does not retain ownership rights in the materials. Rather, the institution/ biobank should become the "protector" of the samples. The biobank should not only protect the samples at a technical level (i.e. by utilising correct storage methods at specific temperatures and ensuring meticulous transportation methods etc.), but should also protect the materials to the extent provided for in the research protocol and MTA. Ethico-legal protections are key to ensuring justice and fairness in research. These considerations are also vital when one considers the dire litigious impacts which could arise, should such protections be overlooked.

One model, which rests on the notion that biobanks should be founded on a "charitable trust" roots itself in the supposed philanthropic nature of medical research.[240] This model outlines that the biobank should operate as a "trustee or steward" between the researcher and the donor of samples. The donor would provide his/her materials with

[239] Regulation 5 of the Regulations Relating to Research with Human Participants Notice 719 in *Government Gazette* 38000 of 19 September 2014.

[240] Winickoff DE & Winickoff RN. 2003. "The Charitable Trust as a Model for Genomic Biobanks." *New England Journal of Medicine* 349(12): 1180-84.

a benefit sharing and philanthropic intent.[241] The donor would still have a right to control the use of his/her samples and the biobank would promote the redistribution of the samples and spread the results of research into the community, thereby acting as the philanthropic intermediary and promoting a culture of philanthropy within society.[242] Another model, which may provide for more protections and accountability in the research setting, is the model of custodianship.

Custodianship is the caretaking obligation for materials, as well as the obligation to protect, guard and maintain, from initial collection to final distribution of research findings. It endorses key practices and operating principles for responsible oversight of materials collected for research. Embracing the custodial model would ensure transparency in research, fairness to research participants, and shared responsibility amongst all stakeholders involved in the research.[243] Custodianship does not entail the right to ownership but acknowledges that a sample provided for research is a "gift" to be used, only with informed consent, to advance science for the benefit of society. Custodianship does not regard materials as profit-making commodities. In considering what custodial principles are applicable to research projects, biobanks and investigators should align their custodial obligations with the objective of the project. Custodianship will not replace ownership but rather form the umbrella under which ownership rights vest. In this way, public health interests would take precedence over the "exclusivity of rights" argument that institutions may put forward when it comes to human materials. I submit that the model of custodianship should replace the ownership model as public interests for the sake of the greater good and collective are better served under the latter concept. In addition, the mindset of "owning" materials will shift towards protectionisms which in turn, will provide for the justice that research participants deserve.

As there is currently no precedent in South Africa regarding ownership, custodianship

[241] Ibid. See also: Winickoff DE & Neumann LB. 2005. "Towards a social contract for genomics: property and the public in the "Biotrust" Model." *Genomics, Society and Policy* 1:8-21.

[242] Colussi IA. 2012. "Philanthropy and Research Biobanks: The Model of Biotrust." *Conversations on Philanthropy* IX: 105-117.

[243] Yassin R, Lockhart N, del-Riego MG, Pitt K, et al. 2010. "Custodianship as an Ethical Framework for Biospecimen-Based Research." *Cancer Epidemiology, Biomarkers & Prevention : A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology*, 19(4): 1012–1015.

or proprietary rights, guidance may be sought from international law in this regard. In terms of section 39 of the Constitution,1996, when interpreting the Bill of Rights, courts must consider international law and may consider foreign law. I will now provide a discussion on specific international precedent that may be instructive when legal issues regarding ownership, custodianship and proprietary rights in materials are deliberated.

3.5 Foreign case law

Foreign case law suggests[244] that when dealing with the issue of ownership of human tissues, there are no firm 'rules' *per se*. Each situation will have to be determined by the facts presented in that particular case. I will now discuss a few seminal cases which are relevant to the discussion around ownership of materials.

The case of *Washington University v Catalona*[245] involved a former Washington University surgeon, William Catalona, M.D., who was engaged in research using the prostate cancer repository. Dr. Catalona had argued unsuccessfully in the lower courts that research participants who donated tissue and blood samples to the University for prostate cancer research could require the University to transfer their tissues to him at his new place of employment.[246] The Court upheld a unanimous 2007 ruling by the Eighth U.S. Circuit Court of Appeals that stated prostate tissue and serum samples donated to Washington University may continue to be used by the institution for cancer research. The Appellate Court had affirmed the lower federal district court ruling that donors who gave tissue or serum samples to the University for research cannot later compel the school to transfer ownership of the samples to another research institution. The Court held that under the specific facts of the case, the men who participated had donated their tissue to the university as a gift and they could not get it back or have it

[244] Gibson SF. 2008. "The Washington University v Catalona: Determining ownership of genetic samples." *Jurimetrics J* 48: 167-191; Ivey LM. 1990-1992. "Moore v Regents of the University of California: Insufficient protection of patients' rights in the biotechnological market." *Georgia Law Review* 25: 490; and Lavoie J. 1989. "Ownership of Human Tissue: Life after Moore v. Regents of the University of California." *Virginia Law Review* 75(7): 1363 - 1396.

[245] Gibson SF *op cit* (2008) at 167-191.

[246] Washington University School of Medicine in St. Louis. Accessed November 09, 2017. https://medicine.wustl.edu/.

sent to another researcher. However, the Eighth Circuit Court indicated that the men retained the right to stop participating in the research by:

(i) declining to answer any additional questions;
(ii) not donating more tissue; or
(iii) disallowing the use of their tissue for future research.

This means that the men retained the right to order the university to stop using their tissue, and the university could not merely strip their names off their samples and continue to use them as they pleased. This suggests that an individual may have a tangible interest in his or her own tissues. This case highlights how courts have struggled to reconcile legal tradition and precedent with novel ethical and legal challenges arising from the use of human tissue in the biotechnology era. This case illustrates that even though samples were donated to the university for the purpose of cancer research, the institution could not use the samples as they pleased without any regard to the rights of the participants.

In *Moore v Regents of the University of California* the physician treating Mr Moore for hairy-cell leukaemia in 1976, removed samples of his blood, bone marrow aspirate and other tissues and fluid for examination.[247] The physician and his research assistant knew upon taking these samples that the tissues had potential commercial and scientific value as material for medical research, but they did not disclose this information to Moore.[248] In 1979, University of California, Los Angeles (UCLA) Medical Centre researchers established and patented a cell line from Moore's cells. The patent was assigned to the Regents of the University of California (Regents) who assisted the researchers in commercial development of the cell line and products to be developed from it. When Moore discovered that his cells had been used in developing the patent, he took legal action against Regents and UCLA Medical Centre researchers and doctors involved in his care. The California Supreme Court found that Moore had no property rights to his discarded cells or any profits made from them.

[247] Ivey LM o*p cit* (1990-1992) at 490.
[248] *Ibid.*

In *Greenberg v. Miami Children's Hospital Research Institute*[249] the same principles that were applied in *Moore* were used. It was found that a research product developed from human tissue is factually and legally distinct from the original excised tissue, such that a tissue specimen becomes the property of the researcher and thus prevents the donor from asserting rights in the resulting patent or commercial product.[250] Because in *Greenberg* the materials were voluntarily donated without a contemporaneous expectation of return, no property interest in the tissue and genetic matter that was donated was acknowledged, even though commercial benefit accrued as a result.

However, the California Supreme Court in *Moore* cautioned that: "we do not purport to hold that excised cells can never be property for any purpose whatsoever…"[251] The settlement between the members of the Havasupai tribe, Arizona Board of Regents and Arizona State University[252] suggests that the defendants and their counsel in this matter applied the qualifying language as set out in Moore, seriously.[253] The Havasupai tribe alleged that researchers from Arizona State University had collected blood samples to study the prevalence of diabetes in their tribe, yet, subsequently and without their permission, the researchers used the blood samples to study genetic markers for other disorders, including schizophrenia and alcoholism.[254] The Havasupai Tribe filed an initial lawsuit against Arizona Board of Regents and the Arizona State University in 2004, however, this lawsuit was dismissed due to a procedural error. The Arizona Court of Appeals later reinstated the lawsuit which led to a protracted legal battle. The parties agreed to settle the matter in April 2010 in order to remedy the problematic situation. Arizona State University agreed to compensate members of the tribe monetarily, return the blood samples and provide other forms of assistance to the disadvantaged Havasupai. The significance of this settlement highlights that the rights of participants can indeed be violated when they are not fully informed about how their samples, in this case blood samples, might be used. By questioning the honesty of

[249] 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
[250] Hakimian R & Korn D *op cit* (2004) 2500-05.
[251] *Moore v Regents of the University of California* 51 Cal. 3d 120;271 Cal. Rptr. 146; 793 P 2d 479.
[252] Harmon A. Boston.com. April 22, 2010. Accessed November 09, 2017. http://archive.boston.com/news/education/k_12/articles/2010/04/22/arizona_state_settles_dna_case_with_tribe/.
[253] Baulig LT. 2010. "Are there property rights in Human Tissue? The law "Lacks" definitive answers." *The Journal of Lancaster General Hospital* 5(3): 87-90.
[254] *Ibid.*

researchers from Arizona State University and probing whether they had been involved in exploiting a vulnerable population, this case cast a negative image on the university, which portrayed itself as a respectable institution for American Indian studies.[255]

Genetics experts and civil rights advocates assert that the continuous and growing debate over a researcher's responsibility to communicate the range of personal information that may be sourced from Deoxyribonucleic acid (DNA) at the time it is initially collected, may be further fuelled by the outcomes of this case.[256]

One may only speculate on the outcome of this matter, had a precedent been created in court. The university's decision to settle, however, possibly indicates apprehension by the university that litigation would have been successful. In a 2014 Canadian judgment, the Ontario Superior Court of Justice decided, as a preliminary issue, that tissue removed from a body for diagnostic medical tests is "personal property" belonging to the hospital where the procedure was performed.[257] This case involved an action of medical negligence instituted by the estate of a deceased patient against two doctors for failing to diagnose colorectal cancer of the deceased, who died in 2011. The doctors requested to have access to the liver tissue biopsied from the deceased. Before considering whether the defendant doctors had a right to access the liver tissue in order to determine whether the deceased patient had hereditary non-polyposis colorectal cancer, the court had to address the issue of ownership of the relevant tissue.

An earlier UK judgment that has also made reference to ownership of male gametes is that of Y*earworth v North Bristol NHS Trust*,[258] which involved the negligent destruction of the sperm of six men that was stored prior to their cancer treatment. In this case, the Court of Appeal for England and Wales held that, for the purposes of the negligence claim, the men "owned" their sperm as the sperm was deposited solely for their own benefit. "Ownership" of human tissue or human biological materials,

[255] Harmon A *op cit* (2010).
[256] *Ibid.*
[257] *Piljak Estate v. Abraham,* 2014 Ontario Superior Court of Justice 2893 (CanLII).
[258] *Yearworth v North Bristol NHS Trust* [2009] 3 WLR 118.

hence, although possible in certain circumstances, is not clear cut. What these cases may point to is that although the position that all human biological material is not property remains the *status quo*, some courts seem willing to deal with novel cases on an *ad hoc* basis, which over time, may extend the circumstances under which human biological material could be viewed as legal property.

While individuals have the right to donate bodily tissues for research purposes, and while a tangible interest in one's tissues exists, the right to own and control use of donated tissues vanishes once those tissues leave the body. The loss of ownership rights means loss of any claim to commercial benefit gained from cell lines or other commercial products derived from research on the donor's tissues.[259] However, this does not mean that the institution/biobank which receives those tissues, becomes the automatic owner either. According to the American Medical Association's Code of Medical Ethics,[260] potential commercial applications must be disclosed to a donor before a profit is realised on products developed from commercial materials.[261] Only with this knowledge can a donor truly make an autonomous decision to donate or not to donate his/her materials. Guidance on the exact apportionment of profits (if any) has not been explored in South African law. Therefore, the practitioner or researcher who intends to utilise an individual's materials, will have to obtain prior informed consent of the individual to do so and inform the individual of their intention to do so. I recommend that this should include a very clear exposition of the intended uses of the individual's tissue, as far as possible, as well as any foreseeable profit that may result from the use of the tissue.

In the United Kingdom, separated body parts can under certain circumstances, if skill and labour have been applied thereto, be owned by an individual. This view was confirmed in 1998 in *R v Kelly*.[262] In this case, a technician who worked at the Royal College of Surgeons removed body parts and gave these to an artist who used the

[259] Schleiter KE. 2009. "Donors Retain No Rights to Donated Tissue" *American Medical Association Journal of Ethics* 11(8): 621-625.
[260] *Ibid.*
[261] Commercial Use of Human Biological Materials, American Medical Association, Code of Medical Ethics Opinion 7.3.9. Accessed November 10, 2017. https://www.ama-assn.org/delivering-care/commercial-use-human-biological-materials.
[262] *R v Kelly* [1999] 2 WLR 384.

body parts as moulds to create sculptures. Both the technician and the artist were subsequently charged with theft. They argued that parts of corpses are not property and could therefore not be stolen under the British Theft Act.[263] The Court of Appeal held that parts of a corpse are capable of being stolen, if they have acquired different attributes by virtue of the application of skill. As the body parts in question had been preserved and used as specimens, they became fit for proprietary rights.

It is clear that confusion exists both nationally and internationally regarding ownership of human materials and resultant intellectual property claims that may arise as a result of such ownership vesting in a participant or institution/biobank. International guideline documents are also not clear in this regard. Recently, the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks[264] introduced the following clause regarding ownership and intellectual property:

> Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered and contractually defined before collecting and sharing the material. Intellectual property issues should be addressed in a policy, which covers the rights of all stakeholders and communicated in a transparent manner.[265]

Although the Declaration does not provide specific detail regarding who, in effect, owns the materials, it does make it clear that protections for ownership must be agreed to contractually before the materials are collected and shared. This is the first international guideline document that specifically outlines that protections for ownership must be contained within a legally binding agreement and that intellectual property issues are addressed in the form of a policy.

It is unreasonable to suggest that commercial benefits of a patent created through an inventive step should be attributed towards a research participant/s by virtue of using their sample. However, it is as equally unreasonable to leave the research participant out of the process, as it is his/her materials that have contributed towards the patent.

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[263] 1968.

[264] WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

[265] Clause 18.

Therefore, potential commercial benefits must be disclosed to a participant before a profit is realised on products in order for a participant to make an informed decision whether to participate in the research or not, knowing that they may or may not receive any commercial benefits (if any arise) as a result of the R&D process. It is suggested that instead of becoming consumed with the confusion, in the interim, one should attempt to regulate these issues through third party agreements, as an answer to these questions will not be found in our current ethico-legal framework. I further submit that the model of custodianship should replace the ownership model, as public interests are better served under the latter concept. In addition, the mindset of "owning" materials and having an "exclusivity of rights" approach will shift towards protectionisms, which in turn, will provide for the justice that research participants deserve. With this in mind, I will now discuss the concept of benefit sharing as an added mechanism of serving justice, both to researchers and research participants.

3.6 Benefit Sharing

Benefit sharing is the process or act of sharing in the benefits that derive from research in a manner that is fair and equitable.[266] One may question the necessity for benefit sharing when a recipient biobank sponsors/funds research activities within a country. This area of discussion is relatively unexplored and unclear. When one considers benefits being generated from genetic research, it is very uncertain with whom and by which mechanisms these benefits should be shared. Several models have been proposed but even the guiding principles remain vague. The concept of benefit sharing must be balanced with the idea of public interests and population health that are central to the purpose of biobanks.[267] The philosophical principle behind the concept of benefit sharing is simple and is a matter of justice.[268] Those who contribute to scientific research ought to share in its benefits.[269] This is particularly relevant considering the exploitation of South Africa and the developing world in general,

[266] The Human Research Ethics Committee Medical: Material Transfer Agreement for Human Biological Materials, developed by Mahomed S through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand with support from the Wits Biobanks Ethics Committee and Wits Legal Office. Accessed October 21, 2017. https://www.wits.ac.za/ethics/biobanks-ethics-committee/.

[267] Cambon-Thomsen A, Rial-Sebbag E & Knoppers BM. 2007. "Trends in ethical and legal frameworks for the use of human biobanks." *European Respiratory Journal* 30(2): 373-82. doi:10.1183/09031936.00165006.

[268] Schroeder D & Lucas JC (eds) *Benefit Sharing: From Biodiversity to Human Genetics.* Netherlands: Springer. (2013) at 9.

[269] *Ibid.*

regarding what is termed 'biopiracy' in research. Certain definitions of biopiracy include criteria such as the acquiring of exclusive monopoly control through use of intellectual property and in particular patenting, and the lack of prior informed consent.[270] This power imbalance still exists in certain arenas and needs to be corrected in an attempt to restore equilibrium where research participants and the providing institution receive some form of benefit for the utilisation of their genetic resources. In the information sheet the research participant should be informed that they may or may not receive benefits directly or indirectly as a result of the research process. This should be left open as the type of research that occurs in biobanks is laboratory based and it may take many years for an 'end product' benefit to be realised. The term "benefit" should not only denote a monetary compensatory value. It should also include capacity building in the participant community. In this way, vulnerable individuals may benefit directly or indirectly from the use of their materials. The actual benefit itself should not be viewed as an exchange i.e.: human materials for money. Therefore, the benefit sharing arrangement must be carefully crafted and due consideration given to all options that may form possible benefits. Information on data usage and the rights of publication of research findings must also be included in the protocol, as well as how the distribution of direct benefits of the research among affected participants will be apportioned.[271] Therefore, negotiated benefits should include, amongst others, the sharing of information, royalties, acknowledgement of the providing institution as the source of the material, publication rights, transferring of technology or materials, and capacity building (e.g.: training and development of South African researchers or assisting with the building of a clinic in the community which forms the participant base).[272]

There is argument that participation in scientific research should always be altruistic in nature. This is how access to human genetic resources has been governed

[270] Hamilton C. 2006. "Biodiversity, Biopiracy and Benefits: What Allegations of Biopiracy tell us about Intellectual Property." *Developing World* Bioethics 6(3):158-173; and Chennells RS. *Equitable Access to Human Biological Resources in Developing Countries: Benefit Sharing without Undue Inducement.* School of Health: University of Central Lancashire, PhD theses, April 2014.

[271] Dhai A. Steve Biko Centre for Bioethics *Practical Ethics and Regulatory Guide for Researchers and Research Ethics Committee Members* (2015) at 51.

[272] The Human Research Ethics Committee Medical: Material Transfer Agreement for Human Biological Materials, developed by Mahomed S through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand with support from the Wits Biobanks Ethics Committee and Wits Legal Office Accessed October 21, 2017. https://www.wits.ac.za/ethics/biobanks-ethics-committee/.

historically in prosperous nations.[273] However, exporting this notion into developing countries could lead to the emergence of serious concerns around exploitation. A discussion of two relevant cases below, that involve benefit sharing mechanisms, describe how positive outcomes could be arrived at while engaging in benefit sharing within developing world communities.

3.6.1 The Majengo case study

The Majengo sex workers case involved follow-up studies on 850 female sex workers in Kenya. It was thought that they could contribute to the development of a vaccine against HIV. This was part of an ongoing collaborative project by researchers from the universities of Nairobi and Manitoba.[274] The women were extremely socio-economically disadvantaged and unable to access quality healthcare in any other way than through their involvement in the clinic which was set up by the research team.[275] The women provided individual informed consent to participate in the ongoing study which utilised their blood, cervical, vaginal and saliva samples.[276] The Kenyan regulatory environment includes access to non-human genetic resources and subsequent benefit sharing thereof.[277] However, no regulation or policy existed in respect of human genetic resources. In 2005, national guidelines for research and development of HIV/ AIDS vaccines[278] were developed in specific response to the Majengo case. These guidelines provide a framework for addressing issues of financial compensation for research participants through MTAs and Research and Development Agreements. The guideline's MTA template provides for the "fair and equitable sharing of benefits" derived from the use of biological materials.[279] An

[273] Lucas JC, Schroeder D, Arnason G, Andanda P, Kimani J, Fournier V & Krishnamurthy M. *Donating human samples: Who benefits? Cases from Iceland, Kenya and Indonesia.* In *Benefit Sharing: From Biodiversity to Human Genetics* Netherlands: Springer. (2013) at 95-128.

[274] *Ibid*. See also: Lucas JC, Schroeder D, Chennells R, Chaturvedi S & Feinholz D. *Sharing Traditional Knowledge: Who benefits? Cases from India, Nigeria, Mexico and South Africa.* In *Benefit Sharing: From Biodiversity to Human Genetics.* Netherlands: Springer. (2013) at 65-93.

[275] Andanda P & Cook Lucas J. 2007. "Majengo HIV/AIDS Research Case. A Report for GenBenefit." Accessed November 10, 2017.

[276] *Ibid.*

[277] *Ibid.*

[278] Republic of Kenya, Ministry of Health, Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines. 2005. Accessed November 10, https://www.globalgiving.org/pfil/1108/projdoc.pdf.

[279] Kenya National Guidelines *op cit* (2005) at Appendix 5: Biological Material Transfer Agreement.

argument has been made that benefit sharing agreements could effectively be incorporated into the cooperative research and development agreements. These agreements will then be binding and enforceable in domestic law.[280] The Kenyan guidelines further require science and ethics committees in the country to verify the ethical integrity of HIV/AIDS vaccine trial protocols in accordance with internationally accepted ethical guidelines, for example, the ethical considerations in HIV preventative vaccine research of the joint United Nations programme on HIV/AIDS (UNAIDS).[281] Guidance Point 10 of the aforementioned document states that: "The research protocol should outline the benefits that persons participating in HIV preventative vaccine trials should experience as a result of their participation. Care should be taken so that these are not presented in a way that unduly influences freedom of choice in participation."[282] While this guidance document is not legally enforceable, it does list what should be considered as minimum benefits for participants in HIV preventative vaccine trials.

The main benefit received by the Majengo participants in the study was healthcare. Prior to the research team establishing a clinic in the slums of Majengo, the participants had no option but to utilise a treatment centre in Nairobi, where services were poor and where healthcare providers discriminated against sex workers.[283] The sex workers now have non-discriminatory access to healthcare within walking distance. Apart from the direct benefits in terms of healthcare, the clinic also offers a "safe haven" which enables the women to form new relationships, social networks and develop a sense of solidarity, creating a community environment. Additionally, research publications have brought the participants international exposure which could assist in safeguarding the women's rights to any benefits that may accrue from ongoing research activities. This case outlines a situation where, as a direct result of the research process, participants benefited both physically and socially by gaining

[280] Andanda P & Cook Lucas J *op cit* (2007); and Lucas JC, Schroeder D, Arnason G, Andanda P, Kimani J, Fournier V & Krishnamurthy M. *Donating human samples: Who benefits? Cases from Iceland, Kenya and Indonesia.* In *Benefit Sharing: From Biodiversity to Human Genetics* Netherlands: Springer. (2013) at 95-128.

[281] Kenya National Guidelines *op cit* (2005).

[282] United Nations 2000, UN AIDS Guidance document: Ethical considerations in HIV preventive vaccine research." Accessed November 10, 2017. http://data.unaids.org/publications/irc-pub01/jc072-ethicalcons_en.pdf.

[283] Bandewar SVS, Kimani J, Lavery JV. 2010. "The origins of a research community in the Majengo observational cohort study, Nairobi, Kenya." *BMC Public Health* 10:630.

access to much needed healthcare. The research also displayed that, with the right motivation, a disadvantaged and poor population could manage the demands of antiretroviral treatment and achieve the same adherence levels as the general population. This unforeseen outcome is of great significance and benefit to all those affected by HIV/AIDS, independent from the search for a successful preventative vaccine.

3.6.2 The San Hoodia case

The next scenario does not involve human genetic material; however, it is an example of how one of the first benefit sharing agreements was negotiated in South Africa in the absence of an enabling domestic legal environment. The San people (among the oldest communities in southern Africa) historically acquired traditional knowledge on the use of *Hoodia gordonii*, a moist plant found in the Kalahari desert, which the San have customarily consumed to limit hunger on their lengthy, tiring journeys.[284] The San people were at first unaware that the South African Council for Scientific and Industrial Research (CSIR), an arm of the SA government, were patenting an appetite suppressant which was produced from the Hoodia plant. (No credible clinical trials have, to date, documented its safety or efficacy). The CSIR also had plans to commercialise a Hoodia pharmaceutical product without the San people providing their consent, and there was no discussion surrounding the sharing of benefits derived from the subsequent commercialisation.[285] The CSIR and Phytopharm, a pharmaceutical company with a plant extract division, negotiated an exclusive license that transferred rights for research and commercial use of the patent for the development of Hoodia products. Phytopharm then granted licenses to Pfizer and the food multinational, Unilever.[286] With the involvement of NGOs, in 2003 the San people and the CSIR negotiated one of the first benefit sharing agreements. This provided the San with a share of the royalties derived from the sale of the products containing Hoodia.[287] The benefit sharing agreement received criticism, however, although far

[284] Tellez V. (undated). "Recognising the traditional knowledge of the San people: The Hoodia case of benefit-sharing." Accessed November 10, 2017. http://www.ipngos.org/NGO%20Briefings/Hoodia%20case%20of%20benefit%20sharing.pdf.
[285] *Ibid.*
[286] *Ibid.*
[287] *Ibid*

from perfect, it is an example for potential future benefit sharing mechanisms which allow for communities to receive recognition for their traditional knowledge and share in the commercialisation of products based on their knowledge.[288]

There are still many challenges for the San in their struggle for the proper recognition of their associated knowledge. There are instances where they do not receive any revenue from the sale of Hoodia-based products traded in the international market as such products are commercialised outside the CSIR agreement.[289]

Conventional research may not necessarily involve the utilisation of research participants' or their communities' traditional knowledge, however, it does involve utilising their materials to further the objectives of the particular research project. In 2005, the Patents Amendment Act[290] (PAA) was enforced wherein certain definitions were inserted to the PA and requirements placed on an applicant for a patent to furnish information relating to any role played by an indigenous biological resource,[291] a genetic resource,[292] traditional knowledge[293] or use in an invention. In addition, section 30 of the PA was amended by the insertions of sections 30(3A) and 3B which provide that:

> Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. [Sub section (3A) inserted by section 2 of the PAA.]
>
> The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous

[288] *Ibid.*
[289] *Ibid.*
[290] 20 of 2005.
[291] According to section 1 of the BA, from which the PA derives this definition, an Indigenous Biological Resource means: "any resource consisting of any living or dead animal, plant or other organism of an indigenous species; any derivative of such animal, plant or other organism; or any genetic material of such animal, plant or other organism."
[292] According to section 1 (a) of the PAA, a Genetic Resource means: "any indigenous genetic material; or the genetic potential or characteristics of any indigenous species."
[293] According to section 1(b) of the PAA, Traditional Knowledge means: "the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource." Further, Traditional Use means: "the way in which or the purpose for which an indigenous community has used an indigenous biological resource or a genetic resource."

> biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. [Sub section (3B) inserted by section 2 of the PAA]

The intention of inserting the above section was to create protections for indigenous biological resources, genetic resources and traditional knowledge. However, the way in which the preceding terms are defined, suggests that indigenous and genetic resources do not include human biological materials. Yet, the obligation of an applicant to furnish proof of his/her authority to make use of traditional knowledge may encourage applicants to enter into third party agreements/benefit sharing mechanisms for such use thereof.

I will next discuss the ethico-legal framework in South Africa with regard to benefit sharing in order to assess the adequacy of this provision in our law.

3.7 National perspective on Benefit Sharing

3.7.1 The Biodiversity Act 10 of 2004 (BA)

The Biodiversity Act[294] (BA) specifically excludes human material from its application, but it does provide for: (amongst others) the sustainable use of indigenous biological resources; and the fair and equitable sharing of benefits arising from bioprospecting or involving indigenous biological resources. Currently, the BA is the only piece of legislation that sets out what a "benefit" may constitute for bioprospecting or any other kind of research involving indigenous biological resources. The Act defines a benefit to include both monetary and non-monetary returns.[295] Therefore, capacity building or training would form a benefit under the Act. The Act also obligates applicants to apply for a permit before any export of the resource is undertaken for research purposes.[296] The protection of the interests of any organ of state or community providing or giving access to the indigenous biological resources and the indigenous community involved is measured before any permit referred to above is issued.[297] With regard to the protection of an indigenous community, the issuing authority will consider the

[294] 10 of 2004.
[295] Section 1.
[296] Section 81(1)(b).
[297] *Ibid.*

traditional uses of the indigenous biological resources or the knowledge of or discoveries about the indigenous biological resources before authorising such permit for use of the resources.[298]

Section 82(2)(b) of the BA makes it mandatory for the applicant and stakeholder to enter into an MTA which regulates the provision of or access to the resources and a benefit sharing agreement that provides for sharing by the stakeholder[299] in any future benefits that may be derived from the relevant bioprospecting.[300] A permit will not be granted if the preceding two agreements are not entered into by the parties. The benefit sharing agreement must specify: the type of indigenous biological resources to which the relevant bioprospecting relates; the area or source from which the indigenous biological resources are to be collected or obtained; the quantity of resources to be collected or obtained; any traditional uses of the resources by an indigenous community; and the present potential uses of the resources.[301] The benefit sharing agreement must also name the parties to the agreement; set out the manner in which and the extent to which the resources are to be utilised; set out the manner in which and the extent to which the stakeholder will share in any benefits that may arise; provide for regular review of the agreement; and comply with any other matters that may be prescribed.[302] The agreement or any amendment thereto will have to be submitted to the Minister for approval and will not take effect unless approved by the Minister.[303] Any monies arising from the benefit sharing agreement and MTA are kept in a bioprospecting trust fund and are considered to be trust money managed by the Director General who will be accountable for the funds.[304]

As stated above, the BA is the only piece of South African legislation that regulates benefit sharing agreements in terms of providing a definition and outlining what the agreement should contain. Although human material is excluded from the Act, we

[298] Section 82(1)(b)(ii).

[299] According to section 82 of the BA, a Stakeholder means: "(a) a person, including any organ of state or community, providing or giving access to the indigenous biological resources to which the application relates; and (b) an indigenous community or a specific individual (i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or (ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting."

[300] Section 82(2)(b)(i)&(ii).

[301] Section 83(1)(b).

[302] Section 83(1)(c)–(g).

[303] Section 83(2).

[304] Section 85.

should consider the Act as a starting point to develop a benefit sharing agreement of a similar nature, which could be incorporated into an MTA, relevant to research involving human material.

3.7.2 Department of Health, National Ethics Guidelines: Ethics in Health Research - Principles, Structures and Processes

This ethical guideline provides guidance in respect of all forms of research involving animals, human participants, human biological materials and data collected from living or deceased persons, including human embryos, fetuses, fetal tissue, reproductive materials and stem cells.[305] South African research ethics committees are encouraged to adopt these principles in assessing all health research projects.[306] In respect of benefits, the Guideline provides that a risk-benefit analysis should precede carrying out the research and that the likelihood of benefits should outweigh the anticipated risk of harm to participants. The Guideline further indicates that there should be a fair balance of risks and benefits among all role-players involved in research, including participants, participating communities and the broader society, in order to express the principle of equality in the research context. In addition, there should be a reasonable likelihood that the population from which participants are drawn, will benefit from the research results, if not immediately, then in the future.[307] In addition, the HPCSA General Ethical Guidelines[308] make it clear that with regard to data and specimen storage and transfer:

> There must be *justifiable reasons and benefits for the country* which should be provided to Research Ethics Committees for data and specimens to leave the country. This should only be done after a Material Transfer Agreement has been signed and submitted to the local Research Ethics Committee.[309] (*my emphasis*)

[305] National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Guidelines) *Second Edition.*
[306] *Ibid.*
[307] *Ibid.*
[308] HPCSA "Guidelines for Good Practice in Health Care Professions: General Ethical Guideline for Health Researchers." September 2016 Booklet 13.
[309] HPCSA "Guidelines for Good Practice in Health Care Professions: General Ethical Guideline for Health Researchers." September 2016 Booklet 13 at 11-12.

It may be argued that ethical guidelines have no legal status. However, it is important to note that in terms of current legal literature, domestic ethical guidelines are considered to be "soft law" which can be used as guidelines in instances where local legislation is silent. International guidelines are considered to be customary international law.[310] In order to qualify as customary international law, an ethics guideline must be supported by the consistency and generality of being widely accepted as practice.[311] Nevertheless, there is still a large gap between legislative documents with legal status and ethical guidelines.[312] Furthermore, it is difficult to compel objectors to the ethical guidelines to comply, which raises concerns surrounding the alleged binding nature of customary international law.[313] However, failure to comply with the ethical guidelines in respect of health research, could lead to possible negligence or unprofessional conduct on the part of the health researcher, which could in turn have serious legal consequences.

Benefit sharing could be one way in which sustainable, long term research with human subjects is achieved. Without a legal requirement for the incorporation of benefit sharing agreements into the research process in South Africa, and with the current ethical guidelines lacking steadfastness in this regard, it is left up to ethics committees to regulate these arrangements on a case-by-case basis. In the absence of clear domestic legislation regarding benefit sharing in the context of human research, a brief description of certain international perspectives relevant to research on human material will follow.

3.8 International Perspectives on Benefit Sharing

3.8.1 The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) to the Convention on

[310] Lucas JC, Schroeder D, Chennells R, Chaturvedi S & Feinholz D. *Sharing Traditional Knowledge: Who benefits? Cases from India, Nigeria, Mexico and South Africa.* In *Benefit Sharing: From Biodiversity to Human Genetics.* Netherlands: Springer. (2013) at 333- 364.
[311] *Ibid.*
[312] *Ibid.*
[313] *Ibid.*

Biological Diversity (CBD) is a supplementary agreement to the CBD.[314] It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. The Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and South Africa is a signatory thereto. It is significant that "access to affordable treatments by those in need especially in developing countries" is included in Article 8 of the Protocol, amongst the special considerations that must be observed when regulating access to genetic resources. Although the Protocol excludes human genetic resources, its principles may be used when developing a framework of benefit sharing for human materials.

The Protocol creates incentives to safeguard and sustainably use genetic resources, therefore enhancing the contribution of biodiversity to development and human well-being. Among the parties who are required to provide their informed consent and agree to mutual terms are indigenous and local communities that hold genetic resources and/or associated traditional knowledge.[315] With regard to benefit sharing, each party is obligated to take administrative, legislative or policy measures to ensure that benefits are shared fairly and equitably with the party who provides the resources.[316] Capacity building is also emphasised in the Protocol. Parties must participate in capacity development, capacity building, and strengthening of human resources and institutional capacities.[317]

Under the Protocol, communities who hold genetic resources and related traditional knowledge are afforded extensive consideration and protection:

- Prior informed consent must be provided by these communities for utilisation and access to their resources.

[314] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. Convention on Biological Diversity, 2011. (The Nagoya Protocol) Accessed November 13, 2017. https://www.cbd.int/abs/text/default.shtml.
[315] *Ibid.*
[316] Kamau EC, Fedder B & Winter G. 2010. "The Nagoya Protocol on access to genetic resources and benefit sharing: What is new and what are the implications for provider and user countries and the scientific community?" *Law Environment and Development Journal* 6(3):246-262.
[317] *Ibid.*

- Benefits must be shared in a fair and equal manner with the communities whose genetic resources or traditional knowledge were utilised.
- Parties shall establish mechanisms to notify users of traditional knowledge about their obligations.
- Parties shall organise community meetings, establish a help desk for communities, and involve communities in the implementation of the Protocol, to increase awareness of genetic resources and traditional knowledge held by communities.
- The Protocol further calls for capacities of communities to be improved, which will enable their effective participation in implementing the objectives of the Protocol.[318]

The Protocol therefore, attempts to ensure benefit-sharing and protects vulnerable populations and groups to limit unprincipled abuse of genetic information.[319]

3.8.2 World Medical Association Declaration of Helsinki

Section 17 of the Declaration states:

> All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.[320]

In addition, when risks are found to outweigh the potential benefits, an assessment must be made with regard to continuing, modifying or stopping the study.[321] Section 19 of the Declaration explains that certain groups or individuals may be considered to be vulnerable and should receive considered protection. Section 20 further states that medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of the group. Additionally, the group should stand to

[318] The Nagoya Protocol.
[319] Kamau EC, Fedder B & Winter G *op cit* (2010) at 246-262.
[320] Section 17.
[321] Section 18.

benefit from the knowledge, practices or interventions that result from the research.[322] Significantly, section 34 of the Declaration further states:

> In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.[323]

Therefore, the Declaration does endorse the concept of benefit sharing and places a burden on the researcher to ensure that risks do not outweigh potential benefits.

3.8.3 The United Nations Educational, Scientific and Cultural Organisation's (UNESCO's) Universal Declaration on the Human Genome and Human Rights (1997)[324] and Universal Declaration on Bioethics and Human Rights (2005)[325]

The Declaration on the Human Genome and Human Rights, to which South Africa is a member state, was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997. The following year, the United Nations General Assembly endorsed the Declaration.

Article 12(a) of the Declaration appears to embrace the concept of sharing benefits on the basis of common property and distributive justice. It states that: "Benefits from advances in biology, genetics and medicine concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual." This implies that benefits concerning the human genome could be considered common property and should therefore be made available to all.[326] Article 19 indicates that when international co-operation occurs, developing

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[322] *Ibid.*

[323] Section 34.

[324] UNESCOs Universal Declaration on the Human Genome and Human Rights. Accessed November 13, 2017. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/.

[325] *Ibid.*

[326] Schroeder D & Lucas JC (eds) *Benefit Sharing: From Biodiversity to Human Genetics.* Netherlands: Springer. (2013) at 56.

countries should benefit from the achievements of scientific and technological research in order for their use in favour of economic and social progress to be for the benefit of all.

The Universal Declaration on Bioethics and Human Rights advocates the sharing of benefits within the international community and emphasises the need to share benefits with developing world countries as well.[327] Therefore the importance of benefit sharing with developing world countries, whose populations largely contribute to the participant base of health research, is emphasised in both these declarations.

3.8.4 The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation[328] (CIOMS guidelines)

As indicated previously, the latest version of these guidelines was published in 2016 and it has broadened the scope of health research to include biobanking. With regard to benefits, the Guidelines are very detailed. Guideline 2 of the CIOMS guidelines outlines provisions for research conducted in low-resource settings.[329] These guidelines are specific that the obligation of sponsors and researchers extends to making every effort to make available any intervention or product developed and knowledge generated[330] for the participant population or community and to assist with building local research capacity. Additional benefits such as investments in the local

[327] UNESCOs Universal Declaration on Bioethics and Human Rights. Article 15. Accessed November 13, 2017. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/.

[328] CIOMS Guidelines. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/.

[329] Guideline 2: Research conducted in low-resource settings at 3-5.

[330] The CIOMS Guidelines indicate that: "When the outcome is scientific knowledge rather than a commercial product, complex planning or negotiation among relevant stakeholders may not be needed. There must be assurance, however, that the scientific knowledge gained will be distributed and available for the benefit of the population. To that end, agreement must be reached with the local community about the form such dissemination should take. One example might be a study that learns why a health condition such as neural tube defects is prevalent in a particular population. Another example could be a study that results in knowledge to educate the population about foods to eat or avoid in order to promote or maintain health." at 4-5.

health infrastructure, training laboratory personnel and educating the public about the nature of research and the benefits resulting from a particular study,[331] should also be provided to the participant population or community, in order to ensure an overall fair distribution of the benefits and burdens of the research.[332] Part of this obligation also includes consultation and engagement with communities in making plans for any intervention or product developed.[333] Therefore, this Guideline promotes the creation of local social value to ensure that people in low-resource settings receive equitable benefits from their participation in health-related research.[334]

Research must also be responsive to the health needs or priorities of a particular community. Should the knowledge to be gained from the research only benefit populations other than those involved in the research, the "responsiveness requirement" will be violated, which, in turn, will raise serious concerns about justice, which requires a fair distribution of the benefits and burdens of research.[335] Consultation with the community includes how any successful products and possible financial gain will be distributed e.g.: through a benefit-sharing agreement.[336]

Guideline 3 lists provisions in respect of the equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research.[337] Guideline 3 states that :

> Sponsors, researchers, governmental authorities, research ethics committees and other stakeholders must ensure that the benefits and burdens of research are equitably distributed. Groups, communities and individuals invited to participate in research must be selected for scientific reasons and not because they are easy to recruit because of their compromised social or economic position or their ease of manipulation. Because categorical exclusion from research can result in or exacerbate health disparities, the exclusion of groups in need of special protection must be justified. Groups that are unlikely to benefit from any knowledge gained

[331] CIOMS Guideline, page 5. According to the Guideline, additional benefits may also include: "contributions that research or research partnerships make to the overall scientific environment of such countries and communities." at 5.
[332] Guideline 2 at 3.
[333] *Ibid.*
[334] CIOMS Guidelines at 3.
[335] CIOMS Guidelines at 4.
[336] CIOMS Guidelines at 5.
[337] Guideline 3: Equitable distribution of the benefits and burdens in the selection of individuals and groups of participants in research at 7-8.

> from the research should not bear a disproportionate share of the risks and burdens of research participation. Groups that are under-represented in medical research should be provided appropriate access to participate.[338]

Equity in the distribution of the benefits of research requires that research does not disproportionately focus on the health needs of a limited class of people, but instead aims to address diverse health needs across different classes or groups.[339] Consideration must be given with regard to the over-use of participants, communities and societies as this creates a situation where these particular participants, communities and societies are overburdened and will be unlikely to enjoy the benefits of new knowledge and products developed as a result of the research.[340]

Guideline 8[341] reiterates that researchers and sponsors who plan to conduct research in these communities should contribute to capacity-building for research and review. Such capacity building includes, but is not limited to the following activities:

- research infrastructure building and strengthening research capacity;
- strengthening research ethics review and oversight capacity in host communities;
- developing technologies appropriate to health care and health-related research;
- educating research and health-care personnel and making arrangements to avoid undue displacement of health care personnel;
- engaging with the community from which research participants will be drawn;
- arranging for joint publication consistent with recognized authorship requirements and data sharing;
- preparing a benefit-sharing agreement to distribute eventual economic gains from the research.[342]

[338] Guideline 3 at 7.
[339] Guideline 3 at 8.
[340] *Ibid.* The Guideline further states that:
"A disproportionate selection of disadvantaged or convenient populations is morally problematic for several reasons. First, it is unjust to selectively invite poor or marginalized individuals or groups to participate in research because this concentrates the risks and burdens of research on people who already experience increased risks and burdens from social and economic disadvantage. Second, these individuals and groups are also the most likely to be excluded from, or to have difficulty accessing, the benefits of research. Third, the broad inclusion of different social groups helps to ensure that research is conducted in a socially and ethically acceptable manner. When research is concentrated in disadvantaged or marginalized groups, it may be easier to expose participants to unreasonable risks or undignified treatment. Furthermore, research results obtained from disadvantaged populations may not be appropriately extrapolated to the general population." at 8.
[341] Guideline 8: Collaborative partnerships and capacity building for research and research review. at 29-31.
[342] Guideline 8 at 29.

Guideline 11,[343] which provides for the collection, storage and use of biological materials and related data, indicates that institutions in which biological material and related data are archived after collection for research purposes or as "left-overs" from clinical diagnosis or treatment must have a governance structure in place in which any benefits from the research that are expected to accrue is regulated.[344] Likewise, Guideline 12 which deals with the collection, storage and use of data in health-related research contains a similar provision in respect of an institution's governance structure with respect to the regulation of the accrual of any benefits from the research.[345]

There is argument which suggests that in principle, participants in developing world countries should continue to receive benefits originating from the studies which they had enlisted in, beyond the research period.[346] Zong[347] indicates that this is based on the ethical principles of beneficence and justice as reciprocity. She asks however, how far the obligations of beneficence and reciprocity extend to participants in developing countries, which remains contentious as no agreement exists whether post-study provision should be mandatory in practice. Guideline 2 of the CIOMS guidelines supports the notion of post-study benefits by indicating that:

> Even if research addresses a question that has social value for the community or population where it is carried out, the community or population will not benefit from successful research unless the knowledge and interventions that it produces are made available to them and products are reasonably priced.[348]

In addition, the Guidelines mention the implementation of certain benefits such as improving health infra-structure, training, education and the distribution of knowledge, all of which will add value and benefit a community long after the research project ceases.

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[343] Guideline 11: Collection, storage and use of biological materials and related data. at 41-45.
[344] Guideline 11 at 42-43.
[345] CIOMS Guidelines at 48.
[346] Zong Z. 2008. "Should post-trial provision of beneficial experimental interventions be mandatory in developing countries?" *J Med Ethics* 34(3): 188-192.
[347] *Ibid.*
[348] CIOMS Guidelines at 5.

3.8.5 The World Medical Association Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (Declaration of Taipei)[349]

The Declaration of Taipei is quite clear that research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives.[350] In addition, if data or biological materials are collected and stored in a Health Database or Biobank for multiple and indefinite uses, consent is only valid if the participants have been adequately informed about:

> When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.[351]

The Declaration further highlights that:

> The interests and rights of the communities concerned, in particular when vulnerable, must be protected, *especially in terms of benefit sharing*.[352] (*My emphasis*)

From the above, it is clear that benefit sharing is very much part of the health research process and cannot be overlooked. In addition, a benefit does not only constitute a monetary transaction. Any form of advantage or even assistance to the participant community and the providing institution could constitute a benefit. The international guidelines emphasise the importance of the concept of benefit sharing especially with regard to developing world countries. However, without a legal requirement for the incorporation of benefit sharing into the research process in South Africa, and with our local ethical guidelines lacking robustness in this regard, it is left up to ethics committees to regulate these arrangements on a case by case basis.

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[349] WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

[350] Section 8.

[351] Section 12.

[352] Section 17.

3.9 Conclusion

Ownership in human materials has not been adequately developed nationally and internationally. In terms of the South African ethico-legal framework, a distinction is drawn between ownership of human tissues and human tissue related inventions, which are usually at stake when it comes to benefit sharing from human biological resources. The settled legal position is that the object of a patent is to protect technical disclosure rather than the rights of the physical object itself.[353] Therefore, the property ownership argument has not been favoured as a basis for benefit sharing with research participants and there is currently no agreement on how to move forward.[354] It is suggested that the term "ownership" in a legal sense is in itself problematic. The holder of the human materials should be regarded as a custodian and not an owner *per se*. The research process is ultimately based on trust. The participants trust the researcher with their materials and provide their informed consent for the use of their materials. Biobank research involves so many complicated ethical and legal issues. Researchers and institutions seem removed from the actual communities, without whom, no scientific progress could be made. A properly regulated benefit sharing arrangement, which can be incorporated into an MTA, coupled with the model of custodianship, may reinforce the trust relationship, bring researchers, institutions and communities closer and allow for sustainable, long term future research. It is essential that developing world institutions and communities benefit from the research process in some way.

However, while benefit sharing and the custodianship model may promote the researcher-participant trust relationship, if fundamental privacy precautions cannot be achieved, the trust relationship will eventually erode. In the next chapter, I will outline the South African position with regard to privacy and confidentiality safeguards and point out the significance of these safeguards.

[353] Schroeder D & Lucas JC *op cit* (2013) at 54.

[354] Simm K. 2007. "Benefit sharing frameworks: justifications for and against benefit sharing in human genetic research." A Report for GenBenefit. Accessed November 13, 2017. https://www.uclan.ac.uk/research/explore/projects/assets/cpe_genbenefit_frameworks.pdf.

Chapter 4

Privacy and Confidentiality in South Africa

4.1 Introduction

Public health research is ultimately supported for the enhancement of knowledge and benefit of the public in general.[355] However, while one purpose of public health research is to enhance knowledge, this has to be balanced with adequate protections for participants' privacy rights. Health in general, generates very sensitive information which could be very harmful to individuals or a community, if exposed.[356] Therefore, every precaution must be taken to protect the privacy of research participants and the confidentiality of their personal information. The South African Law Commission has observed that:

> Privacy is a valuable and advanced aspect of personality. Sociologists and psychologists agree that a person has a fundamental need for privacy. Privacy is also at the core of our democratic values. An individual therefore has an interest in the protection of his or her privacy.[357]

Confidentiality, which is a characteristic of privacy, results as a consequence of the nature of the relationship between parties. Confidentiality is often described as an ethical issue, however, it is also a legal obligation.[358] These two concepts (i.e. privacy and confidentiality) will be discussed in more detail later on in this chapter. Currently, as no set of specific legislation exists with regard to the regulation of biobank research, differing pieces of legislation and policy documents have to be drawn upon in determining the legal framework pertaining to the protection of and access to private information of research participants in biobank research, as well as private information

[355] Ursin LO. 2010. "Privacy and Property in the Biobank Context" *PMC US National Library of Medicine* 22(3): 211–224.

[356] Baulig LT. 2010. "Are there property rights in Human Tissue? The law "Lacks" definitive answers." *The Journal of Lancaster General Hospital* 5(3): 87-90.

[357] South African Law Reform Commission, *Privacy and Data Protection Discussion Paper* 109 project 124. 2005.

[358] Medical Protection Society Casebook and Resources, Respect for patient confidentiality. Accessed December 07, 2017. http://www.medicalprotection.org/southafrica/advice-booklets/common-problems-managing-the-risks-in-hospital-practice-in-south-africa/respect-for-patient-confidentiality.

generated by that research. The nature of biobank research entails that private information of research participants are collected and stored for possible future uses. It is therefore necessary to explore the protection of privacy and confidentiality in this context.

4.2 Constitutional protections

Previously, the right to privacy was a right largely recognised at common law[359] and not the subject of significant codification. Presently, the right to privacy with regard to health is protected by the common law, the Constitution, 1996, and various pieces of legislation which are discussed below.

A seminal case which recognised the independent right to privacy in South African law is O*'Keeffe v Argus Printing and Publishing Co Ltd.*[360] In this case, a journalist's photograph and name was published in a newspaper, without her consent, in the context of an advertisement for guns and ammunition. Watermeyer AJ concluded that: "unauthorised publication of a person's photograph and name for advertising purposes was capable of constituting an aggression upon that person's dignity where this was understood to incorporate a wide range of personality interests, including her interest in privacy."[361] Therefore, the accepted common law principle is that when a person's privacy is infringed, this results in the violation of a person's personality interests in the form of that person's dignity.[362] After the judgement in *O'Keeffe*, the courts began to shape the principle of privacy which now provides a remedy for the public disclosures of private facts.[363] In addition, the protection and recognition of the right to privacy as

[359] In terms of the common law, the courts in South Africa have treated a violation of privacy as an infringement to dignity under the *actio iniuriarum.* According to Neethling J, Potgieter JM & Visser PJ. *The Law of Delict* (3rd ed). *Butterworths* (1999) at 15: "The Roman law concerning liability for injury to personality (*iniuria)* is of cardinal importance to our law since it was adopted almost without change in South Africa…In the course of time the protection of personality was extended considerably by praetorian reforms…the protection of personality was also made applicable to the following non – physical interests: *good name*, *dignity*, *feelings of chastity* and *privacy*."

[360] 1954 3 SA 244 (C).

[361] Scott H. 2007. "Liability for the mass publication of private information in South African Law: NM v Smith (Freedom of Expression Institute as Amicus Curiae) Stellenbosch Law Review 18(3): 387-404.

[362] Slabbert MN. 2008 "Genetic privacy in South Africa and Europe: a comparative perspective (2)" *THRHR* 71:1:81 at 5. See also: Burchell J. 2009. "The Legal Protection of Privacy in South Africa: A Transplantable Hybrid." *Electronic Journal of Comparative Law* 13(1).

[363] Burchell J *op cit* (2009). See also: Slabbert MN *op cit* (2008): "In subsequent cases such as *Universiteit van Pretoria v Tommie Meyer Films (Edms) Bpk*,[1977 4 SA 376 (T) 384] *National Media Ltd v Jooste*, [1996 3 SA 262 (A) 271] *Bernstein v Bester NO* [1996 2 SA 751 (CC) 789] and *Swanepoel v Minister van Veiligheid en*

a fundamental human right, provides an indication of its importance. The right to privacy as outlined in section 14 of the Bill of rights of the Constitution, 1996,[364] states that:

> Everyone has the right to privacy, which includes the right not to have-
> (a) their person or home searched;
> (b) their property searched;
> (c) their possessions seized; or
> (d) the privacy of their communications infringed.

In terms of section 14, the right to privacy includes the right not to have one's person searched. The physical examination of a person in the health care/ health research context can then be interpreted to be an invasion of privacy. Such examination may only occur if the person waives his/her right to privacy for the purpose of examination in the health care context. Further, information related to the health status of a person is inextricably bound to issues of privacy.[365] As mentioned above, the concept of confidentiality is an aspect of privacy and results as a consequence of the nature of relationships between people.[366]

Confidentiality is often described as an ethical obligation, however, it is very much a legal requirement in the medical sector.[367] The main difference between the rights to privacy and confidentiality is that while the right to privacy may be invoked to prevent anyone from accessing an individual's personal information, confidentiality rests on a trust relationship and therefore binds specific individuals only.[368]

Sekuriteit, [1999 4 SA 549 (T) 553] privacy has been referred to as an "individual condition of life characterised by seclusion from the public and publicity," which "embraces all those personal facts which the person concerned has himself determined to be excluded from the knowledge of outsiders and in respect of which he has the will that they be kept private." It follows from this that a person's privacy can only be infringed when others learn of true private facts about this person against his or her will and determination."

[364] Chapter 2 of the Constitution of the Republic of South Africa, 1996.

[365] Carstens PA & Pearmain D. *Foundational principles of South African medical law*. Durban: Lexis Nexis. (2007) at 32.

[366] For example: the doctor – patient; attorney – client relationship.

[367] See for example: Section 7 of the Choice of Termination of Pregnancy Act 92 of 1996; sections 12, 13,133 and 134 of the Children's Act 28 of 2005 and section 14 of the National Health Act 61 of 2003.

[368] Wlodarski A. Section 27 power point slides, Lecture on confidentiality, August 2010. Accessed September 07, 2017. http://section27.org.za/.../uploads/2010/07/Lecture-7-Confidentiality.pdf.

In *Seetal v Pravitha*[369] the court held:

> Yet a blood test on somebody without his consent is unquestionably an invasion of his privacy. And the invasion is no less such because on just about every occasion the test is otherwise innocuous.

Such information is personal and confidential and could affect a person's psychological integrity if disclosed without his/her permission. In addition, the wrongful disclosure of personal information may result in a breach of the affected person's privacy. In *NM V Smith,*[370] at least two inter-related reasons for the constitutional protection of privacy,[371] were identified, the first stemming from the constitutional idea of what it means to be a human being, implicit in which is the right to choose what personal information is released into the public arena.[372] The more intimate the information, the more important it becomes to safeguard privacy, dignity and autonomy in that an individual makes the primary decision whether to release the information.

The second reason for protecting privacy is the democratic need to reduce the power of the state and to prevent it from denying liberty and dignity by interfering with personal private space.[373] O'Regan J further highlighted the inter-relationship between privacy, liberty and dignity as the key constitutional rights which construct our understanding of what it means to be a human being. Therefore, all these rights are interdependent and mutually reinforcing.[374] In *National Coalition for Gay and Lesbian Equality and Another v Minister of Justice and Others*,[375] Ackermann J held:

> Privacy recognises that we all have a right to a sphere of private intimacy and autonomy which allows us to establish and nurture human relationships without interference from the outside community… One of the considerations is the nature of the relationship concerned: an invasion of the relationship between partners, or parent and child, or other intimate, meaningful and intensely personal relationships will be a strong indication of a violation close to the core of privacy. Another consideration is the extent to which the body of a person is invaded: physical searches or examinations are often invasive of privacy….As we observed before, the constitutional

[369] 1983 (3) SA 827 (D).
[370] *NM and Others v Smith and Others* (CCT69/05) [2007] ZACC 6; 2007 (5) SA 250 (CC); 2007 (7) BCLR 751 (CC) (4 April 2007).
[371] Hughes A. 2014. "Human Dignity and fundamental rights in South Africa and Ireland*" Pretoria University Law Press* at 265.
[372] *Ibid.*
[373] *Ibid.*
[374] *Ibid.*
[375] CCT11/98) [1998] ZACC 15; 1999 (1) SA 6; 1998 (12) BCLR 1517 (9 October 1998).

> commitment to human dignity invests a significant value in the inviolability and worth of the human body. The right to privacy, therefore, serves to protect and foster that dignity.

Consequently, as mentioned above, a violation of privacy will result in an infringement of a person's human dignity[376] as the publication of private information could lead to the impairment of the right to have a person's dignity protected. Section 10 of the Bill of Rights states that:

> Everyone has inherent dignity and the right to have their dignity respected and protected.

The right to dignity is regarded as one of the most fundamental rights contained within the Bill of Rights. In *S v Makwanyane*,[377] Mokgoro J likened life and dignity to two sides of the same coin, in that a violation of the right to life is a direct violation of the right to dignity. Further, in *S v Makwanyane,* O'Regan J stated that the recognition of a right to dignity is the acknowledgment of human beings' intrinsic worth. Human beings are entitled to be treated with respect and concern. She further stated that dignity is "a founding value of the new Constitution." It could be said that human dignity forms the basis of various other rights which have been entrenched specifically in the Bill of Rights. This is illustrated remarkably well by *Dawood v Minister of Home Affairs.*[378] This case focused on the rights of foreign spouses with regard to immigration permits and the issue of the constitutional protection of family life and marriage was raised. It was held by Van Heerden J that protection must be afforded to the institution of marriage and family life by the interpretation of the right to dignity.[379] Therefore, as the common law principle upholds that a violation of a person's privacy results in an infringement of that person's dignity, we cannot regard these two fundamental rights as completely separate from each other.

The Constitutional Court in *NM v Smith* upheld the individual's right to choose what personal information to reveal to others and to prohibit or place boundaries on further dissemination of the information.[380] Although specific privacy rights are mentioned in section 14 of the Bill of Rights, this list is not exhaustive. For example, in *Klein v*

[376] *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A). See also: Hughes A *op cit* (2014) at 265.
[377] *S v Makwanyane and Another* 1995 (3) SA 391 (CC).
[378] *Dawood v Minister of Home Affairs* 2000 (1) SA 997 (C).
[379] *Dawood v Minister of Home Affairs* 2000 (1) SA 997 (C) at 1038B-C.
[380] Hughes A *op cit* (2014) at 265.

Attorney-General,[381] the restoration of computer information that had been erased by its owner and the subsequent handing over of such information to the state for use in criminal proceedings, was held to be a violation of the owner's privacy right. However, the constitutional right to privacy, like its common law counterpart,[382] is not an absolute right and may be limited in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.[383] According to section 36(1) of the Constitution, 1996 which is commonly referred to as the "limitation clause," a right in the Bill of Rights may be limited by taking all relevant factors onto account, including:

a. the nature of the right;
b. the importance of the purpose of the limitation;
c. the nature and extent of the limitation;
d. the relation between the limitation and its purpose; and
e. less restrictive means to achieve the purpose.

Therefore, any alleged violation of the fundamental right to privacy will have to be assessed against the limitation clause in the Constitution. In the context of biobank research, where private information may become accessible to researchers, and then transferred between institutions and/ or countries, particular care must be taken to balance the right to privacy of the research participant with the public health benefit of research. This is where the notion of informed consent, as discussed in Chapter 2 becomes exceedingly important.

4.3 The National Health Act

Section 14 of the NHA[384] stipulates that all information of a person receiving treatment, including information relating to his/her health status, treatment or stay in a health establishment, is confidential. In addition, such information may not be disclosed without consent in writing; by means of a court order or should the law require such

[381] *Klein v Attorney-General,* Witwatersrand Local Division 1995 (2) SACR 210 (W).
[382] As a common law right, the right to privacy is limited by the legitimate interests of others and the public interest. As a fundamental right enshrined within the Bill of Rights, the right to privacy is subject to limitation by section 36 of the Constitution. See: South African Law Reform Commission, *Privacy and Data Protection Discussion Paper* 109 project 124. 2005.
[383] Section 36 of the Constitution of the Republic of South Africa, 1996.
[384] 61 of 2003.

disclosure; or if such non-disclosure would represent a serious threat to public health.[385] However, the NHA creates an exception to this rule by allowing for a health worker or health care provider to disclose personal information of the person receiving treatment, if it is necessary for any legitimate purpose within the ordinary course and scope of their duties, where such disclosure is in the best interests of the person receiving treatment.[386] In addition, the NHA contains provisions for the access to and protection of health records.[387] Yet, the NHA does not specifically outline the extent to which personal information should be safeguarded.

The right to privacy has further developed to a large extent over the last two decades with the advent of the Constitution, the NHA and the increasing awareness of research participant protections. A concept that was predominantly interpreted by the common law, is now becoming increasingly governed by statute. I will now discuss certain statutes that impact privacy rights with specific regard to biobank research.

4.4 The Protection of Personal Information Act 4 of 2013[388] (POPI)

POPI is a relatively new, ground-breaking piece of legislation that has significant and far reaching consequences for all entities that process personal information of individuals. It was promulgated into law on 26 November 2013 and impacts how personal information is dealt with. Health is obviously one of the most sensitive areas for many people when it comes to issues of privacy.[389] Lack of privacy of health information can harm a patient (and in the case of biobanks, a research participant) in many ways. A breach of a person's privacy could impact their career prospects, employment status have an adverse effect on their own mental state, lead to victimisation and stigmatisation and may even cause problems in their personal family relationships.

The purpose of the Act is to give effect to the constitutional right to privacy, by safeguarding the processing of personal information subject to justifiable limitations that are aimed at: balancing the right to privacy against other rights particularly the

[385] Section 14.
[386] Section 15(1).
[387] Sections 16 & 17.
[388] 4 of 2013.
[389] Carstens PA & Pearmain D *op cit* (2007) at 943.

right of access to information; and protecting important interests, including the free flow of information within the country and across international borders.[390] POPI also aims to regulate the manner in which personal information may be processed; provide persons with rights and remedies to protect their personal information from processing that is not in accordance with the Act; and establishing voluntary and compulsory measures, including the establishment of an Information Regulator, to ensure respect for and to promote, enforce and fulfil the rights protected by the Act.[391]

As of the date of this thesis, only certain sections of POPI were enacted,[392] however, it is anticipated that the remaining sections will become enforceable in the near future. It is therefore important to analyse the sections of POPI that will have a bearing on biobank research in the future. In terms of POPI, a responsible party means "a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for processing personal information."[393] For the purposes of POPI, a biobank falls within the definition of a responsible party. The definition of personal information as per section 1 of POPI outlines the range of information to which POPI would apply. According to section 1, personal information means:

> Information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including but not limited to-
>
> (a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person;
> (b) information relating to the education or the medical, financial, criminal or employment history of the person;
> (c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person;
> (d) the biometric information of the person;
> (e) the personal opinions, views or preferences of the person;

[390] Long title and Preamble of the Act.
[391] *Ibid.*
[392] According to Proclamation No 25 *Government Gazette* 37544 of 7 April 2014, the following sections have come into operation: Section 1; Part A of Chapter 5; section 112; and section 113.
[393] Section 1.

(f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;
(g) the views or opinions of another individual about the person; and
(h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.

The above list is not exhaustive and from this definition, it is clear that the application of POPI is wide-ranging. The nature of information collected from research participants for storage and subsequent use within a biobank, is certainly "personal information" as contemplated by the Act. Section 6 of POPI provides for certain exclusions to which the Act would not apply. In particular, section 6(1)(b) indicates that the Act would not apply to the processing of personal information that has been de-identified[394] to the extent that it cannot be re-identified again.[395] Should this be the case, then questions could arise as to whether POPI would in fact apply to biobank research or any research in which materials are de-identified. However, re-identified in accordance with the Act is defined as follows:

> Re-identify in relation to personal information of a data subject, means to resurrect any information that has been de-identified, that-
> (a) identifies the data subject;
> (b) can be used or manipulated by a reasonably foreseeable method to identify the data subject; or
> (c) can be linked by a reasonably foreseeable method to other information that identifies the data subject.[396]

When considering the definition of "re-identified" as provided for above, it may be argued that even though an initial sample may be de-identified as defined by the Act, the process of re-identifying the sample would be very possible, especially considering that the specific sample may contain DNA or other re-identifiable genetic material. In this instance, where data can be re-identified, the provisions of POPI would certainly apply to the personal information of the data subject. The main ethical concern with

[394] Section 1 of POPI, defines De-identified as: "…in relation to personal information of a data subject, means to delete any information that- (a) identifies the data subject; (b) can be used or manipulated by a reasonably foreseeable method to identify the data subject; or (c) can be linked by a reasonably foreseeable method to other information that identifies the data subject."
[395] Section 6(1)(b).
[396] Section 1.

regard to identifiability is confidentiality. It is essential that data subjects understand the notion of identifiability and the different levels of anonymisation in order to assess the individual consequences of participation.[397] Merely indicating that data is de-identified or anonymous is insufficient. In addition, biobank research implies risks for identifiable groups and communities because anonymity of the individual does not necessarily translate to anonymity of the group. Furthermore, confusion arises as the same terms in different guidelines have different meanings. The five levels of anonymisation utilised in Europe provide a clearer indication of levels of identifiability. The levels of anonymisation are: anonymous, unlinked anonymised, linked anonymised, coded and identified.[398]

Complete anonymity is found to be appropriate only for archaeological samples. As it is always possible to identify the data subject through DNA, where samples contain any trace of DNA, they are not truly anonymous.[399] The term "anonymised" signifies storage of biological material alongside associated information such as age, medical treatment, etc. However, all identifying material is removed either irreversibly (unlinked anonymised) or reversibly (linked anonymised). Identification of linked anonymised samples is usually achieved by use of a code[400] which researchers and other users of the samples do not have access to. Coded samples have the same characteristics as linked anonymised samples, the difference being that researchers and users have access to the code.[401] Finally, identified samples allow for information of identification. e.g., name, address, telephone number, etc. Pathology laboratories usually store samples in their identified form.[402] Therefore, from a practical point of view, complete anonymisation of biological materials that contain DNA is not possible.

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[397] Cambon-Thomsen A, Rial-Sebbag E & Knoppers BM. 2007. "Trends in ethical and legal frameworks for the use of human biobanks." *European Respiratory Journal* 30(2): 373-82.

[398] Elger BS, Caplan AL. 2006. "Consent and anonymization in research involving biobanks: Differing terms and norms present serious barriers to an international framework." *EMBO reports* 7(7): 661-666.

[399] *Ibid.*

[400] *Ibid.*

[401] *Ibid.*

[402] *Ibid.*

Section 11 of POPI relates to when personal information may be processed.[403] Notably, personal information may only be processed with the consent of the data subject[404] (i.e.: research participant in the case of a biobank). Another applicable ground for the processing of personal information is section 11(1)(b), where processing of personal information is permitted on a contractual basis. An example of this would be an agreement to donate biological material for cancer research. Section 11(1)(f), which allows for processing of personal information for pursuing legitimate interests of the responsible party or of a third party to whom the information is supplied, is an important provision given the situation where, for example, personal information may be passed on to a third party research facility. However, it would be sensible to proceed with caution in this regard. Whether or not a third party is entitled to the personal information, is subject to consent of the research participant, interpretation and dispute in certain circumstances.[405]

Section 13 imposes a further condition for the law for processing of personal information in that it must be collected for a specific, explicitly defined and lawful purpose relating to a function of the responsible party. The responsible party is required to take steps to ensure that the data subject is aware of the purpose for which the information is collected. This may be difficult to achieve when one considers that future uses of samples may not be specified or even contemplated at the time that the initial research project is undertaken, with regard to biobank research.

Section 14(2) restrains responsible parties from retaining personal information for longer than is necessary for achieving the purpose for which the information was collected. Yet, records of personal information may be retained for longer periods if: (1) their retention is required or authorised by law; (2) the responsible party reasonably requires the records for its lawful purposes in connection with its function or activity; (3) the retention of the record is required by the contract between the parties thereto;

[403] According to section 1 of POPI, Processing means: "any operation or activity or any set of operations, whether or not by automatic means, concerning personal information, including- (a) The collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation or use;(b) Dissemination by means of transmission, distribution or making available in any other form; or (c) Merging, linking, as well as restriction, degradation, erasure or destruction of information."

[404] According to section 1 of POPI, Data subject means: "the person to whom personal information relates."

[405] Dinnie D & Malherbe J, Opinion by Norton Rose Fulbright 2014. "Biobank- Opinion" at 3.

or (4) the data subject has consented to the longer retention of the record.[406] If the responsible party wishes to retain personal information for historical, statistical or research purposes, such party may do so if they first establish appropriate safeguards against the records being used for any other purpose. This provision serves as a precondition which a biobank is obliged to comply with. Failure to provide appropriate safeguards will mean that any records so retained will have been retained unlawfully. Section 14(3) also requires responsible parties who have used records of personal information pertaining to data subjects to retain those records for any period prescribed by law.

If there is no prescribed period in law, the responsible party must retain those records for a period which will allow the data subject a reasonable opportunity to request access thereto. Currently, as regards biobanks, there is no retention period prescribed by law. Therefore, the responsible party should retain any records of personal information for a period which allows a research participant or providing entity a reasonable opportunity to request access thereto. The determination of a "reasonable period" may be decided by the particular REC when the initial research project is considered for approval, failing the implementation of minimum and maximum periods of retention for biobank research in South African legislation.

In accordance with sections 14(4) and 14(5), once responsible parties are no longer authorised to retain records of personal information, they must destroy or delete these records or alternatively de-identify the records as soon as is reasonably practicable. The destruction or deletion of records must be done in a manner that prevents their reconstruction in any intelligible form.

Section 14(6) outlines circumstances where the processing of personal information is restricted. Where a responsible party no longer requires the personal information for achieving its purpose but requires it for purposes of proof (evidence), the responsible party must restrict processing of that personal information.[407] The same restriction will apply where the data subject contests the accuracy of the record or where the processing is unlawful and the data subject opposes its destruction or deletion but

[406] Section 14(1).
[407] Section 14(6)(b).

requests the restriction of its use instead, or the data subject requests to transmit the personal data into another automated processing system.[408] Personal information may only be processed for purposes of proof, or with the data subject's consent, or for the protection of the rights of another natural or legal person, or where such processing is in the public interest.[409] In this instance the treatment of processing restricted personal information contained within a biobank will require a research participant's consent or may continue for purposes of proof only or where the interests of the public are served.

Section 26 provides for a general prohibition on processing special personal information, subject to the provisions of section 27. Special personal information includes religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information of a data subject.[410] However, the prohibition on processing personal information does not apply where the processing is for historical, statistical or research purposes to the extent that the purpose serves a public interest; or it is impossible or would involve a disproportionate effort to obtain consent from the data subject; and sufficient guarantees are provided to ensure that the individual privacy of the data subject is not adversely affected to a disproportionate extent.[411] Therefore, a biobank may process special personal information as defined by the Act, where the processing is for historical, statistical or research purposes and where the abovementioned qualifications are met. Interestingly, section 32 provides special authorisation for instances where data concerning a subject's health or sex life may be lawfully processed. Research does not qualify as one of those instances. Nevertheless, as referred to above, research does qualify as an exception under section 27 of POPI. A definition of health or sex life is not provided for in the Act.

Section 72 stipulates conditions for the transfers of personal information outside of South Africa and is extremely important to consider in the context of biobank research. This section stipulates that a responsible party (in our case, a providing

[408] Sections 14(a)(c) & (d).
[409] Section 14(7).
[410] Section 26(a).
[411] Section 27(d).

institute/biobank) may not transfer personal information of a research participant (data subject) to a third party who is in a foreign country (a recipient institute/biobank) unless:

(i) the third party who receives the information is subject to a law, binding corporate rules[412] or binding agreement which provide an adequate level of protection that:
- effectively upholds principles for reasonable processing of the information that are substantially similar to the conditions for the lawful processing of personal information relating to a data subject who is a natural person and, where applicable, a juristic person; and[413]
- includes provisions that are substantially similar to section 72 of the Act;[414]

(ii) the data subject consents to the transfer;[415]

(iii) the transfer is necessary for the performance of a contract between the data subject and the responsible party, or for the implementation of pre-contractual measures taken in response to the data subject's request;[416]

(iv) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the responsible party and a third party; or[417]

(v) the transfer is for the benefit of the data subject, and-
- it is not reasonably practicable to obtain the consent of the data subject to that transfer; and[418]
- if it were reasonably practicable to obtain such consent, the data subject would be likely to provide consent.[419]

[412] According to section 72(2)(a) of POPI, Binding Corporate Rule means: "personal information processing policies, within a group of undertakings, which are adhered to by a responsible party or operator within that group of undertakings when transferring personal information to a responsible party or operator within that same group of undertakings in a foreign country." Further in accordance with section 72(2)(b), A Group of Undertakings means: "a controlling undertaking and its controlled undertakings."
[413] Section72(1)(a)(i).
[414] Section 72(1)(a)(ii).
[415] Section 72(1)(b).
[416] Section 72(1)(c).
[417] Section 72(1)(d).
[418] Section 72(1)(e)(i).
[419] Section 72(1)(e)(ii).

Interestingly, apart from section 72 providing conditions for the transfer of personal information outside of South Africa, it also makes reference to the transfer being for the benefit of the data subject. Historically, as discussed in Chapters 2 and 3, Africa as a continent has been subjected to exploitation, with specific regard to health research and the treatment of participants. The benefit of the research participant is not always a requirement taken into consideration when research is conducted. Although this concept is not expanded upon in further detail in POPI, it is the first piece of legislation that makes reference to a transfer of materials (which includes human materials), benefiting the research participant. From the above analysis, it is evident that biobanks may process personal information, subject to complying with the Act. Special personal information may be processed for research purposes and consent is not always a requirement where it is impossible to obtain. When transferring personal information outside South Africa, foreign institutions/ biobanks must contain similar protections as those contained in the Act.

The protection of personal information safeguards contained within the Act, ensure that individual privacy rights are respected and that control is placed with the data subject as to what, how and when personal information may be processed. It is of further importance to note that the holder of personal information has an obligation towards a data subject to inform him/her when a breach of personal information takes place, should such breach occur. When Soni Play Station was involved in a dispute with its customers due to a violation of their personal information, it was found that Soni Play Station should have informed its customers that the breach took place immediately, instead of shutting down their network and not informing customers of the breach of personal information they had suffered until later on.[420] Once confidentiality is violated, it is irrelevant from the participant perspective who made the breach or disclosure. The information is public and cannot be reversed. From a legal liability perspective, it does make a difference who made the disclosure, but the point is that the harm which the concept of privacy seeks to address has already occurred.

[420] Baker LB & Finkle J. 2011. "Sony Play Station suffers massive data breach." Reuters Edition. Accessed December 08, 2017. https://www.reuters.com/article/us-sony-stoldendata/sony-playstation-suffers-massive-data-breach-idUSTRE73P6WB20110426.

More recently, Swiss-based Sophia Genetics undertook a massive fundraising campaign which aims to grow its database of 125 000 genomes to 1 million in the next three years.[421] This is achieved by allowing its 330 partner hospitals across Europe to have access to Sophia's data mining systems in exchange for their patients' DNA data from the hospitals. While the company strives towards a more effective way of tackling illnesses through access to "searchable global information systems," privacy activists indicate that this type of data pooling is "part of a 'Big Brother' moment for healthcare, where patients' sacrosanct information becomes a commodity traded between healthcare providers and commercial entities." When attempting to draw the line between overstepping privacy of the participant/s on the one hand and promoting health research for the common good of mankind, on the other hand, it is difficult to provide exact boundaries as the nature of technologies are always developing and changing.

At the time of writing this thesis, draft Regulations in respect of POPI were published and opened to the public for comment.[422] The draft Regulations put in place different administrative and procedural obligations that the Act imposes. These include how to object to the processing of personal information, request for the correction or deletion of personal information or the destruction or deletion of a record of personal information, and the duties and responsibilities of information officers. The obligations of the information officer are perhaps the most crucial duties which the draft Regulations aim to enforce. An information officer is essentially an organisation's "go to person" with regard to public and private bodies as per the Act.[423] According to provision 4 of the draft Regulations, an information officer must ensure that:

a. a compliance framework is developed, implemented and monitored;
b. adequate measures and standards exist in order to comply with the conditions for the lawful processing of personal information;
c. preliminary assessments are conducted;
d. a manual for the purpose of the Promotion of Access to Information Act and the Act is developed detailing—

[421] Withers I. "The big data revolution: the high price of a force for good." The Telegraph. September 16, 2017. Accessed December 08, 2017. http://www.telegraph.co.uk/business/2017/09/16/big-data-revolution-high-price-force-good/.

[422] Regulations Relating to the Protection of Personal Information, published 8 September 2017 (Draft Regulations). Accessed September 11, 2017 from the Information Regulator of South Africa's website: http://www.justice.gov.za/inforeg/docs.html.

[423] Sections 55 and 56.

(i) the purpose of the processing;
(ii) a description of the categories of data subjects and of the information or categories of information relating thereto;
(iii) the recipients or categories of recipients to whom the personal information may be supplied;
(iv) the planned trans-border or cross border flows of personal information; and
(v) a general description allowing preliminary assessment of the suitability of information security measures to be implemented and monitored by the responsible party;

e. the manual referred to in paragraph (d) is available—
(i) on the website, of the responsible party; and
(ii) at the office or offices of the responsible party for public inspection during normal business hours of that responsible party;

f. internal measures are developed together with adequate systems to process requests for information or access thereto; and

g. awareness sessions are conducted regarding the provisions of the Act, regulations made in terms of the Act, codes of conduct, or information obtained from the Regulator.[424]

Therefore, the draft Regulations create various responsibilities for the information officer to fulfil. These stringent requirements would apply to biobanks as well. In particular, the biobank would have to ensure that it has measures in place to safeguard the sensitive personal information that it contains. A manual detailing the planned trans-border or cross border flows of personal information, amongst other information as mentioned above will be required. The biobank will also have to ensure that there are internal measures and adequate systems in place to process requests for, or access to information. The Act itself offers appropriate direction in terms of protecting the right to privacy, by safeguarding the processing of personal information subject to justifiable limitations. The following piece of legislation that I will discuss next deals with accessing information.

4.5 The Promotion of Access to Information Act 2 of 2000[425] (PAIA)

Section 32 of the Constitution, 1996 provides that:

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

[424] Provision 4 of the Draft Regulations at 2.
[425] 2 of 2000.

(2) National legislation must be enacted to give effect to this right and may provide for reasonable measures to alleviate the administrative and financial burden on the state.[426]

PAIA was enacted during 2000 and came into operation on 9 March 2001.[427] It constitutes the legislation enacted to give effect to the constitutional right of access to information in accordance with section 32(2) of the Constitution.[428] PAIA attempts to balance the right to information with the right to privacy and impacts how information should be accessed. Consequently, there are certain provisions contained within PAIA that afford protections of certain personal information to individuals.

The non-exhaustive definition of personal information in PAIA is quite similar to the definition found in section 1 of POPI and includes, amongst others, race, gender, medical history, any identifying number, symbol or other particular assigned to the individual and private or confidential correspondence.[429] Personal information excludes information about an individual who has been deceased for more than 20 years. In the case of a biobank, personal information as contemplated by PAIA would include samples procured from a research participant, however, samples belonging to a participant who has been deceased for more than 20 years will not be included in the definition of personal information under the Act. Sections 34 and 63 of PAIA provide for the mandatory protection of privacy of a third party who is a natural person. These sections state that public and private bodies[430] (i.e. a biobank) must refuse access to

[426] Sections 32(1)&(2) of the Constitution of South Africa,1996.

[427] South African History Archive - PAIA Unpacked: A Resource for Lawyers & Paralegals. 2013 at 9. Accessed December 10, 2017. http://www.saha.org.za/publications/paia_unpacked_a_resource_for_lawyers.htm.

[428] *Ibid.*

[429] Section 1 of PAIA.

[430] Section 1 of PAIA defines a Private Body as: "a natural person who carries or has carried on any trade, business or profession, but only in such capacity; a partnership which carries or has carried on any trade, business or profession; or any former or existing juristic person but excludes a public body." Section 1 of PAIA defines a Public Body as: "any department of state or administration in the national or provincial sphere of government or any municipality in the local sphere of government; or any other functionary or institution when: exercising a power or performing a duty in terms of the Constitution or a provincial constitution; or exercising a public power or performing a public function in terms of any legislation."

a record if its release would involve the unreasonable disclosure[431] of personal information about a third party who is a natural person, including a deceased person.

Therefore, in terms of PAIA, the unreasonable disclosure of personal information about a third party, including a deceased individual, is prohibited. The right to bodily and psychological integrity, which implies a right to give or refuse informed consent, the right to privacy, the right to dignity and the right to life together, imply a wider approach to questions of health.[432] As indicated above, the right to privacy may be breached by the wrongful disclosure of certain facts.[433]

Privacy in relation to the right to bodily integrity is also recognised in the Choice on Termination of Pregnancy Act[434] which acknowledges a pregnant minor's right to choose whether or not to consult with her parents, guardian, family members or friends before the pregnancy is terminated. This choice of whether or not disclosure may be made is essentially based on the principles of privacy.

However, there are instances in accordance with PAIA where a record may not be refused insofar as it contains information:

a. about an individual who has consented to the release;
b. already publically available;
c. about an individual who was informed, before the information was given to the private body, that the information belonged to a class of information that would or might be made available to the public;

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[431] In *Centre for Social Accountability v The Secretary of Parliament and others* (298/2010) [2011] ZAECGHC 33; 2011 (5) SA 279 (ECG); [2011] 4 All SA 181 (ECG) (28 July 2011) the Eastern Cape High Court considered what would constitute an "unreasonable disclosure." The court found that a three-part test should be applied:
(1) is the information said to be personal covered by the principle of freedom of identity;
(2) did the individual subjectively harbor a legitimate and reasonable expectation that such information would be protected by the right to privacy; and
(3) does society have an objective legitimate and reasonable expectation that the information should be protected. The court found that if all of these criteria are satisfied then the disclosure of the information would be "unreasonable."

[432] Carstens PA & Pearmain D *op cit* (2007) at 944.

[433] In *Bernstein v Bester NNO* 1996 (2) SA 751 (CC) the Constitutional Court observed that: "The difficulty that remains is the determination of the scope of the provision as a whole or, as it is commonly called, 'the right to privacy'. Use of this term has not been unproblematic, since in terms of a resolution of the Consultative Assembly of the Council of Europe this right has been defined as follows: "The right to privacy consists essentially in the right to live one's own life with minimum interference. It concerns private, family and home life, physical and moral integrity, honour and reputation, avoidance of being placed in a false light, non-revelation of irrelevant and embarrassing facts, unauthorised publication of private photographs, protection from disclosure of information given or received by the individual confidentially."

[434] 92 of 1996.

d. about the physical or mental health or well-being of a person who is under 18 years of age or who is incapable of understanding the nature of the request and is in the care of the requester, where the release of the information would be in the person's best interests;
e. about a deceased individual, where the requester is the individual's next of kin or is making the request with the written consent of the individual's next of kin;
f. about an individual who is or was an official of a public or private body and which relates to the position or functions of the individual.[435]

In the case of biobank research, information that is already publically available (e.g. published results of research) has no protection under the Act. Similarly, if the participant was advised that certain personal information would be made public, the Act affords no protection in terms of access to these records. Further, should the next of kin require access to a deceased participant's records, the biobank may be obliged to provide this information. PAIA also provides for the protection of research information of a third party or private body and protects records from release where the disclosure of the information may seriously disadvantage research of third parties or the information holder. In order to be protected, the record must contain information that would be likely to expose the body (third party or information holder), a person that is or will be carrying out the research on behalf of the body, or the subject matter of the research, to serious disadvantage.[436]

However, the protection of access to information is limited and must be granted if the disclosure of the record would reveal evidence of: a substantial contravention of, or failure to comply with the law; or imminent and serious public safety or environmental risk; and the public interest in the disclosure of the record clearly outweighs the harm.[437] The determination of a "public" interest will have to be considered on a case by case basis. A similar provision is contained in section 14 of POPI referred to above. Therefore, should personal information require retrieving in the public interest, such information will not be protected from disclosure under the Act. PAIA does afford protections to the privacy of personal information and impacts the way in which information is accessed. POPI appears to be wider-reaching and seems to place more emphasis on consent of the data subject/ research participant as compared to PAIA.

[435] Section 63(2).
[436] Section 69(2).
[437] Section 70.

Yet, the definition of personal information in POPI only extends to an identifiable, living, natural person,[438] whereas PAIA provides that personal information excludes information about an individual who has been deceased for more than 20 years. If the individual has been deceased for less than 20 years, any of the deceased's personal information would fall under the ambit of protections afforded under the Act. With regard to protections afforded to deceased individuals, one should refer to PAIA and other relevant legislation (e.g.: NHA).

The following piece of legislation has relevance in terms of electronic communications and is of significance considering the fast paced technological advances we are experiencing with regard to evolving methods of correspondence and communication.

4.6 The Electronic Communications and Transactions Act 25 of 2000[439] (ECTA)

The ECTA was promulgated on 2 August 2002 and came into force on 30 August 2002.[440] The main objective of the ECTA is to enable and facilitate electronic communications and transactions in the public interest.[441] In terms of the ECTA, electronic communication is defined as "a communication by means of data messages."[442] Additionally, "data" is defined as "electronic representations of information in any form."[443] Neither PAIA nor POPI defines data, however, it could be argued that the definition of personal information as provided for in both POPI and PAIA, could extend to electronic representations of personal information in any form. For the purposes of the ECTA, a biobank falls within the definition of a data controller.[444]

The essence of data protection is to provide a person control over their personal information subject to certain prescribed limitations outlined in law. The definition of personal information in the ECTA is the same as that contained in PAIA and similar to

[438] Section 1 of POPI.
[439] 25 of 2002.
[440] Gereda SL & Thornton L (ed).*The Electronic Communications and Transactions Act*. *Telecommunications Law in South Africa*, STE publishers. (2006) 262-294 at 268.
[441] Section 2(1).
[442] Section 1.
[443] *Ibid*.
[444] Section 1 of the ECTA defines a Data Controller as: "any person who electronically requests, collects, collates, processes or stores personal information from or in respect of a data subject."

the definition provided for in POPI and includes (but is not limited to) race, gender, identity, medical history and an identifying number assigned to the individual.[445]

Chapter 8 of the ECTA contains provisions for the protection of personal information that has been obtained through electronic communications.[446] The nine principles for electronically collecting personal information are outlined in section 51 of the ECTA. Section 50(2) provides that a data controller (i.e. a biobank) may voluntarily subscribe to the principles outlined in section 51 by recording such fact in any agreement with a data subject. However, a data controller who chooses to subscribe to the listed principles must subscribe to all the principles and not merely to parts of them.[447] Furthermore, section 50(4) provides that the rights and obligations of the parties in respect of the breach of the principles outlined in section 51 are governed by the terms of any agreement between them. A brief description of the nine principles for electronically collecting personal information is provided for below.

A data controller:

(i) must have the written permission of the data subject for the collection, collation, processing or disclosure of any personal information on that data subject, unless permitted or required by law;[448]
(ii) may only electronically request, collect, collate, process or store personal information of a data subject that is necessary for the lawful purpose for which the personal information is required;[449]
(iii) must disclose the specific purpose for which any personal information is being requested, collected, collated, processed or stored, in writing to the data subject;[450]
(iv) may not use the personal information for any other purpose than the disclosed purpose without the express written permission of the data subject; unless permitted or required to do so by law;[451]
(v) must, for as long as the personal information is used and for a period of at least one year thereafter, keep a record of the personal information and the specific purpose for which the personal information was collected;[452]

[445] Section 1.
[446] Section 50(1).
[447] Section 50(2). See also: Gereda SL & Thornton L *op cit* (2006) at 278.
[448] Section 51(1).
[449] Section 51(2).
[450] Section 51(3).
[451] Section 51(4).
[452] Section 51(5).

(vi) may not disclose any personal information held by it to a third party, unless required or permitted by law or specifically authorised to do so in writing by the data subject;[453]
(vii) must, for as long as the personal information is used and for a period of at least one year thereafter, keep a record of any third party to whom the personal information was disclosed and the date on which and the purpose for which it was disclosed;[454]
(viii) must delete or destroy all obsolete personal information;[455]
(ix) A party controlling personal information may use that personal information to compile profiles for statistical purposes and may freely trade with such profiles and statistical data, as long as the profiles or statistical data cannot be linked to any specific data subject by a third party.[456]

From the above list, it is apparent that a biobank will be obliged to comply with certain provisions regarding electronically collecting personal information. The very essence of progressive health research is to collect, collate and store data for future research purposes. Should biobanks not comply in this regard, a litigious nightmare could arise if research participants become disgruntled or unsettled as to how their personal information is being utilised. Furthermore, with the advances in technology and data bases being hacked relatively frequently,[457] personal information of research participants could possibly be leaked out into the public domain or be utilised with no authority. This is a concern that biobanks should bear in mind when determining how and where the results of their research or data will be stored electronically.

During February 2013, the Scientific American released an article outlining how Yaniv Erlich, a geneticist at the Massachusetts Institute of Technology's Whitehead Institute for Biomedical Research and undergraduate student Melissa Gymrek managed to decipher the identity of fifty individuals whose DNA was available online in free-access

[453] Section 51(6).
[454] Section 51(7).
[455] Section 51(8).
[456] Section 51(9).
[457] Press, Associated. "US General says South Korea Databases Hacked." NDTV.com. June 05, 2014. Accessed December 10, 2017. https://www.ndtv.com/world-news/us-general-says-south-korea-databases-hacked-575630. See also: Trautman LJ. 2012 "Threats Escalate: Corporate Information Technology Governance Under Fire." *BePress*. Accessed December 10, 2017. https://slideblast.com/uploads-00-1c-f5-001cf542-3186 400f-b886-2a26ac6beb6f-fulltext-stamped_59ccff3f1723dd736ff3585c.html. See also: Washington, Associated Press. "Chinese hackers 'broke into US federal personnel agency's databases'." The Guardian. July 10, 2014. Accessed December 10, 2017. https://www.theguardian.com/technology/2014/jul/10/chinese-hackers-us-office-personnel-management-databases.

databases, by using a computer and an internet connection.[458] Using meta-data about the anonymous genomes included in the database, the researchers narrowed the field of possible DNA matches down to ten thousand men of a particular age who resided in Utah when they donated their DNA. Erlich and Gymrek then plugged the genomes into two of the Internet's most popular genealogy sites, Ysearch and SMGF.[459] These recreational sites provide free access to databases that connect Y-STR markers to surnames. The researchers found that eight of their samples strongly matched the surnames of Mormon families in Utah. Erlich and Gymrek's findings were published in the journal of *Science.*

Another unsettling case occurred during February 2014, when the Telegraph released an article regarding a medical records database which could possibly pose a privacy risk and undermine the confidentiality of patients'.[460] The aim of the data-sharing scheme was to improve health care and help medical research. However, there was a growing backlash against the scheme with family doctors and privacy campaigners raising fears that data could be misused.[461] The National Health Service (NHS) officials repeatedly sought to assure the public that the risks were minimal, stating that the majority of information passed on to third parties would be anonymised or "pseudonymised" meaning that it is almost impossible for patients to be identified.[462] But the risk assessment by NHS England, the body behind the scheme, warned that patients could be re-identified if the database data is combined with other information.[463] As a result, patients may have withheld providing information to the clinicians that were treating them, which would compromise the quality of data received and defeat the purpose of the aims of the data-sharing scheme.

Section 85 of the ECTA defines cyber-crime as the actions of a person who, after taking note of any data becomes aware of the fact that he/she is not authorised to

[458] Ferguson W. "A Hacked Database Prompts Debate about Genetic Privacy." Scientific American. February 05, 2013. Accessed December 10, 2017. https://www.scientificamerican.com/article/a-hacked-database-prompts/.
[459] *Ibid*.
[460] Donnelly L. "NHS admits new medical records database could pose privacy risk." The Telegraph. February 16, 2014. Accessed December 10, 2017. http://www.telegraph.co.uk/news/nhs/10642740/NHS-admits-new-medical-records-database-could-pose-privacy-risk.html.
[461] *Ibid*.
[462] *Ibid.*
[463] *Ibid*.

access that data and continues to do so. Section 86 outlines that unauthorised access to, interception of or interference with data is an offence. In *Die Staat v M Douvenga*[464] the Court was required to decide whether an employee was guilty of an offence under section 86(1) of the ECTA.[465] It was alleged in this case that the accused (an employee) intentionally and without the necessary permission to do so, gained entry to data which she knew was contained in confidential databases and/or contravened section 86(1) by sending this data per e-mail to her fiancé to "hou" (keep).[466] The accused argued that her employer had given her the passwords and codes to obtain access to the database and that she therefore had the authority to access the database.

However, the Court held that the accused had neither permission nor consent to access the information in the database for her own personal purposes.[467] The accused could also not provide an explanation to the Court regarding why she accessed and forwarded the information to another computer. The Court concluded that the accused was on a frolic of her own when she gained access to her employer's database and that therefore, the employer could not be held vicariously liable for the accused's actions. Furthermore, it was established that the information and data subject were attached to one another and had to be handled by the data controller in a manner that complies with section 51(4)[468] of the ECTA. The accused was found guilty of contravening section 86(1) of the ECTA and sentenced to a fine or three months imprisonment.[469]

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[464] *Die Staat v M Douvenga (neé Du Plessis)* District Court of the Northern Transvaal, Pretoria, case no 111/150/2003, 19 August 2003, (unreported).

[465] Section 86(1) of the ECTA provides that: "Subject to the Interception and Monitoring Prohibition Act, 1992 (Act 127 of 1992) a person who intentionally accesses or intercepts any data without authority or permission to do so, is guilty of an offence."

[466] Gereda SL & Thornton L *op cit* (2006) at 282. See also: *Die Staat v M Douvenga (neé Du Plessis)* District Court of the Northern Transvaal, Pretoria, case no 111/150/2003, 19 August 2003, (unreported).

[467] In *Minister of Police v Rabie* 1986(1) SA 117 (A) it was held that: "It seems clear that an act done by a servant solely for his own interests and purposes, although occasioned by his employment, may fall outside the course or scope of his employment and that in deciding whether an act by the servant does fall within the course and scope of employment, some reference is to be made to the servant's intention."

[468] Section 51(4) of the ECTA states that: "a data controller may not use the personal information for any other purpose than the disclosed purpose without the express written permission of the data subject; unless permitted or required to do so by law."

[469] *Die Staat v M Douvenga (neé Du Plessis)* District Court of the Northern Transvaal, Pretoria, case no 111/150/2003, 19 August 2003, (unreported). See also: Gereda SL & Thornton L *op cit* (2006) at 282.

The provisions for the protection of personal information may be contained within various Acts and in law, however, the risks regarding the privacy of electronic data are very real and cannot always be prevented. Perhaps the most realistic approach to take is to inform participants of the privacy risks upfront in order for them to make an informed decision whether to participate in the research or not. With regard to biobank research, privacy infringements of personal information may only take place years after the initial research is carried out. Nevertheless, perhaps informing participants of any risk that may occur in respect of their privacy is more favourable than not informing them of the privacy risks at all, or only informing them when the risk occurs. The above legislation has a general bearing on biobank research. In order not to be repetitive, only certain specific ethical guidelines that have an impact on the privacy and confidentiality of research participants, will next be discussed.

4.7 Department of Health, National Ethics Guidelines: Ethics in Health Research - Principles, Structures and Processes

It is important to note that the ethical basis, as opposed to the basis in our law, for patient privacy is widely recognised, even at an international level.[470] Failure to observe patient privacy strikes at the heart of the fiduciary relationship between a health professional and a patient. Trust between the patient and the health care professional is critical to the optimal utilisation of health services by patients for their ultimate well-being. The same principles apply when one considers the relationship between researcher and research participant. This Guideline recognises the

[470] Carstens PA & Pearmain D *op cit* (2007) at 947. See also: The European Standards on Confidentiality and Privacy in Healthcare which state *inter alia* that: "As the rule of confidentiality in medical care indicates, …..a major source of the requirement of confidentiality is the fact that the relationship between the health care professional and the patent is, or should be, one of 'fidelity' or 'trust'. Within the relationship between the health care professional and the patient, there exists a tacit understanding on the part of the patient that confidential information will not be further used or disclosed without the awareness and consent of the patient. The patient has, thus, a reasonable expectation that information shared with the health care professional will not be further shared with anyone else. A different, though related, reason for not using or disclosing personal information is that the patient may not want it to be disclose or used. Just as the patient has a right to self-determination in various other health care matters, it is the patient's decision as to who should have access to personal health care information……The confidential nature of the relationship between health care professional and patient and respect for the patient's autonomy constitute *prima facie* reasons for the protection of personal information." Accessed December 11, 2017. https://www.bing.com/cr?IG=D1134FF799904465A5B71AEEEFBD3FDF&CID=00B9F012417C62672182FB4740D363C9&rd=1&h=jqpZ8faPHuq5k9AwhIop70DcLuaHgg76o6gZZr7JmlM&v=1&r=https%3a%2f%2fdanskprivacynet.files.wordpress.com%2f2008%2f06%2feuropean-standards-on-confidentiality-and-privacy-in-healthcare1.pdf&p=DevEx,5064.1.

importance of privacy and confidentiality as key ethical norms when research on human participants is contemplated.[471] It states that:

> privacy is concerned with who has access to personal information and records about the participant; including clinical health care records. On the other hand, 'confidentiality' is about ensuring that appropriate measures will be implemented to prevent disclosure of information that might identify the participant (inadvertently or not) either during the course of the research or afterwards.[472]

An onus is placed on the researcher to ensure privacy and confidentiality interests throughout the research process, including when disseminating study results or findings.[473] Privacy and confidentiality safeguards must be included within the research protocol[474] and a participant should be informed what information will be collected; why it is being collected; what will happen to it; how long it will be retained; whether it will identify the person; whether it will be shared with others and why; and whether it will be sent outside South Africa and why.[475] Therefore, privacy and confidentiality safeguards must also be included within the informed consent process.[476]

The Guidelines reiterate the privacy protections with regard to personal information as detailed in the POPI above. The Guidelines move on to highlight the perceived tension between "the right to privacy and the need for free flow of information in a society that seeks to make progress on economic, social, health care and educational fronts..." However, the POPI does not have any negative consequences for research activities that involve personal information of participants. Nevertheless, it does contain stricter measures of control in terms of storage, access, distribution and dissemination of data.

The Guidelines explicitly recognise the importance of protecting the privacy interests of children, specifically with regard to their genetic privacy interests and explore the

[471] National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." Paragraph 2.3 at 15.
[472] Paragraph 2.3.7 at 17.
[473] *Ibid.*
[474] Paragraph 3.1.8 at 23.
[475] *Ibid.*
[476] Paragraph 3.5.2.3 at 52.

limits to privacy and associated privacy risks[477] within the biobank setting.[478] With regard to the identifiability of biological materials and data, the Guidelines specify that an REC must take into consideration eliminating or minimising (at the least) any privacy and autonomy risks as a result of re-identification.[479] However, the practicality of this provision may be challenged on the basis that there has been a significant increase of research projects seeking ethics approvals within institutions in the country[480] and, as a result, REC's currently experience a substantial escalation in the number of protocols that require their review and attention, which ultimately leads to a situation of work overload.[481] The aforementioned, coupled with the fact that REC's may not always have sufficient capacity and/ or competency to ensure that such risks are mitigated and/ or eliminated, may pose a real challenge in this regard. Secondary uses of materials and data will have to undergo a formal ethics review process, however, the Guidelines indicate that research which relies exclusively on secondary use of anonymised materials and data do not require to undergo formal ethics review, provided that no identifiable information is generated.[482]

With regard to genetic research, the Guidelines state that the proposal must include a plan which outlines how information revealed by such genetic research will be managed and must be explained to participants.[483] Sharing research findings with participants must also include an opportunity for the participant to decide whether he/she would like to personally receive the information and whether this information may be shared with biological relatives.[484] Therefore, the Guidelines vigorously promote the privacy and confidentiality interests of research participants for health related research, with obligations placed on both the researcher and REC in that regard. RECs should be adequately supported to carry out the duties and obligations placed on them, specifically with regard to eliminating and mitigating privacy risks.

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[477] The National Guidelines define Privacy Risks as: "potential harms to participants from collection, use and disclosure of personal information for research purposes."
[478] Paragraph 3.3 at 41 – 44.
[479] Paragraph 3.3.3 at 42.
[480] Cleaton-Jones P. 2016. "What changes are there in decisions by the Wits Human Research Ethics Committee (Medical) and in process errors by research applicants between 2003 and 2015?" *SAJBL* 9(2): 69-72.
[481] *Ibid.*
[482] Paragraph 1.1.10 at 8.
[483] Paragraph 3.3.8 at 44.
[484] *Ibid.*

The legal and ethical considerations outlined in our legislative and ethical frameworks above are further mentioned in several country level ethical guidelines published by the HPSCA. The HPCSA was established by the Health Professions Act,[485] replacing the old South African and Medical Dental Council as the supreme statutory body regulating the medical profession. Being registered as a health practitioner under the Health Professions Act confers certain rights and privileges. Corresponding to these rights and privileges are the ethical duties a health practitioner/ researcher owes to individuals and society. These duties are outlined in various Guidelines of Good Practice, issued by the Health Professions Council of South Africa.[486] Certain HPCSA guidelines have a direct bearing on privacy and confidentiality of research participants, in particular regard to biobank research.[487] Perhaps the most important and relevant guideline from the HPSCA, with regard to confidentiality in biobank

[485] 56 of 1974.

[486] HPCSA. 2016. Booklet 13: "Guidelines for Good Practice in Health Care Professions: General Ethical Guidelines for the Health Care Professions." This Booklet sets out the value-oriented principles to which health care professionals should subscribe in terms of their conduct. Everything ethically required of a professional to maintain good professional practice is grounded in these core ethical values and standards. The core ethical values and standards required of health care practitioners include, amongst others, include the following:
Respect for persons: Health care practitioners should respect patients as persons, and acknowledge their intrinsic worth, dignity, and sense of value; **Best interests or well-being - Non-maleficence**: Health care practitioners should not harm or act against the best interests of patients, even when the interests of the latter conflict with their own self-interest; **Best interest or well-being - Beneficence**: Health care practitioners should act in the best interests of patients even when the interests of the latter conflict with their own personal self-interest; **Human rights**: Health care practitioners should recognise the human rights of all individuals; **Autonomy**: Health care practitioners should honour the right of patients to self- determination or to make their own informed choices, and to live their lives by their own beliefs, values and preferences; **Integrity**: Health care practitioners should incorporate these core ethical values and standards as the foundation for their character and practice as responsible health care professionals; **Truthfulness**: Health care practitioners should regard the truth and truthfulness as the basis of trust in their professional relationships with patients; **Confidentiality**: Health care practitioners should treat personal or private information as confidential in professional relationships with patients - unless overriding reasons confer a moral or legal right to disclosure; **Compassion**: Health care practitioners should be sensitive to, and empathise with, the individual and social needs of their patients and seek to create mechanisms for providing comfort and support where appropriate and possible; **Tolerance**: Health care practitioners should respect the rights of people to have different ethical beliefs as these may arise from deeply held personal, religious or cultural convictions; **Justice:** Health care practitioners should treat all individuals and groups in an impartial, fair and just manner; **Professional competence and self-improvement**: Health care practitioners should continually endeavour to attain the highest level of knowledge and skills required within their area of practice; and **Community**: Health care practitioners should strive to contribute to the betterment of society in accordance with their professional abilities and standing in the community.

[487] For example: HPCSA. 2016. Booklet 13: "Guidelines for Good Practice in Health Care Professions: General Ethical Guideline for Health Researchers." The content of this guideline is drawn from a variety of sources, including the South African Constitution, the Department of Health's Ethics in Health Research: Principles, Structures and Processes, the South African Medical Research Council's Guidelines for Ethics in Medical Research and the Declaration of Helsinki.

research, is the General Ethical Guidelines for Biotechnology Research.[488] These guidelines are intended as a live document which are subject to continuous change.[489] They provide certain measures aimed at protecting the privacy of research participants, which include: potentially identifiable (coded) storage methods. In this instance, data may have identifiers removed and substituted with a code. However, the process is reversible since the code could be used to re-identify the person to whom the data relates.[490] A de-identified storage method ensures the utmost protection of confidential information. Normally the identifiers are removed permanently or the data has been de-identified permanently. The de-identified information cannot be retrieved and remains anonymous, ensuring confidentiality.[491] Similar terms are found in our Department of Health, National Ethics Guidelines.[492] It is important to note that where there is no specific legal requirement, health researchers should conform to the higher standard, or in the case of no legal provisions, to the ethical guidelines. Now that I have addressed the national position with regard to privacy and confidentiality, I will move on to discuss the international perspective in this regard.

4.8 International Instruments

Privacy of a patient or research participant is an internationally well-recognised principle, although not protected as comprehensively as one might hope.[493] I will provide a brief discussion on selected international instruments that emphasise (*inter alia)* the protection of patient privacy and confidentiality below.

[488] HPCSA "Guidelines for Good Practice in Health Care Professions: General Ethical Guidelines for Biotechnology Research in South Africa." 2008 at 20.

[489] *Ibid.*

[490] *Ibid.*

[491] *Ibid.*

[492] According to the National Guidelines: "coded data or materials means identifiers are substituted by a number, symbol or other method to provide a code; a key to the code exists so that the specimen can be linked to its original source." at 77. These Guidelines do not define "de-identified" but do provide that: "Anonymous data or specimen is data or biological materials without any overt identifying information or link to a specific donor." at 41.

[493] Purdue News. "Patient privacy at risk in hospital hallways, lobbies, cafeterias." Accessed December 11, 2017. https://news.uns.purdue.edu/html4ever/2004/040608.Mattson.privacy.html.

4.8.1 The Declaration of Helsinki

The Declaration of Geneva of the World Medical Association binds physicians to the words "the health of my patient will be my first consideration,"[494] and to the International Code of Medical Ethics, which declares that: "a physician shall act only in the patient's best interest when providing medical care."[495]

Furthermore, according to the Code, a physician's duty extends to respecting a patient's right to confidentiality:

> It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality.[496]

The Declaration of Helsinki makes it very clear that: "[w]hile the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects."[497] It explicitly states that protecting the wellbeing of vulnerable research participants is essential. The Declaration is thus primarily concerned with protecting those involved in research and promoting ethical research and further states that "no national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration."[498]

In South Africa, as in most other countries, researchers are therefore required to uphold the principles of the Declaration as it promotes the protection of vulnerable populations who are likely to participate in clinical trials and other medical research.

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[494] WMA Declaration of Geneva, as amended by the 68th WMA General Assembly, Chicago, United States, October 2017. Accessed December 12, 2017. https://www.wma.net/policies-post/wma-declaration-of-geneva/.

[495] WMA International Code of Medical Ethics as amended by the 57th WMA General Assembly, Pilansberg, South Africa, October 2006. Accessed December 12, 2017. https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/.

[496] *Ibid.*

[497] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013 at paragraph 8. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

[498] Paragraph 10.

In accordance with the Declaration, the primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality. With regard to privacy and confidentiality, the Declaration indicates that participation by competent individuals as subjects in medical research must be voluntary.[499] Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.[500] Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.[501] Another international instrument which has an impact on biomedical research involving human beings is the CIOMS guidelines, which will be discussed in relation to privacy, below.

4.8.2 The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation[502] (CIOMS guidelines)

These Guidelines acknowledge their historical foundations in the Declaration of Helsinki and set out how these values might be applied in current practice.[503] The Guidelines recognise that sharing of data or samples for future research purposes can pose a risk to participants, especially when adequate safeguards to protect confidentiality are not in place.[504] In this regard, the Guidelines place an obligation on researchers, sponsors and research ethics committees to ensure that the study poses a socially valuable research question and employs sound scientific methods for addressing the particular

[499] Paragraph 25.
[500] *Ibid.*
[501] Paragraph 24.
[502] The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) Geneva 2016. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/.
[503] Macrae DJ. 2007. "The Council for International Organizations and Medical Sciences (CIOMS) Guidelines on Ethics of Clinical Trials." Proceedings of the American Thoracic Society 4(2): 176-79 at 177.
[504] CIOMS Guidelines at 11.

question. A risk assessment will involve ensuring that plans and processes are in place to adequately manage and reduce risks, which includes, installing safeguards to protect the confidentiality of sensitive personal data.[505] The Guideline provides some direction with regard to protecting the confidentiality of data by means of using anonymised or coded data:

> Custodians of biological materials must arrange to protect the confidentiality of the information linked to the material, by sharing only anonymized or coded data with researchers, and limiting access to the material of third parties. The key to the code must remain with the custodian[506] of the biological material.[507]

Therefore, the Guideline promotes that access to the material by third parties must be limited. One way in which to achieve control over the use of samples and data is to enter into a MTA, which the Guideline supports as a requirement.[508] However, it is recognised that the possibility of complete anonymisation is becoming increasingly "illusionary" as the possibility of cross-matching large datasets improves.[509] In addition, the more difficult anonymisation becomes, the more important it will become to retain the ability to remove personal data from a dataset.[510]

The Guidelines further point out that institutions which store biological materials and related data, must have a governance structure in place to regulate how confidentiality of the link between biological specimens and personal identifiers of the donors is maintained; who may have access to the materials, and under what circumstances; and to which other sources of personal information the results of analyses on the materials may be linked.[511] Importantly, while the Guidelines put in place specific requirements to safeguard confidentiality, they recognise the limitations involved when confidentiality of biological material and data is concerned. In specific, the Guidelines outline three reasons why confidentiality is limited:

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[505] *Ibid.*
[506] The Guidelines refer to biobank custodian and data custodian, however, an exact definition of custodian is not provided for within the Guidelines.
[507] Guidelines at 41.
[508] *Ibid.* A discussion on Material Transfer Agreements is canvassed in chapter 6 of this thesis.
[509] Guidelines at 44.
[510] *Ibid.*
[511] Guidelines at 42- 43.

1. There is a risk associated with data being stolen or leaked and therefore being obtained by unauthorised third parties, even with good governance structures in place.[512]
2. Data may become re-identified or identifiable, even if the data is anonymised or coded.[513]
3. A legal obligation may require that confidential data is released.[514]

However, the Guidelines indicate that these limitations must be anticipated and disclosed to potential participants. In addition, safeguards to confidentiality as well as the limitations in respect of same must be included within the informed consent process and expanded upon in the protocol.[515] In addition, Guideline 22 of the CIOMS Guidelines deals specifically with the use of data obtained from the online environment and digital tools in health-related research which has a specific impact with regard to the complexities of biobank research. This Guideline advises that:

> 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. Researchers should assess the privacy risks of their research, mitigate these risks as much as possible and describe the remaining risks in the research protocol. They should anticipate, control, monitor and review interactions with their data across all stages of the research.[516]

An onus is created on researchers to inform persons whose data may be used in the context of research in the online environment, of the measures in place to safeguard privacy and the risks involved that may remain despite these safeguards being in

[512] Guidelines at 51.

[513] According to the Guidelines: "…data from different sources (for example, health records, employment records, etc.) may be linked due to technological advances, which increasingly enable researchers or others to identify individuals even when working with anonymized or coded data. Identification is also possible when the context in which the research is conducted is narrow (for example, small hospital) or very specific (for example, patients with rare diseases). Pooling data from a number of comparable sources may reduce but not completely eliminate the possibility of identifying individuals. In addition, genetic information derived through comprehensive technologies (for example, whole-genome sequencing) increasingly allows identifying individuals." at 51.

[514] According to the Guidelines: "Some jurisdictions require the reporting to appropriate agencies of certain communicable diseases or evidence of child abuse or neglect. Similarly, (health) authorities and research ethics committee accrediting agencies may have the legal right to inspect study records, and a sponsor's compliance audit staff may require and obtain access to confidential data." at 51.

[515] Appendix 1 and 2 of the Guidelines at 99-106.

[516] Guideline 22 at 83.

place.[517] The Guidelines state that an assessment of privacy risks should include "the range of threats to privacy, the aspects that exacerbate those threats, the likelihood of disclosure of information given those threats, and the extent, severity and likelihood of risks arising from those disclosures."[518] The Guidelines acknowledge that certain privacy risks may be difficult to predict as data is accumulated, combined and used in a wide variety of contexts.[519] Researchers using mobile phones and apps to collect data must be aware that these devices and applications each may have vastly different privacy-related characteristics and limitations.

Significantly, the Guidelines recognise that privacy risks extend beyond just the presence or absence of specific fields, attributes or keywords in a set of data.[520] "Much of the potential for privacy risks stems from what can be inferred about individuals from the data as a whole (i.e. inference risks), or when the data is linked with other available information."[521] Mitigating privacy risks should include a systematic analysis of the primary and secondary uses of the data, which should consider re-identification risks and inference risks. This analysis should take into account not only whether a person can be directly associated with a particular attribute, but also the extent to which attributes that may be revealed or inferred depend on an individual's data and the potential harm that may result. The potential uses of the data, which in turn affects data management, output, and the privacy controls that may ultimately be suitable, must also be taken into account. The types of uses or analytic purposes intended impact the choice of privacy controls at each stage, as some techniques may enable or restrict certain types of uses of the data.[522] Furthermore, institutions or organisations that share data should "employ data use agreements,"[523] observe additional privacy protections beyond de-identification and data security, as appropriate, and appoint an independent panel that includes members of the public to review data requests. However, the safeguards that are put in place to mitigate privacy risks and protect the privacy of participants must not unduly impede access to data.[524] The Guidelines set

[517] *Ibid.*
[518] Guideline 22 at 84.
[519] *Ibid.*
[520] *Ibid.*
[521] *Ibid.*
[522] Guideline 22 at 85.
[523] Guidelines at 92.
[524] Guidelines at 93.

out privacy and confidentiality safeguards concisely and offer methods of protection. However, these safeguards must be carefully balanced with accessing materials to further research.

4.8.3 The World Medical Association Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (Declaration of Taipei)[525]

The intent of the Declaration of Taipei is to provide regulation in respect of the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In accordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.[526]

Paragraphs 9 and 10 of the Declaration indicate that physicians act as stewards of the information provided by their patients and as such they have specific obligations to ensure that the dignity, autonomy, privacy and confidentiality of their patients are respected. The rights to autonomy, privacy and confidentiality also entitle individuals to exercise control over the use of their personal data and biological material.[527] In addition, the Declaration acknowledges that confidentiality is essential for maintaining trust and integrity in Health Databases and Biobanks:

> Knowing that their privacy will be respected gives patients and donors the confidence to share sensitive personal data. Their privacy is protected by the duty of confidentiality of all who are involved in handling data and biological material.[528]

The Declaration also creates an onus on a researcher to ensure that a participant is informed of how his/her privacy will be protected in the event that data and biological materials are collected and stored for multiple and indefinite uses.[529] In addition,

[525] WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.
[526] Paragraph 3.
[527] Paragraph 9.
[528] Paragraph 10.
[529] Paragraph 12.

governance arrangements must include arrangements to ensure the protection of privacy.[530] The draft Declaration stipulated that anonymous or pseudo anonymous data is always preferable to identifiable data, whenever satisfactory for the purpose of a health database.[531] Yet, the finalised Declaration does not create a firm position in this regard.

4.8.4 The Organisation for Economic Co-operation and Development (OECD) Guidelines on Human Biobanks and Genetic Research Databases[532]

The OECD guidelines aim to provide guidance for the establishment, governance, management, operation, access, use and discontinuation of Human Biobanks and Genetic Research Databases (HBGRDs). The Guidelines specify that operators of the HBGRD should consider and minimise risks to participants, their families and potentially identifiable populations or groups whose specimens and data are included in the HBGRD.[533] Further, the collection, processing, handling, storage, transfer and destruction of human biological materials and data should be conducted in a manner that protects the privacy of the participants and the confidentiality of their specimens and data.[534]

Point 6.5 of the Guideline indicates that the operators of the HBGRD should protect privacy and confidentiality through a combination of mechanisms including, for example: secure storage of human biological materials and data, coding and encryption of these, logging of any access to specimens or data, data enclaves, and honest broker systems.[535]

Furthermore, data protection should involve, where appropriate, the separation of information that can readily identify an individual from other data, including genotypic data.[536] It is also indicated in the Guidelines that where feasible, participant identifying

[530] Paragraph 21.
[531] Sections 8&9 of the draft Declaration of Taipei.
[532] OECD Guidelines on Human Biobanks and Genetic Research Databases (OECD Guidelines) (2009) 1. Accessed November 07, 2017. http://www.oecd.org/sti/biotech/44054609.pdf.
[533] OECD Guidelines at 13.
[534] *Ibid*.
[535] *Ibid.*
[536] Guidelines at 14.

data should be encrypted from the point of collection through all phases of data handling including storage, manipulation and transfer of data. Finally, operators of the HBGRD should ensure that only a restricted number of properly authorised staff, and in accordance with the obligations of confidentiality, have access to information identifying or potentially identifying participants. Such access should be monitored and documented and only be exercised when necessary.[537]

The Guidelines specify that access to human biological materials and data should be based on objective and clearly articulated criteria, and should be consistent with the participants' informed consent. Further, materials should only be transferred when the recipient has adequate standards in place regarding privacy and confidentiality.[538] This is of particular importance when one considers specimens leaving the country for research purposes. Researchers should only have access to materials that are coded or anonymised, such that the participant cannot be identified, and researchers should be required to not attempt to re-identify participants. However, under exceptional conditions, researchers may be provided with access to materials that are not coded or anonymised.[539] The operators of HBGRDs should not make accessible or disclose participants' materials to third parties except when required by law.

Under the best practices section of Access to Data, the Guidelines stipulate that operators of the HBGRD should have in place mechanisms to review applications for access to human biological materials and/or data.[540] The best practice further encourages having mechanisms in place for review of the envisaged uses materials for consistency with the types of research uses agreed to by a participant.[541] Of note, the Guidelines refer to access agreements which should stipulate the terms of access for researchers to whole or a part of the database. Users of data should also sign confidentiality agreements when access pertains to data that is not publicly available.[542] The consent of the type of research to which the participant agreed to should be incorporated into the information management system and operators of the

[537] *Ibid.*
[538] Point 7B.
[539] Point 7D.
[540] Point 7.2.
[541] Point 7.3.
[542] Point 7.5.

HBGRD should formulate policies and procedures setting out the manner in which an individual participant can request information and data about him/herself contained in the HBGRD, how those requests will be handled, and which information and data, if any, can be made available.[543]

The Guideline further states that since protecting the privacy of participants and the confidentiality of materials is significant, personnel should receive training in regard to their obligations of confidentiality, particularly with regard to requests for access. The HBGRD's personnel should sign agreements that set out their duties to protect the privacy of participants and the confidentiality of materials.[544]

It is evident that the OECD Guidelines provide comprehensive detail with regard to the responsibility of a biobank to maintain the privacy and confidentiality of data and regulate its access thereto. South Africa is not too far behind the international arena with regard to the protection of participant privacy and confidentiality of data. However, (and until all the sections of POPI are enacted) most of these concepts are contained within policy and guidelines rather than statute. As mentioned previously, international instruments such as the OECD Guidelines may be used as guidance principles but are not legally enforceable under South African law.

4.9 Conclusion

It is clear from the above analysis that privacy and confidentiality of the research participant is of utmost significance. There have been great strides made towards the ultimate protection of a research participant's privacy both nationally as well as internationally. A breach of private information could cause disorder and disrupt research critically in that participants may develop a distrust of the research process, which may lead to litigious proceedings being instituted against the institution/biobank concerned.[545] There are currently a few different positions with regard to protecting the identifiability of materials. It is essential that research participants understand the notion of identifiability and the different levels of anonymisation in order to assess

[543] Point 7.8.
[544] Point 7.2.
[545] E.g.: The Havasupai Tribe and Arizona State University matter discussed in Chapter 3 of this thesis.

the individual consequences of participation. In addition, biobank research implies risks for identifiable groups and communities because anonymity of the individual does not necessarily translate to anonymity of the group.

The South African framework currently provides different options of security methods with regard to identifiability, but leaves the determination of “risk” up to an individual REC. The general position is, however, that data is either coded or anonymised. It is my submission that while there may be an intention to anonymise samples, this intention may not always be realistic. It is well recognised that the possibility of complete anonymisation is becoming increasingly “illusionary” as the possibility of cross-matching large datasets improves. In addition, should the materials contain genetic information (such as DNA), complete anonymisation is near impossible. A researcher can therefore, not make a promise of complete anonymity to a participant, especially where genetic research in a biobank setting is concerned. Furthermore, there may be a need to trace the materials back to an individual/ groups of individuals in the case of an adverse event or should a peculiar/ life altering genetic disposition be found.

The South African position with regard to informed consent, ownership and privacy and confidentiality of participants, as well as the relevant international guidelines which impact these topics have been discussed. In the following chapter, I will compare the ethico-legal frameworks of the United Kingdom, Australia and Uganda with regard to biobank research and attempt to tease out the methods that these countries employ in order to justify an appropriate model for South Africa.

Chapter 5

Ethico-legal frameworks for biobanking in the United Kingdom, Australia and Uganda – A comparative analysis

5.1 Introduction

In the previous chapters, my discussions focussed on addressing key concepts pertinent to biobank research, by primarily analysing the South African position in conjunction with best international practice. The objectives of such discussion was to highlight the relevant complexities of biobank research from a South African perspective, which will lead to ultimately developing appropriate recommendations, that, in turn, will move towards improving our current national framework. However, it is important to re-iterate the international reach of biobank research, which forms the very essence of its successful operation, at this juncture.

As introduced in Chapter 1, the first worldwide endeavour into "big biology" was initiated by the Human Genome Project (1990-2003)[546] which involved an astounding effort on the part of scientists, to map and sequence the entire human genome, with the ultimate purpose being that of improving the effectiveness of healthcare and advancing human health.[547] The massive amount of human biological materials stored and data generated from this project is immeasurable, and other subsequent genomic-related projects have also involved research on an equally ambitious scale.[548] As Meslin and Quaid aptly write: "Now that the human genome has been sequenced, the future of medicine will depend largely on the ability of investigators to gain access to large quantities of HBMs [human biological materials]. However, this research can only proceed with careful consideration of the ethical, legal, and social implications of such

[546] Green ED, Watson JD & Collins FS. 2015. "Human Genome Project: Twenty-five years of big biology." *Nature* 526 (7571): 29-31. doi:10.1038/526029a.

[547] "Overview of the Extramural Research Program." National Human Genome Research Institute (NHGRI). Accessed November 07, 2017. https://www.genome.gov/12010633/overview-of-the-extramural-research-program.

[548] Dove ES. 2015. "Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework." *Journal of Law, Medicine and Ethics* 43 (4):675–89. https://doi.org/10.1111/jlme.12311.

access."[549] In order to meet the increasing demand for human specimens and data, the world has witnessed the emergence of biobanks on a scale not seen before.[550]

Currently, in the private, public and non-profit sectors, there are plans to establish many more and larger scale biobanks,[551] to service the demand that evolving scientific research has advanced and will continue to advance in years to come. Biobanks must have effective operational systems in place which will allow for the collection, storage, analysis and distribution of materials, for future and as yet, unspecified research. It is this extensive networking, coupled with unspecified future research that defines the very nature of biobanking.

For the reasons above, it would be prudent to consider the ethico-legal framework, relevant to South Africa, in conjunction with analysing ethico-legal systems utilised in specific developed countries and other developing sub-Saharan African countries, insofar as they relate to biobank research. This is particularly significant, as such analysis will place our current local framework into perspective and substantiate the need for improvement.

South Africa's colonised past has had a unique influence on its current mixed legal system.[552] Generally, the South African legal system may be described as multi-layered, incorporating many similarities to the legislative system adopted in the UK.[553] South African medical law is also founded on English medical law, not to mention the fact that the UK is a frontrunner in issues relating to the regulation of human tissues.[554] Similarly, as former colonies of the British Empire, the Australian

[549] Meslin EM & Quaid KA. 2004. "Ethical issues in the collection, storage, and research use of human biological materials." *Journal of Laboratory and Clinical Medicine* 144(5): 229-34. doi:10.1016/j.lab.2004.08.003.

[550] Rothstein MA, Knoppers BM & Harrell HL. 2016. "Comparative Approaches to Biobanks and Privacy." *The Journal of Law, Medicine & Ethics* 44 (1):161–72. https://doi.org/10.1177/1073110516644207.

[551] *Ibid* at 161.

[552] Lenel B. 2002. "The History of South African Law and its Roman-Dutch Roots." unpublished essay. See also: Supreme Court of Appeal of South Africa, History and background, Accessed December 12, 2017. http://www.justice.gov.za/sca/historysca.htm.

[553] Supreme Court of Appeal of South Africa, History and background, Accessed December 12, 2017. http://www.justice.gov.za/sca/historysca.htm.

[554] Following the establishment of the Warnock Committee in 1982. For more information on the Warnock Committee and its report, see the HFEA 2009, "Warnock report." Accessed December 12, 2017. http://www.hfea.gov.uk/134.html.

and Ugandan[555] legal systems are rooted in English law. Australia is another progressively leading country in respect of health research[556] and Uganda has taken strides to improve its framework with regard to the ethical and social issues around genomic research.[557] It will be practical to observe established systems based on western influences and ideals and compare these to a developing African framework, which, like South Africa, has its roots in a fairly young democracy. For these reasons, I will now discuss the ethico-legal frameworks of the UK, Australia and Uganda with regard to biobank research. After such discussion, I will comparatively analyse each ethico-legal system (including the South African system) and provide an opinion for the improvement of our current national framework.

5.2 United Kingdom (UK)

5.2.1 Background and Biobanking activities

In 2015, the WHO ranked the UK, which spends approximately ten percent of its gross domestic product (GDP) on health services, an impressive 18 out of 191 surveyed countries, in respect of the efficiency of it healthcare system.[558] As of 1 January 2017, the population of the UK was estimated to be over 65 million people.[559] Health care is provided by the National Health Service (NHS) which is funded by public tax and which is free for any UK resident.[560] Investment in clinical and general research is through the National Institute of Health Research and the Medical Research Council (respectively), which supports the clinical and translational work of the NHS.

With regard to genomic research, the UK played a leading role in the Human Genome Project and at a country level, dedicated specific funding to capitalise on genomic

[555] Mahoro B & Matte L. 2013. "The Ugandan Legal System Sample Cases, History of Uganda." *Hauser Global Law School Program, New York University School of Law*. Accessed December 12, 2017. http://www.mcgeorge.edu/Documents/sampleCasesHistoryUganda.pdf.

[556] Chalmers D. 2015. "Biobanking and Privacy laws in Australia." *Journal of Law Medicine and Ethics* 43(4): 703–713 at 705.

[557] Nnamuchi O. 2016. "Biobank and Genomic Research in Uganda: Are Extant Privacy and Confidentiality Regimes Adequate?" *Journal of Law Medicine and Ethics* 44(1): 85-95 at 87.

[558] World Health Report: World Health Organisation Assesses the World's Health Systems. Accessed December 12, 2017. http://www.who.int/whr/2000/media_centre/press_release/en/.

[559] United Kingdom (UK) Population. Country meters. Accessed December 12, 2017. http://www.countrymeters.info/en/United_Kingdom(UK)/.

[560] Kaye J, Bell J, Briceno L & Michell C. 2016. "Biobank Report: United Kingdom." *Journal of Law Medicine and Ethics* 44(1): 96–105 at 96.

progress.[561] In 2005, a national, population-scale biobank (i.e. the UK Biobank) was established to advance health research by collecting a wide range of clinical and medical information from participants, with sample storage reaching approximately 14 million samples.[562] Over 500 000 participants contributed their samples to participate in a wide range of research into common diseases occurring in the UK. Apart from the population-scale UK Biobank, there are several other biobanks, including: small-scale biobanks; university research biobanks; clinic-based biobanks; and specific disease-focussed biobanks which operate within the UK.[563] Needless to say, with several biobank projects currently underway, and a national population-scale biobank, which supports the investigation into a wide range of diseases occurring in the local population, the UK is one developed country at the forefront of biobank research in Europe. Of note, it is significant to mention that the UK was included into the European Union's (EU) Biobanking and Biomolecular Research Infrastructure project in 2015. This project aims to create a new community legal framework for biobanking[564] which may assist in the development of a harmonised framework across Europe. In addition, this project will enable the development of a registry of biobanks across the UK. I will next provide an overview of the current ethico-legal framework relevant to biobank research in the UK.

5.2.2 Ethico-legal framework and governance structures relevant to biobank research

Interestingly, the UK is one of a few countries in the world that does not have a written Constitution. An accumulation of various statutes, conventions, judicial decisions and treaties may collectively be referred to as the "British Constitution." The fact that the Constitution is not written down in one codified document, may be attributed to the UK's history as a nation and colonialist state. Unlike other countries that have

[561] Human genome: UK to become world number 1 in DNA testing. Accessed December 12, 2017. https://www.gov.uk/government/news/human-genome-uk-to-become-world-number-1-in-dna-testing.

[562] UK Biobank: The foundation for the establishment of UK Biocenter. Accessed December 12, 2017. http://www.ukbiocentre.com/media/5475/case%20study%201%20-%20uk%20biobank%20uk%20biocentre.pdf. See also: Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) 96-105.

[563] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 97.

[564] *Ibid* at 97. See also: Community Legal Framework for a European Research Infrastructure Consortium. (ERIC) Council Regulation (EC) No 723/2009 of 25 June 2009. Accessed December 12, 2017. http://ec.europa.eu/research/infrastructures/pdf/council_regulation_eric.pdf.

experienced regime change or revolution and have had to develop their legal principle structures at a foundational level, the UK legal framework, in its entirety, has evolved over a long period of time with relative stability.[565]

National Parliament in the UK establishes laws for the entire country. In the UK, there is no specific legislation related to biobank research,[566] however, this does not mean that biobanks operate in a completely unregulated terrain. Similar to the current South African situation, differing Acts, policies, regulations, common law doctrines, codes of practice, conventions, declarations and recommendations apply in terms of their relevance to a specific scenario.[567] It has been contended that the legal system which applies to medical research is disjointed and that such fragmentation is as a result of reactionary responses to public health scandals.[568] For example, the Human Tissue Act, 2004 was implemented after the Alder Hey organ scandal[569] in which organs of children were retained by the Alder Hey Children's hospital without consent. The UK is also currently subject to European Directives and Regulations as a European Union member state, which may change in future, following the UK's vote to leave the EU. Post-Brexit legislation may in future, supersede EU laws. In the interim, the interpretation of EU laws will still have an influence on the UK legal system until the finalisation of formalised processes to exit the EU are enforced.[570]

As the complexities of biobanking span over various different pieces of legislation, it is necessary to consider which laws are most relevant. Some significant UK statutes include the:

- Human Tissue Act 2004 (applies only in England, Wales and Northern Ireland, except for provisions relating to DNA and the storage of relevant material[571] for

[565] London's Global University, the Constitution Unit. What is the UK Constitution? September 07, 2015. Accessed December 13, 2017. https://www.ucl.ac.uk/constitution-unit/whatis/uk-constitution.

[566] Kaye J, Gibbons S, Heeney C, Smart A. *Governing Biobanks: Understanding the Interplay between Law and Practice*. Parker M (ed) Oxford: Hart Publishing (2012) at 52.

[567] *Ibid.*

[568] Kaye J. *The Regulation of Human Genomics Research.* In Kumar D & Eng C (eds) *Genomic Medicine: Principles and Practice.* Oxford University Press (2015).

[569] Hall D. 2001. "Reflecting on Redfern: What can we learn from the Alder Hey story?" *Archives of Disease in Childhood BMJ* 84(6): 455-456.

[570] Norton Rose Fulbright, Brexit–UK and EU legal framework as at June 2016. Accessed December 13, 2017. http://www.nortonrosefulbright.com/knowledge/publications/136975/brexit-uk-and-eu-legal-framework.

[571] "When a sample contains even a single human cell, it is classified as 'relevant material.'" See: Sathar MA & Dhai A. 2012. "Laws regulations and guidelines of developed countries, developing countries in Africa, and

transplantation, which are UK-wide);[572]

- Data Protection Act 1998;
- Human Rights Act 1998;
- National Health Service Act 2006;
- Freedom of Information Act 2000;
- Human Fertilisation and Embryology Act 1990 and 2008;
- Access to Health Records Act 1990;
- Health and Social Care Act 2012;
- Care Act 2014;
- Computer Misuse Act 1990; and the
- Electronic Communications Act 2000.

I will not describe each Act in detail at this stage, but rather provide their relevance to biobank research in the discussion in sections 5.2.3 and 5.2.4 below. As mentioned above, the UK is also currently subject to certain EU regulations and directives applicable to medical research, including the Tissues and Cells Directive 2004/23/EC,[573] the Clinical Trials Regulation No 536/2014,[574] and the Data Protection Directive 95/46/EC[575] which will be repealed by the generally applicable European Data Protection Regulation 2016/679.[576] The aforementioned Regulation entered into force on 5 May 2016, however, will only come into effect from mid-2018.

As there is no specific legislation directly applicable to biobank research, certain funding bodies, such as the Medical Research Council and the Wellcome Trust Charity have created their own guidance documents or codes of practice, compliance with

BRICS regions pertaining to the use of human biological material (HBM) in research. " *SAJBL* 5(1); 51-54 at 52.

[572] NHS, Health Research Authority: Standard Operating Procedures version 7.2 in effect as of January 2017. Standard Operating Procedures for Research Ethics Committees at 199. Accessed December 13, 2017. http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf.

[573] Directive 2004/23/EC, (31 March 2004) of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells at 48-58.

[574] Regulation (EU) No 536/2014, (16 April 2014) of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC at 99.

[575] Directive 95/46/EC of the European Parliament and of the Council (24 October 1995) on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

[576] Regulation (EU) 2016/679 of the European Parliament and of the Council (27 April 2016) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

which, although not binding under UK law, (in most instances) forms the minimum standard in order to receive funding.[577] Adherence to internal guidance documents is often viewed as a demonstration of good practice and provides an attempt at regulating biobank research, in the absence of a legislative framework.

Before 2011 there was no singular body responsible for the oversight of research processes in the UK. However, this position changed with the establishment of the Human Research Authority[578] (HRA) whose main purpose is to protect and promote the interests of patients and the public in health and social care research. The National Research Ethics Service (NRES) falls under the ambit of the HRA and it is responsible for providing guidance and the system of accreditation for RECs in the UK.[579] The NRES is a core function of the HRA and one of its functions is to audit RECs in the UK on a regular basis. The Confidential Advisory Group, which also falls under the ambit of the HRA, provides advice on uses of data as set out in the legislation. Notably, it provides independent expert advice to the HRA with regard to whether research applications to access patient information without consent, should or should not be approved.[580] There are different oversight bodies in the UK that provide governance roles in respect of biobanks; the HRA being one such body. Other oversight bodies include: the Human Tissue Authority; the Information Commissioner; the Human Fertilisation and Embryology Authority; the General Medical Council and the National Health Service.

The Human Tissue Authority's regulatory role extends to organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public[581] and is responsible for licensing collections of human biological samples. The Information Commissioner has the authority to enforce compliance to the Data Protection Act by audits, issuing fines and through investigations. The Information Commissioner is, in addition, able to subject public health care organisations to a compulsory audit. The audits review how

[577] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 98.
[578] NHS Health Research Authority: HRA Approval. Accessed December 13, 2017. http://www.hra.nhs.uk/.
[579] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 99.
[580] NHS Health Research Authority: Our committees and services. Accessed December 13, 2017. http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/.
[581] The Human Tissue Authority: The regulator for human tissues and organs. Accessed December 13, 2017. https://www.hta.gov.uk/about-us.

the NHS maintains patients' personal information and may review the security of data, the management of records, staff training and data sharing.[582] The health sector acquires some of the most sensitive personal information of individuals, however, breaches of data caused by poor procedures and insufficient training is a reality in the UK as is the case in many other parts of the world.[583]

The Human Fertilisation and Embryology Authority is an independent regulator with a number of powers of inspection and enforcement for ensuring compliance, but its governance is limited to the use of gametes and embryos in fertility treatment in research.[584] The General Medical Council is an independent organisation which aims to protect patients and improve medical education and practice across the UK. This body sets the standards that medical practitioners need to adhere to and protects patients' safety.[585] It is therefore evident that there are a number of oversight bodies that may have a role in the governance of biobanks within the UK.

Should research require NHS premises, staff or patients, research approval must be sought from a NHS REC.[586]The Standard Operating Procedures for Research Ethics Committees issued by the HRA apply in the case of biobanks.[587] This document sets out standard operating procedures (SOPs) for RECs within the UK Health Department's Research Ethics Service.[588] According to the HRA SOPs, ethical approval is required for researchers in England, Wales and Northern Ireland under the

[582] ICO given new powers to audit NHS. Accessed December 13, 2017. https://www.icsa.org.uk/knowledge/governance-and-compliance/news-digest/february-2015-ico-given-new-powers-to-audit-nhs.

[583] Carrión Señor I, Fernández-Alemán JL & Toval A. 2012. "Are Personal Health Records Safe? A Review of Free Web-Accessible Personal Health Record Privacy Policies." *J Med Internet Res* 14(4). See also: El Emam K, Jonker E, Arbuckle L & Malin B. 2015. Correction: A Systematic Review of Re-Identification Attacks on Health Data. *PLoS ONE* 10(4).

[584] The Human Fertilisation and Embryology Authority. Accessed December 13, 2017. http://www.hfea.gov.uk/.

[585] General Medical Council, Working with Doctors Working for Patients. Accessed December 13, 2017. http://www.gmc-uk.org/about/role.asp.

[586] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 99.

[587] In accordance with the Standard Operating Procedures for Research Ethics Committees, version 7.2 as at January 2017, a research tissue bank or biobank is defined as: "A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending." at 205. Accessed December 13, 2017. http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf.

[588] NHS, Health Research Authority: Standard Operating Procedures version 7.2 in effect as of January 2017. Accessed December 13, 2017. http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf.

following circumstances: to store or use the tissue of living or deceased person(s) for a research project on a premises without a licence from the Human Tissue Authority; to store or use tissue from a living person for a research project, without consent, where the samples are anonymised; to analyse human DNA in material from the body of a living person (or using the results of DNA analysis) without consent, in circumstances where the tissue donor cannot be identified; to store or use tissue for a research project where consent is required and the tissue is from adults who lack the capacity to consent for themselves; and to export tissue which is taken from a living person(s) and where there is no consent for future research uses.[589] In accordance with the SOP, a research database means:

> A structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research project with defined endpoints.[590] (underlined for emphasis)

In accordance with the SOP, organisations responsible for the management of research databases anywhere in the UK may apply for ethical review of their arrangements for collection, storage and use of data, including arrangements for the release of non-identifiable data for analysis by external researchers.[591] It is prudent to note at this juncture that REC approval is only legally required where the activities of a research database would include accessing or otherwise processing the identifiable data of patients or service users, outside their normal care team, without consent.[592] Therefore, applications for ethical review of research databases are normally made on a voluntary basis.[593] Ethical approval will allow the Research Database team to collect, store and use identifiable data for the purposes for which consent has been sought.[594]

According to section 11.7 of the SOP, RECs normally review databases established by organisations within the UK only; however, applications related to non-UK databases may be accepted for review, where the database plans to collect data relating to UK participants. This extends the protection mechanism and oversight procedures to organisations outside the UK where UK participants' data are being

[589] Section 12.4.
[590] Section 11.7.
[591] Section 11.1.
[592] Section 11.4.
[593] Section 11.5.
[594] Section 11.22.

stored. Furthermore, an applicant seeking REC approval may also apply for generic approval on behalf of external researchers receiving non-identifiable data to undertake valuable scientific studies, as data sharing is encouraged in order to achieve full research potential, provided that adequate safeguards are in place to protect confidentiality.[595] However, powers to inspect research projects once they have commenced do not extend to REC's under this policy document. Therefore, REC approval appears to be a once off process rather than a continuous one.

In the case of UK Biobank, the Wellcome Trust and the Medical Research Council (UK Biobank funders) established their own internal ethical and governance framework to ensure that management of the national biobank is in the public's best interests. This framework has been acclaimed as an example of state-of-the-art biobank governance[596] as it outlines the biobank's stance on consent, maintains a commitment to participant confidentiality, describes withdrawal provisions, outlines confidentiality and security procedures, provides guidance on access to data and samples, offers guidance in respect of benefit sharing and direction in the event of asset transfer and biobank closure.[597] While this ethical and governance framework is not legally binding, UK Biobank would suffer irreversible damage in the event of a breach, which could eventually lead to public distrust in the biobank, wide-spread participant withdrawal and ultimate closure. In order to maintain public trust, effective mechanisms to protect participant autonomy and privacy must be in place. I will next consider the frameworks for informed consent and privacy in the UK, specific to biobank research.

5.2.3 Informed consent for biobank research

It can be understood that consent by its very nature and the range of information required in respect of consent differs, depending on the specific legal context. This is no different in the UK where, for example, in the context of medical research, consent legitimises what could otherwise be construed as a tort of battery.[598] There is a higher standard of disclosure required in the instance of information provided before medical

[595] Section 11.23.
[596] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 98.
[597] UK Biobanks Ethics and Governance Framework, Version 3.0, (October 2007). Accessed December 13, 2017. http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6.
[598] Kennedy I & Grubb A (eds). *Medical Law*. 3rd edition London: Butterworths: (2000) at 589.

treatment, regarding any non-disclosures, which may be construed as negligence on the part of the practitioner. For example, in *Montgomery v Lanarkshire Health Board,*[599] the Supreme Court recently held[600] that:

> [t]he "informed choice" qualification rests on a fundamentally different premise: it is predicated on the view that the patient is entitled to be told of risks where that is necessary for her to make an informed decision whether to incur them… [par 61] [T]he doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances, of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it. [para 87]

Therefore, a reasonable patient standard must be met which will require the disclosure of minor, yet significant risks and a practitioner should reasonably be aware that a patient would attach such significance to a particular risk/s. In this context, this case outlines that the principle of informed consent is part of English law. It is also pertinent to observe that such "reasonable standard of disclosure" could be extended to participants involved in medical research. I will now discuss relevant legislation and policy guidelines that have a bearing on informed consent in the biobank research context.

The Human Tissue Act 2004 (HTA) requires a license for the storage and use of human tissue and therefore relates to all biobanks or human genetic databases in the UK. As a general rule, in accordance with the HTA, consent from an appropriate person[601] is required before relevant bodily materials may be removed, stored and

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[599] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

[600] At paras 61 and 87.

[601] Section 2 of the HTA sets out the meaning of "appropriate consent" in relation to activities regarding the body of a deceased child, or relevant material from living or deceased children. For the purposes of this section, children are persons under the age of eighteen. Living children who are competent to do so may give their own consent. If they are not competent or choose not to decide, appropriate consent will be that of a person with parental responsibility for them. Section 3 of the HTA sets out the meaning of "appropriate consent", in relation to activities concerning the body of a deceased adult or relevant material from a person who is (at the time of the activity) a living or deceased adult. If the adult is alive his own consent is required. If an adult lacks the capacity to consent, section 6 of the HTA enables the Secretary of State to specify in regulations the circumstances in which there is to be deemed to be consent to activities regulated by the HTA in relation to adults who lack capacity to consent for themselves, where a decision of theirs about such matters is not already in force. (This must be read together with the Mental Capacity Act 2005.) Accessed December 13, 2017.

used from a living or deceased person.[602] However, consent is not always legally required for the storage and use of human tissue for research purposes. Some important exceptions to the general consent rule include: tissue which is an "existing holding";[603] tissue which has been collected from a living person for other purposes (e.g.: surplus tissue taken with consent for diagnostic or therapeutic purposes) where the researcher is unable to identify the person, and the research is ethically approved by a REC;[604] and imported tissues.[605] There is also the "100 year rule" which allows tissues to be stored and used for research purposes from the body of a person who died before 1 September 2006 and where at least 100 years have lapsed since their death.[606]

Under English common law, consent is required to remove any human tissues from a living person; yet, consent of a living person may be given for diagnostic or therapeutic purposes. If the intention is to store and use the tissue for research purposes, it is good practice to seek specific consent for the research; however, it is not a legal requirement. Tissues from living persons may be stored and used for research without consent provided the research is ethically approved and that the participant is not identifiable.[607]

Importing or exporting tissues is not a licensable activity under the Human Tissue Act, though, once tissues are imported, their storage or use for research purposes is subject to licensing by the Human Tissue Authority, unless the tissues will be used for a specific research project only and ethical approval has been granted by a NHS REC.

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http://www.legislation.gov.uk/ukpga/2004/30/part/1.

[602] Section 1.

[603] Section 9 of the HTA indicates that it is lawful to retain and use, without consent, human tissue already held in storage for research purposes on the day before the HTA came into effect ("existing holdings"). This applies to tissue from the living or the deceased. It does not however imply that such tissue can be freely used without regard to ethical consideration.

[604] Section 1(9).

[605] The NHS, Health Research Authority, Questions and answers – The Human Tissue Act 2004. Accessed December 13, 2017. http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-the-human-tissue-act-2004/. According to the HTA Code of Practice on the Import and Export of Human Bodies, Body Parts and Tissue, it is lawful to store and use for research, without consent, human tissue which has been imported but the importer should comply with the best practice set out in the Code. Accessed January 17, 2017. https://www.hta.gov.uk/search?search_api_views_fulltext=import&sort_by=search_api_relevance&sort_by=search_api_relevance&=Apply.

[606] NHS, Health Research Authority, Standard Operating Procedures version 7.2.

[607] *Ibid.*

It is desirable for imported tissues to be stored in a licensed establishment, where it is possible to do so. If this is the case, there is no requirement for NHS REC approval in order to commence with the research. However, if the premises where the tissues are held do not have a HTA license, each research project using the tissue will require NHS REC approval to comply with the Act.[608] In respect of exporting tissues outside of the UK, there is no legal requirement for licensing or ethical approval. Yet, voluntary applications for approval may be made to a NHS REC. The review of this process is confined to UK activities only; in particular an assessment of the measures in place for informed consent must take place.

A detailed analysis of overseas research projects is not expected/required by the REC. Where appropriate, these projects should be ethically reviewed in the host country. Should the export of materials be envisaged, it is good practice to inform participants that their tissues will be exported outside the UK for use in valid scientific research by overseas collaborators.[609] In the event that tissue from a living person has been properly anonymised and its use has received appropriate REC approval, this tissue may be used for research purposes without the consent of the donor.[610]

As mentioned above, UK Biobank has its own ethical and governance framework which has been praised as an exemplary model of oversight.[611] With regard to consent, the purpose of the biobank is not to enroll individuals who are unable to provide consent.[612] There are specific conditions to which a participant should be willing to consent in order to participate in biobanking activities. Of specific significance is that the participant understands that once he/she donates his/her samples to the biobank, UK Biobank will *retain legal ownership* of the database and the sample collection and that participants relinquish any property rights thereto.[613] Therefore, a participant will not have an expectation of any material, financial or any other gain, should the use of his/her samples and/or data result in a profitable outcome.[614]

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[608] *Ibid.* See also: HTA Code of Practice on the Import and Export of Human Bodies, Body Parts and Tissue.
[609] *Ibid.*
[610] Kaye J, Moraia LB, Curren L, Bell J et al. 2016. "Consent for Biobanking: The Legal Frameworks of Countries in the BioSHaRE-EU Project." *Biopreservation and Biobanking* 14(3): 195- 200 at 198.
[611] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 98.
[612] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 4.
[613] *Ibid* at 5.
[614] *Ibid* at 10.

Consent to participate applies throughout the lifetime of the biobank unless the participant notifies the biobank of his/her intention to withdraw. Additional consent will only be obtained for any proposed activities that fall outside the scope of the existing consent. There are various circumstances under which participants may be re-contacted, these include: to collect new information; to seek consent for proposed new uses which fall outside the scope of the existing consent but that have passed scientific and ethics review; and to enquire whether participants would like to become involved in a study that requires new information or samples.[615]

The UK Biobank's Ethics and Governance Council shall make a decision as to whether re-contact is appropriate for particular proposals. Once a participant enrolls with UK Biobank, they are informed of three scenarios for withdrawal. The first withdrawal scenario is termed "No further contact" and entails that the biobank will no longer contact the participant directly, but will still have permission to utilise information and samples previously provided by the participant. The biobank will also be able to acquire further information from the participant's health-relevant records.[616] The second scenario is called "No further access" and in this situation UK Biobank will no longer contact the participant or use any information from their health-related records; however, the biobank will have the participant's permission to use previously provided information and samples.[617] The final withdrawal option is the "No further use" option and this involves no longer contacting the participant or obtaining further information about them. In addition, previously collected information or samples will not be available to researchers. All samples will be destroyed insofar as this is possible and participant information will be held for archival audit purposes only. Though, the participant is made aware that it is not possible to remove their data from analyses that have already been carried out but that any further analyses using their information will come to a halt.[618]

Although UK Biobank retains legal ownership of samples and data, the policy document makes it quite clear that the biobank will not exercise all of the rights which ownership confers upon it. For example: It will not sell samples but rather serve as a

[615] *Ibid* at 8.
[616] *Ibid* at 9.
[617] *Ibid.*
[618] *Ibid.*

"steward of the resource, maintaining and building it for the public good in accordance with its purpose."[619] The policy outlines that even though it will function as a steward of the resource, it will still provide participants with information about the ways in which their samples are being used. This will be achieved through ongoing engagement with participants and the public by various means of communication through e.g.: websites, helplines, newsletters and public meetings. These platforms of communication will be used to inform participants about the development and uses of their samples and data, how the biobank may be contacted and how to withdraw, amongst other information shared. A participants' panel may also be established with members of the UK Biobank population as representatives. This forum will allow participants to express their views and/or concerns, to which the biobank will respond.[620]

In order to ensure that the biobank functions at its greatest potential for the benefit of public health, a UK Biobank database will hold all results gathered by researchers so that they are available to all researchers with appropriate scientific and ethical approval.[621] In addition, all research users will place their findings (whether positive or negative) in the public domain so that members of the public can benefit from them.[622] The policy document touches on benefit sharing; however, it is limited to the sharing of knowledge which may also be applied to developing or improving healthcare techniques, technologies, materials or routines.[623] In terms of the preferred model of consent adopted by UK Biobank, broad consent[624] has been considered a favorable model that suits biobank research. Certain other biobank projects in the UK have opted to adopt the dynamic consent model[625] as described in Chapter 2. As mentioned

[619] *Ibid* at 12.
[620] *Ibid* at 8.
[621] *Ibid* at 13.
[622] *Ibid* at 14.
[623] *Ibid* at 18.
[624] "Broad consent means consenting to a framework for future research of certain types." See: Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 101. "Effectively, broad consent is 'consent for governance' by others, as judgements about appropriate uses of data and samples often fall to researchers, advisory boards, or research ethics committees, who must take decisions on behalf of research participants." See: Kaye J. 2012. "The Tension between Data Sharing and the Protection of Privacy in Genomics Research." *Annual Review of Genomics and Human Genetics* 13: 415-431, at 422. See also: Kaye J, Heeney C & Hawkins N et al. 2009. "Data Sharing in Genomics: Re-shaping Scientific Practice." *Nature Reviews Genetics* 10(5): 331-335; See also: Steinsbekk KS, Kare Myskja B & Solberg B. 2013."Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?"*European Journal of Human Genetics* 21(9):897-902.
[625] "Among other projects, dynamic consent has been implemented in "Platform for Engaging Everyone Responsibly" (PEER) and in the Rudy Project." See: Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 101.

previously in this chapter, the ethical and governance framework established by UK Biobank is not legally binding, however, it attempts to regulate oversight mechanisms in the absence of a legislative framework specific to biobank research in the country. In addition, UK Biobank funders have established their own internal monitoring body, the Ethics and Governance Council to advise the biobank's board and funders and to publish public reports on the conformance of UK Biobank with its own ethical and governance framework and with the interests of participants and the public. The notion of biobanking entails an extensive sharing of personal data which may hold sensitive information. If this information is leaked or published without consent, this could have a huge implication for researchers and the integrity of the biobank could come into question.[626]

Consent and privacy, while distinct principles in themselves, cannot be separated as these two concepts are inextricably linked. Consent operates to safeguard privacy and confidentiality in many ways in the UK and in other developed and developing countries. It is therefore necessary to next discuss the mechanisms in place to safeguard privacy and confidentiality interests of participants of biobank research in the UK and describe how consent plays a role in safeguarding these interests.

5.2.4 Privacy and Confidentiality

It is significant to note that at the core of biobank regulation in the UK is the distinction between human materials (samples) and the information relating to individuals (data). Consent for the removal and subsequent research on samples has been discussed in the section above; however, the regulation of data generated from the samples themselves or from the participants requires analysis. As mentioned previously in this chapter, a number of different pieces of legislation, policies, guidelines conventions, doctrines, as well as European directives have an influence on the UK's legal system. This is particularly relevant when we consider the privacy framework in the UK. The Data Protection Act[627] (DPA), which in principle is very similar to South Africa's POPI,[628] requires the fair and lawful processing of personal data which includes

[626] E.g.: The Havasupai Tribe and Arizona State University matter discussed in Chapter 3 of this thesis.
[627] 1998.
[628] See chapter 4 for a detailed analysis of POPI.

sensitive personal information[629] derived from medical research that can be linked to an individual.[630] Personal data includes data relating to living individuals who can be identified from the data.[631]

The term "processing" has a very wide meaning under the DPA. It is intended to cover any likely procedure with the data including: collecting, recording, holding of data and the carrying out of any operation on the data, through subsequent disclosure and eventual destruction.[632] Consent is a necessary requirement for personal data to be processed; but, there are instances when personal data may be processed without consent.[633] With regard to research, section 33(2) of the DPA outlines that the further processing of personal data only for research purposes is not to be regarded as incompatible with the purposes for which they were obtained. In addition "explicit consent" is required where the data contains sensitive personal information about an individual unless certain conditions as set out in the Processing of Sensitive Personal Data Order are met.[634] This requires the processing to be in the substantial public interest; necessary for research purposes; does not support measures or decisions with respect to any particular data subject otherwise than with the explicit consent of that data subject; and does not cause, nor is likely to cause, substantial damage or substantial distress to the data subject or any other person.[635] Therefore, this implies

[629] According to section 2 of the DPA, Sensitive Personal Data means: "personal data consisting of information as to—
(a) the racial or ethnic origin of the data subject,
(b) his political opinions,
(c) his religious beliefs or other beliefs of a similar nature,
(d) whether he is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
(e) his physical or mental health or condition,
(f) his sexual life,
(g) the commission or alleged commission by him of any offence, or
(h) any proceedings for any offence committed or alleged to have been committed by him, the disposal of such proceedings or the sentence of any court in such proceedings."

[630] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 97.

[631] An overview of UK data protection law, Accessed January 18, 2017. https://united-kingdom.taylorwessing.com/uploads/tx_siruplawyermanagement/NB_000168_Overview_UK_data_protection_law_WEB.pdf.

[632] Part 1, section 1 of the DPA.

[633] Schedule 2 of the DPA.

[634] The Data Protection (Processing of Sensitive Personal Data) Order 2000. Accessed January 17, 2017. http://www.legislation.gov.uk/uksi/2000/417/schedule/made.

[635] Section 9 of the Data Protection (Processing of Sensitive Personal Data) Order 2000.

that secondary uses of data for research purposes can be lawful without obtaining a specific and explicit consent.[636]

At the time of the writing of this thesis, no UK cases relating to privacy breaches specific to biobanking had been reported. Yet, many areas which concern biobanking (e.g.: privacy) are guided by case law, whether a decision has been handed down by the English courts, the European Court of Human Rights or the European Court of Justice.[637] One example of how the courts have considered issues of privacy in relation to an individual is in the case of *Wood v. Commissioner of Police for the Metropolis.*[638] It was held in this case that:

> …[s]ubject to [certain] qualifications… an individual's personal autonomy makes him – should make him – master of all those facts about his own identity, such as his name, health, sexuality, ethnicity, his own image, of which the cases speak; and also of the "zone of interaction" between himself and others. He is the presumed owner of these aspects of his own self; his control of them can only be loosened, abrogated, if the State shows an objective justification for doing so.[639]

In other words, an individual is the ultimate decision maker regarding the usage of his/her own data. In fact, he/she is the presumed owner of his/her information. In relation to the transfer of data, personal data may only be transferred to a country outside of the European Economic Area (EEA) if that country ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.[640] When deciding whether a country outside the EEA contains adequate safeguards, a published European Commission decision may be relied upon in this regard. Or, such assessment may be based on a number of factors including: the nature of the data being transferred and the purposes for which they are being transferred; the laws in the intended recipient country; and security measures in

[636] Section 33(1)&(2) of the DPA, read together with section 9 of the Data Protection (Processing of Sensitive Personal Data) Order 2000. See also: Tasse AM. 2016. "A Comparative Analysis of the Legal and Bioethical Frameworks Governing the Secondary Use of Data for Research Purposes." *Biopreservation and Biobanking* 14(3): 207- 216 at 211.

[637] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016)at 98.

[638] *Wood v. Commissioner of Police for the Metropolis* (2009) EWCA Civ 414, at §21.

[639] At para 21.

[640] Schedule 1, Part 1 of the DPA.

place. Very few countries outside of the EEA are deemed by the Commission to have sufficient protective measures in place.[641]

Between the United States of America (USA) and the European Commission, a safe harbour agreement was put in place in order to fulfil the "adequate safety" requirement when data is transferred. The safe harbour agreement was implemented in order to ensure compliance by certain USA entities to the data protection principles as envisaged in the 1995 European Data Directive.[642] The agreement was legitimised by allowing US entities to self-certify that they were in compliance with the EU Data directive. The problem with self-certification is that oversight mechanisms to ensure compliance are virtually non-existent. On 6 October 2015, in *Schrems v Data Protection Commissioner*[643] the European Court of Justice (the EU's highest court) ruled that the USA-EU safe harbour agreement was invalid as the rights of EU citizens were unprotected under the terms of the agreement. This case followed hot on the heels of Edward Snowden's revelations about the unscrupulous data gathering activities of the USA National Security Agency (NSA).[644] A privacy related breach may result in a damages claim against the responsible entity. In 2015, a privacy related tort was expressly recognised in a Court of Appeal's ruling in *Google Inc. v Vidal Hall.*[645]

The DPA is one piece of legislation that regulates the processing of data. There are, however, other Acts which may indirectly apply to promote and ensure the protection of privacy rights of individuals. Article 8 of the Human Rights Act[646] (HR Act) states that individuals have a right to respect for their private and family life, their home and their correspondence. The HR Act is not directly enforceable against private entities; but, the Act does require a court or tribunal to interpret any UK legislation in a way that is compatible with the rights as set out in the HR Act. In essence, this would therefore

[641] An overview of UK data protection law. Accessed January 18, 2017 https://united-kingdom.taylorwessing.com/uploads/tx_siruplawyermanagement/NB_000168_Overview_UK_data_protection_law_WEB.pdf.

[642] Rothstein MA, Knoppers BM, & Harrell H. 2016. "Comparative approaches to biobanks and privacy." *Journal of Law, Medicine & Ethics* 44(1): 161-172 at 167.

[643] Court of Justice of the European Union C- 362/14, 6 October 2015.

[644] Rothstein MA, Knoppers BM, & Harrell H *op cit* (2016) at 167.

[645] In *Google Inc V Vidal Hall & Ors* (2015) EWCA Civ 311 the court held that damages will be awarded for the misuse of private information which causes "mere distress." This is in contrast to the previous position which required proof of financial damage in order for distress to be compensated. The test set out in this case is whether the person who publishes the information knows or should know that the information should be kept confidential.

[646] 1998.

compel a court or tribunal to consider individuals' privacy rights where it is appropriate.[647] The Freedom of Information Act 2000 provides for general rights of access to recorded information held by public authorities (e.g.: government departments, the NHS and educational bodies). Should personal (and or sensitive) information be requested, the provisions of the DPA will also have to be considered as disclosure thereof may infringe an individual's right to have their personal data protected.[648]

It has been established that the DPA's protection extends insofar as the personal or sensitive data is identifiable. However, in the case of biobank research, maintaining confidentiality of a sample rests on the effectiveness of the method by which samples are de-identified. I will now discuss certain de-identification policies which minimise the risk of privacy breaches during the course of biobank research.

There are two main methods for de-identifying genomic data: anonymisation (i.e.: irreversibly de-identifying the data); and pseudonymisation (i.e.: separating the identifiers and key-coding data)[649] Anonymisation of data occurs when all identifiers are removed so that it is no longer possible to identify the data. Under EU Directive 95/46/EC and the DPA, data that is no longer identifiable (anonymised data) does not require privacy protections. This is only the case if the data subject can no longer be identified. This same principle is echoed in the new generally applicable European Data Protection Regulation 2016/679, which (as of the date of this thesis) is in force but is yet to come into effect. Therefore, anonymising data makes re-contact impossible, which may cause concerns for cross–border transfers of data, if re-contact is vital to the progress of the research itself.[650]

With regard to biobank research, it is recognised that complete anonymisation is not always possible. It may be necessary to retain a link between participants' identifiable information and their samples and data in order to allow for a follow up of the participant's health; to eliminate redundant data; to confirm correctness and

[647] Human Rights Act 1998. See also: An overview of UK data protection law. Accessed January 18, 2017. https://unitedkingdom.taylorwessing.com/uploads/tx_siruplawyermanagement/NB_000168_Overview_UK_data_protection_law_WEB.pdf.
[648] Freedom of Information Act 2000.
[649] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 100.
[650] *Ibid.*

completeness of data against original records; to establish precise linkages among databases; and to find specific data or samples if participants wish to withdraw from the research.[651] In addition, in the event that a sample contains DNA, true anonymisation will not be possible as re-identification is likely.

Therefore, the standard is limited to the requirements of pseudonymisation. In accordance with the Data Protection Regulation,[652] pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data is not attributed to an identified or identifiable natural person.[653] This means that the data subject is, in effect, re-identifiable and that data protection laws will apply. Identifiers are removed and replaced with a code. This type of de-identification is usually used in research where different sources of data relating to an individual require to be linked over time.[654]

The UK Biobanks Ethics and Governance policy outlines that strict measures must be in place to maintain and protect the confidentiality of samples and data.[655] This is achieved by (reversibly) anonymising and linking samples and data which are stored to very high standards of security.[656] The same protection will contractually apply for any handling or analysis of data or samples by third parties engaged to provide services necessary for developing the resource. Practically, this will be done by UK

[651] UK Biobank Ethics and Governance Framework, Version 3.0 (October 2007) at 11.
[652] 2016/679.
[653] Article 4, section 5.
[654] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 100.
[655] The Resource is available to all bona fide researchers for all types of health-related research that is in the public interest, without preferential or exclusive access for any person. All researchers, whether in universities, charities, government agencies or commercial companies, and whether based in the UK or abroad, will be subject to the same application process and approval criteria. See: UK Biobank Access Procedures: Application and review procedures for access to the UK Biobank resource. Version 1.0 (November 2011) Accessed January 18, 2017. http://www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf.
[656] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 11. According to section 4 of the policy: "A wide variety of measures will be taken to ensure the security of data, samples, the database and the information technology system in general. These include staff training and confidentiality pledges, physical and electronic controls on access to data, cybersecurity, and physical security. This should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than approved research."

Biobank holding participants' encrypted[657] identifiable information. Personal identifying information will be separated from participants' data and samples will only be linked using a unique code. All identifying information will be held in a restricted access database that is controlled by senior UK Biobank staff member. A limited number of staff members will have access to the key to the code which will be used to re-link participants' identifiable information to their samples and data.[658] All UK Biobank staff will be required to sign confidentiality agreements as part of their contracts and researchers will not be able to identify individual participants from the "anonymised" data or samples that are provided to them. In essence, "reversible anonymisation" used by UK Biobank is very similar to the principle of pseudonymisation as described in the European Regulations above.

Having adequate de-identifying policies in place maintains the privacy of the samples and data, yet, only to an extent. Oversight mechanisms which control the actual access to the samples and data provide further protections. The DPA and Data Protection Regulation[659] contain general provisions on accessing personal data; however, appropriate access control may be achieved through various methods such as data access committees and data access agreements.[660] In the UK Biobank, the Board of Directors have the overall decision making authority regarding access to and use of the samples and/or data. Oversight of the review process is delegated to its Access Sub-Committee.[661] A license (for a fee) will be granted in respect of accessing data and/or samples for scientifically and ethically approved research, consistent with UK Biobank's purpose. Should only data be required from the resource, it is not a requirement that the proposal has undergone independent scientific review; though, UK Biobank may still require it under certain circumstances.[662]

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[657] Encryption is typically used to allow statistical analysis of encrypted data without direct access by researchers and to protect data from external cyber-attacks. However, these methods do not safeguard against data leakages which emanate from within an organisation holding the data. See: Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 100.

[658] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 11.

[659] 2016/679.

[660] Kaye J, Bell J, Briceno L & Michell C *op cit* (2016) at 100.

[661] *Ibid*. See also: UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 13.

[662] For example: when the proposed use is potentially contentious or there are concerns about its value, whether for scientific, public health or other reasons. See: UK Biobank Access Procedures: Application and review procedures for access to the UK Biobank resource. Version 1.0 (November 2011). Accessed January 18, 2017. http://www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf.

Licenses will be granted for specific uses under strict terms and conditions in standard access agreements, including compliance with the consent given, the provisions UK Biobanks' Ethics and Governance Framework and any other applicable policies.[663] Interestingly, the license fee may be higher for entities that may be expected to financially gain from the use of the sample(s) and/ or data.[664]

The distinction between samples and data makes the legal position in the UK difficult to interpret. It also raises ambiguity in terms of whether different standards of privacy protections exist in respect of different types of data. However, the new EU Data Protection Regulation[665] makes an attempt at being more specific and includes "genetic data" into the definition of personal data.[666] This is a game changer in the context of biobanks as the new Regulations provide for unambiguous consent[667] to the processing of personal data, except for special categories of data (including genetic data) which will require explicit consent. The effects of the new Regulation are yet to be tested in a practical sense in the UK; but, they do provide a stable and high level of protection for personal data across the EU.

From the above analysis it is clear that the UK relies on different sets of legislation, policies, regulations, directives and the like when considering the concerns which biobank research raises. This may be viewed as a fragmented approach; however, I argue that in the case of biobank research, where so many different aspects (consent, privacy, secondary uses, ownership, transfers, closure etc.) have an impact on participants, researchers, the entity itself and all other stakeholders, regulation cannot be confined or limited to one piece of legislation only. Rather, a regulatory framework

[663] *Ibid* at 13.
[664] *Ibid*.
[665] 2016/679.
[666] According to section 13 of the EU Data Protection Regulation 2016/679, Genetic Data means: "personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question." In addition, section 3 states that: "Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained."
[667] According to section 11 of the EU Data Protection Regulation 2016/679, Consent of the data subject means: "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her."

which is open, evolving and hence flexible and which outlines various specific concerns will be more effective.

Another jurisdiction, regarded as a front-runner in the field of genomic research, is Australia. I will now turn to discuss the Australian position and the impact that biobank research has had on their ethico-legal framework.

5.3 Australia

5.3.1 Background and Biobanking activities

Australia is a relatively small, multi-cultural country comprising about 24 million people, with approximately 10% of its GDP (as is the case in the United Kingdom) spent on health care.[668] Its Aboriginal heritage has had an influence on Australian culture as a whole and traces back some forty thousand years. The population consists of a mix of primarily British, Greek, Italian (amongst other European countries), and Asian descendants.[669] In 2015 the WHO ranked Australia 32 out of 191 countries[670] in respect of the efficiency of its healthcare system, which consists of a combination of private and public providers. As a developed country with a high level of health care, Australians generally have a high life expectancy. Public hospitals are funded by state, territory and Australian governments, but are managed by state and territory governments. The Australian Government and state and territory governments provide funding for and support a variety of other health services, including population health programs, health and medical research, and health infrastructure.[671] Australia holds a leading position with regard to medical and health research[672] and about one quarter of health research occurs within the private sector.

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[668] Chalmers D. 2015. "Biobanking and Privacy laws in Australia." *Journal of Law Medicine and Ethics* 43(4): 703–713 at 703. See also: World Health Report: World Health Organisation Assesses the World's Health Systems. Accessed January 5, 2017. http://www.who.int/whr/2000/media_centre/press_release/en/.

[669] Chalmers D *op cit* (2015) at 703.

[670] World Health Report: World Health Organisation Assesses the World's Health Systems. Accessed January 5, 2017. http://www.who.int/whr/2000/media_centre/press_release/en/.

[671] Australia's health system. Accessed January 19, 2017. http://www.aihw.gov.au/australias-health/2014/health-system/.

[672] According to Chalmers D *op cit* (2015) at 705: "For many years Australia has enjoyed a fine record in scientific and medical research, which has led to innovations in medical devices (electronic heart pacemaker, bionic ear, Begg orthodontics, humidicrib, spray-on-skin, ultrasound scanner, solar scan, first bionic eye implantation) and new drugs (penicillin, lithium, aspro, relenza, cervical cancer vaccine, folate). There have also been advances in medical procedures, particularly in physiotherapy and microsurgery." See

The National Health and Medical Research Council (NHMRC) is Australia's leading funding body, promoting the development and maintenance of public and individual health standards, and supporting a wide range of health research areas including biobank research.[673] During the 2000's, disease specific biobanking entities increased within Australia, with the NHMRC primarily funding these biobanks, their main focus being on cancer related research.[674] There are many ongoing biobanking projects, entities and activities underway in Australia.[675] However, they effectively operate independently of one another, with each biobank having its own internal processes to manage the collection, storage and transfer of samples and data. It may be argued that functioning in this autonomous manner has caused a lack of standardisation and a duplication of efforts and infrastructures.[676]

5.3.2 Ethico-legal framework and governance structures relevant to biobank research

As a former British colony, Australia mirrors a number of elements from the British legal system. The Australian Constitution (The Commonwealth of Australia Constitution Act 1900) sets out, amongst others, the powers and functions of government, the senate, the judiciary and parliament.[677] There are different pieces of legislation relevant to health research in Australia. The National Health Act 1953 provides for health services, pharmaceutical, sickness and hospital benefits and regulates national health services.[678] The Australian Code for the Responsible Conduct of Research[679] sets out the general principles for conducting responsible

also: Research Australia, Australian Health and Medical Research." Accessed January 19, 2017. http://researchaustralia.org/health-medical-research/.

[673] Australian Government NHMRC, Research and funding statistics and data. Accessed January 19, 2017. https://www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data.

[674] Chalmers D, Nicol D, Kaye J, Bell J et al. 2016. "Has the biobank bubble burst? Withstanding the challenges for sustainable biobanking in the digital era." *BMC Medical Ethics* 17:39.

[675] The Australasian Biospecimen Network, which provides a list of Australian Biobanks. Accessed January 20, 2017. http://abrn.net/contact/links/.

[676] Chalmers D *op cit* (2015) at 705.

[677] The Australian Constitution. Accessed January 20, 2017. http://www.aph.gov.au/About_Parliament/Senate/Powers_practice_n_procedures/Constitution.

[678] The National Health Act 1953, Federal Register of Legislation. Accessed January 21, 2017. https://www.legislation.gov.au/Details/C2014C00353.

[679] Australian Government, NHMRC, Australian Research Council, Australian Code for the Responsible Conduct of Research. Accessed January 23, 2017. https://www.nhmrc.gov.au/_files_nhmrc/file/publications/r39_australian_code_responsible_conduct_research_150811.pdf.

research. The NHMRC has also been active in developing detailed policy and guidelines specific to health research (and more recently biobank research) in this regard. Nevertheless, no formal legislation has been enacted specific to biobanks in Australia. For the first time, in 2007, the NHMRC included a section on biobanks in the National Statement on Ethical Conduct in Human Research[680] (the National Statement) which advocates for the ethical review of a biobank and Human Research Ethics (HREC) approval for the collection, processing, storage, consent, transfer and disposal of biospecimens collected for research purposes.[681]

In 2010, the NHMRC issued an Information Paper on Biobanks which provides for relevant information on the establishment, management and governance of biobanks in Australia.[682] In 2011 the Department of Industry, Innovation, Science and Research published a Strategic Roadmap for Australian Research Infrastructure, which specifically outlines the significant impact biobanking has in the health research context[683] and in 2012, the NHMRC released a National Biobank Strategy report which sets out the strategic objectives, advantages, and principles of establishing a national approach to biobanking.[684] It is hoped that a national strategy for the harmonisation of biobanks throughout the country, will support the long term future operation of biobank research, as funding for the long term, is a challenge in the Australian context.[685]

In addition, most biobanks in Australia are members of the Australasian Biospecimens Network (ABN), which have a recognised set of guiding principles; the ABN Network

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[680] Australian Government, NHMRC, National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015) Accessed January 21, 2017. https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf. According to chapter 3.4, section 3.4.4 of the Statement: "For human biospecimens collected for research purposes (including biobanks), there should be ethical review and approval by an HREC of the proposed consent, collection, processing, storage and distribution or disposal." at 38.

[681] *Ibid.*

[682] Australian Government, NHMRC, Biobanks Information Paper, 2010. Accessed January 21, 2017. https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e110_biobanks_information_paper_140520.pdf.

[683] The Department of Industry, Innovation, Science and Research, Strategic Roadmap for Australian Research Infrastructure (September 2011) Accessed January 25, 2017. https://docs.education.gov.au/system/files/doc/other/national_collaborative_research_infrastructure_strategic_roadmap_2011.pdf. See also: Chalmers D, Nicol D, Kaye J, Bell J et al. *op cit* (2016) at 2.

[684] Australian Government, NHMRC, National Biobanking Strategy. Accessed January 21, 2017 https://www.nhmrc.gov.au/_files_nhmrc/file/research/nhmrc_national_biobanking_strategy_130628.pdf.

[685] Chalmers D *op cit* (2015) at 706. See also: Chalmers D, Nicol D, Kaye J, Bell J et al. *op cit* (2016) at 2: "In 2013, the national budget to fund biobanking was cut, significantly affecting the landscape for biobanking in Australia."

Biorepository Protocols.[686] This protocol outlines issues related to consent, privacy, access, processing, storage, collection and data management amongst other principles. It also provides templates useful for consent.

All health research projects must be approved by an HREC in order to comply with the National Statement.[687] Research that is of a "negligible risk"[688] and involves the use of existing collections of data or records that contain non-identifiable data, are exempt from ethical review.[689] Even though Australia does not have specific legislation which addresses the concerns of biobank research, it does (through the NHMRC) have concise policy in this regard, which I will next discuss with specific focus on consent and privacy considerations.

5.3.3 Informed consent for biobank research

As in the UK and in South Africa, consent in Australia forms the foundation on which research is built and (significantly to biobank research) plays a very important role in secondary uses of samples and data. In Australia, the National Statement[690] makes it clear that two themes should always be considered in respect of human research: first, the risks and benefits of the research should be measured and second, the participant's consent must be analysed.[691] The National Statement sets out the general requirements for consent to future use of data and tissue in research and outlines that:

> Consent may be:
> (a) 'specific': limited to the specific project under consideration;

[686] The Australasian Biospecimens Network Biorepository Protocols, March 2007, Accessed January 25, 2017. http://www.iss.it/binary/ribo/cont/ABN_SOPs_Review_Mar07_final.pdf.

[687] Paragraph 5.1.6 of the National Statement at 69.

[688] According to paragraph 2.1.7 of the National Statement: "Research is "negligible risk" where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk." at 15.

[689] Paragraph 5.1.22.

[690] Australian Government, NHMRC, National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). Accessed January 21, 2017. https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf.

[691] Chapter 3.2 of the National Statement: "distinguishes between tissue, data, and banking and it covers a "wide range" of data types and methodologies" and common types of research using databanks...In this sense, biobanks and the inclusion of biospecimens are a sub-set of the wider, more generic term "databanks." See also: Chalmers D *op cit* (2015) at 707.

(b) 'extended': given for the use of data or tissue in future research projects that are:
  (i) an extension of, or closely related to, the original project; or
  (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
(c) 'unspecified': given for the use of data or tissue in any future research.[692]

The National Statement recognises that there may be limited information and understanding about research for which extended or unspecified consent is given, however, it determines that these methods of consent can still be sufficient and adequate for the purpose of consent.[693] The wide-ranging implications of unspecified consent should be explained to the participant and the terms of such unspecified consent should be clearly recorded.[694] It is further recognised that data or tissue, additional to those covered by the original extended or unspecified consent will sometimes be needed for research. In this instance, the National Statement requires that "[c]onsent for access to such additional data or tissue must be sought from potential participants, unless the need for this consent is waived by an ethical review body."[695] In this regard, the NHMRC Biobanks Information Paper[696] explains that in the context of long-term collections as in the case of biobanks, it is practical to view consent as having two constituents: (1) specific consent to collecting the human tissue and associated information for storage; and (2) unspecified or broad consent to use the data for future, undetermined research purposes.[697] The Information Paper further outlines that while it may not be possible to provide the details of specific projects, an effort must be made to describe the nature and the purpose of the research to the participant as specifically as possible.[698]

There is growing support in Australia for broad consent when specific consent is initially provided, with unspecified or broad consent for future uses, and when as much

[692] Chapter 2.2 "General requirements for consent" Section 2.2.14 of the National Statement at 18.
[693] *Ibid.*
[694] Chapter 2.2 "General requirements for consent" Section 2.2.16 of the National Statement at 18.
[695] Chapter 2.2 "General requirements for consent" Section 2.2.18 of the National Statement at 18.
[696] NHMRC, Biobanks Information Paper. As an OECD member country, the Information paper draws from the OECD guidelines, amongst other international instruments. See: List of OECD Member countries. Accessed January 22, 2017. http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm.
[697] NHMRC, Biobanks Information Paper, 2010 at 25.
[698] NHMRC, Biobanks Information Paper, 2010 at 26.

information as possible about these future uses is outlined in detail.[699] The Information Paper specifies that governance and ethical arrangements should be regularly reviewed, taking national and international developments into account in order to make sure that ideal arrangements are in place with regard to consent.[700]

The Information Paper further outlines relevant information that must be conveyed to potential biobank participants (or where relevant, their decision makers), which includes the following: the relevant risks and benefits; the intended purpose for which the samples and data will be used; the clarification of ownership issues with regard to the samples, information and collection; the nature of consent sought; the circumstances when re-consent might be sought; whether minor participants will be involved and how assent will be obtained; ethics and governance arrangements in place for oversight of the research; whether information from or about family members is required for the research; whether participants will be re-contacted and the circumstances under which re-contact will be permitted; whether data will be identifiable, re-identifiable, or non-identifiable (but noting that genetic material is in principle re-identifiable, even if identifiers are removed); the duration of storage, transfer (including international transfer) and disposal procedures; procedures and safeguards in place to protect confidentiality and privacy; details of data linkage; the risk of psychosocial harms (e.g.: stigmatisation or discrimination); whether the research may reveal information of potential importance to the future health of participants or their relatives; whether or not research results will be released to the participant and/or his or her family or health care provider; whether samples and genetic information will be made available for non-research purposes (e.g.: proficiency testing); the possibility of sharing samples and data with commercial entities and the publication of data and its availability on the internet; access policies; policies for ongoing communication with participants; information for contacting the biobank; potential commercialisation and benefit sharing mechanisms; the right to withdraw, the types of withdrawal, the implications of withdrawal and the possibility of withdrawal; arrangements for the samples and data in the event of incapacity or death of the

[699] Chalmers D, Burgess M, Edwards K, Kaye J et al. 2014. "Marking Shifts in Human Research Ethics in the Development of Biobanking." *Public Health Ethics* 8(1): 63-71. See also: Chalmers D *op cit* (2015) at 709.
[700] NHMRC, Biobanks Information Paper, 2010 at 26.

participant; and proposed arrangements in the event that the biobank closes or discontinues its operation.[701]

Consent is generally obtained in writing, however, verbal consent is accepted under certain instances (e.g.: if the participant is illiterate or cannot write). Regarding withdrawal of consent, the consent document must be clear about the participant's absolute right to withdraw; how this right will be exercised; the effects of withdrawal; and the limitations of such withdrawal e.g.: if samples and data have already been processed and/or transferred, withdrawal becomes more difficult to achieve.[702] The principles of withdrawal outlined in the Information Paper are parallel to the UK Biobanks Ethics and Governance policy guidelines. The options for withdrawal are: no further contact; no further access; and no further use.[703]

In the event that a participant loses their capacity or dies, a biobank may provide the next of kin, or a person previously nominated by the participant, the option to withdraw their samples and data or the biobank may specify that upon death or incapacity it will irreversibly anonymise the participant's samples and data. The Information Paper also describes the position opted for by UK Biobank, namely, that a participant's legal incapacity or death does not give his or her relatives the right to withdraw any samples or data on the participant's behalf as this would reduce the value of the resources for research.[704] This must be explicitly agreed to by the participant during the informed consent process. This approach may be viewed as the most practical method for the purposes of progressive health research; however, legal issues may arise with regard to data protection and the impact on the participant's family should relatives be refused the right of withdrawal.[705]

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[701] NHMRC, Biobanks Information Paper, 2010 at 28.

[702] NHMRC, Biobanks Information Paper, 2010 at 29.

[703] According to the NHMRC, Biobanks Information Paper, 2010: "No further contact: means that there will be no further contact with the participant, but permits the continued retention and use of the previously obtained samples and information, and to obtain further information from health relevant records. No further access means: no further contact with the participant or access to health records but permits continued retention and use of the previously obtained samples and information. No further use means: in addition to no longer contacting or obtaining further information about the participant, any information and samples collected previously would no longer be available to researchers." at 30.

[704] NHMRC, Biobanks Information Paper, 2010 at 31.

[705] Árnason, E. 2002. "Personal Identifiability in the Icelandic Health Sector Database." *Journal of Information, Law and Technology.* Accessed January 28, 2017.

A waiver of consent would usually apply to a biobank that includes existing collections of samples and data. Nevertheless, prospective biobanks may require re-consent from participants or where it is not possible, a waiver of consent, where there has been a major modification to the research direction of the biobank.[706] Typically a waiver of consent allows for samples from an existing collection to be used in research, provided that the project has scientific merit; the project is approved by an HREC; and the samples are de-identified.[707] Only an HREC may grant a waiver of consent for research using personal information in medical research under specific circumstances.[708] With regard to the secondary uses of human materials from deceased individuals, although not directly addressed, it may be interpreted that an REC may make a determination in this regard, as death makes consent impossible to obtain.[709] It is evident that there are many similarities between the UK system and the Australian system with regard to obtaining consent for health research. These similarities will be discussed in further detail under the comparative analysis section of this chapter. As consent forms the basis of privacy legislation, I will now analyse the role of privacy with regard to biobank research from an Australian perspective.

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https://pdfs.semanticscholar.org/585e/c30c289c0ba94ff4b2a75642fe0979509db6.pdf?_ga=1.244527045.170330454.1485857281.

[706] NHMRC, Biobanks Information Paper, 2010 at 37.

[707] NHMRC, Biobanks Information Paper, 2010 at 38.

[708] According to the National Statement's general provisions in relation to a waiver of consent:

"Before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk;
b) the benefits from the research justify any risks of harm associated with not seeking consent;
c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
e) there is sufficient protection of their privacy;
f) there is an adequate plan to protect the confidentiality of data;
g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled; and
i) the waiver is not prohibited by State, federal, or international law." (paragraph 2.3.10)

[709] Paragraph 2.3.10 of the National Statement's general provisions in relation to a waiver of consent. In particular (c) where an REC may waive consent where it is impracticable to obtain. See also: Tasse AM. 2016. "A Comparative Analysis of the Legal and Bioethical Frameworks Governing the Secondary Use of Data for Research Purposes." *Biopreservation and Biobanking.* 14(3): 207- 216 at 211.

5.3.4 Privacy and Confidentiality

The foundation of privacy legislation has its principles rooted in human dignity and the respect for individual freedom. As Australia, like South Africa, is an OECD member country,[710] it is influenced by OECD guidelines and principles. This influence is quite prominent within the regulatory framework towards biobank governance[711] and privacy legislation. In fact, the framework for privacy legislation in Australia is premised on the OECD Privacy Principles first published in 1980.[712] In addition, privacy laws have also been developed to be in line with certain EU privacy directives.[713] The Privacy Act 1988 extends to biobanks[714] and requires that privacy is ensured at all times with regard to the use, collection, distribution, access and storage of personal information.[715] However, similar to POPI and the UK Data Protection laws, the Privacy Act only applies to a living individuals and its protections do not extend to deceased individuals.[716] Specifically, the National Statement guidelines[717] deal with privacy in terms of biobank research. At the very core of biobank research, lies the participant's consent to a variety of factors, including that the participant has been made aware of privacy related issues with regard to their samples and data (e.g.: how privacy is maintained during the collection, storage and distribution of samples and data).

Chapter 3.2 of the National Statement outlines three methods in which data[718] may be collected, stored or disclosed. Data may either be individually identifiable, where a specific individual's identity can be reasonably ascertained; re-identifiable, where

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[710] See: List of OECD Member countries. Accessed January 22, 2017. http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm.

[711] In the NHMRC, Biobanks Information Paper, 2010, the OECD principles are consistently incorporated.

[712] See: OECD Privacy Principles, Accessed January 24, 2017. http://oecdprivacy.org/.

[713] Particularly the Directive on Data Protection on Trans-border Data Flow. See: Chalmers D *op cit* (2015) at 707.

[714] See: Part II, Division 1 (under general definitions) where an "entity" is included under the definition of "information recipient." Accessed January 24, 2017. https://www.legislation.gov.au/details/c2014c00076.

[715] In terms of the Privacy Act 119 of 1988: Personal Information means: "information or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not; and

(b) whether the information or opinion is recorded in a material form or not."

[716] Section 6 of the Privacy Act; See also: Tasse AM *op cit* (2016) at 211.
See also: Roth P. 2004. "Privacy proceedings and the dead." *Privacy Law Reporter* 11: 50-51.

[717] NHMRC, National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015).

[718] According to chapter 3.2 of the National Statement: "data are pieces of information, for example:

- what people say in interviews, focus groups, questionnaires, personal histories and biographies;
- analysis of existing information (clinical, social, observational or other);
- information derived from human tissue such as blood, bone, muscle and urine."at 27.

identifiers are removed and replaced with a code. In this situation it still remains possible to re-identify a specific individual by using the code or linking different data sets; and non-identifiable, where the data has never been labelled with individual identifiers or when identifiers have been permanently removed. No specific individual can be identified where data is non-identifiable.[719] The use of "de-identified data" is avoided in the National Statement as it is not always clear what de-identified data refers to.[720] The National Statement further cautions that:

> With advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples should always be regarded as, in principle, re-identifiable.[721]

Emphasising that the potential identifiability of all samples and data is possible highlights the significant need to safeguard the privacy and confidentiality of any stored samples and data, which, if breached, has major implications for biobank governance and public trust. This concern is reiterated in the NHMRC's Biobank Information Paper published in 2010.[722] In the case of Australian biobanks, stored samples are generally coded, which makes the samples potentially re-identifiable.[723]

In terms of the Privacy Act,[724] health and genetic information falls under the definition of "sensitive information," which is "a component of personal information per the Act, and which may only be collected with consent of the participant."[725] The National Statement recognises that "[g]enetic information can sometimes be misused to

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[719] The National Statement at 27.

[720] According to Chapter 3.2 of the National Statement: "While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term 'de-identified data' is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended." at 27.

[721] Chapter 3.2 at 27.

[722] NHMRC Biobanks Information Paper at 41.

[723] Chalmers D *op cit* (2015) at 708. See also: Knoppers BM, Saginur M. 2005. "The Babel of genetic data terminology." *Nat Biotechnol* 23: 925–927, where the precision of the use of the term "re-identifiable" is questioned.

[724] 119 of 1988.

[725] According to the Privacy Act, "sensitive information means:

(a)….
(b) health information about an individual; or
(c) genetic information about an individual that is not otherwise health information; or
(d) biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or
(e) biometric templates."

stigmatise people or to discriminate against them unfairly" and that researchers "should therefore take special care to protect the privacy and confidentiality of this information."[726] Chapter 3.4 of the National Statement further indicates that when biospecimens are imported (or when it is intended that they will be imported) from another country, there is an onus on the researcher to establish whether the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation.

If it cannot be established that the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation, the biospecimens should not be used for research in Australia. Exporting samples for research is allowed in Australia provided that there is ethical approval, or that the exportation of the biospecimens is consistent with the original consent and ethical approval is provided by an HREC.[727] Apart from providing mechanisms of good governance and the protection of autonomy and privacy, the Biobanks Information Paper outlines that cultural sensitivities play a role in the collection, use, dissemination and disposal of data.[728] It notes that certain groups regard human materials as having a "special status" and as deserving of special treatment in its use and disposal.[729] The Information Paper touches on benefit sharing in a very general manner, emphasising that donations for research are made altruistically and that "this altruism is, in principle, protected by the need to obtain consent from donors prior to using human tissue for purposes that may involve commercialisation."[730] The law in Australia regarding ownership and property rights in human tissue remains unsettled[731] as is the case in

[726] Section 3.5.6 of the National Statement at 43.
[727] Paragraphs 3.4.1.3-3.4.1.5 of the National Statement at 40.
[728] Page 52 of the Biobanks Information Paper.
[729] *Ibid.*
[730] NHMRC Biobanks Information Paper Biobanks at 70.
[731] According to the NHMRC Biobanks Information Paper: "Arguments that could be made about the status of human tissue include the following:
- there can never be full property rights in human tissue, but there may be more limited possessory rights;
- there can be some form of property in human tissue when it has undergone transformation (or processing or treatment, to use the wording in the Australian human tissue legislation), in which case ownership would vest in the person or organisation undertaking the transformation (this could be the researcher, the researcher's employer or the biobank);
- there may be ownership of human tissue by the person providing the tissue, but they 'abandon' any claims to ownership when they provide the tissue to the biobank or researcher; or
- the person providing the tissue has ownership rights in it and retains some of those rights."at 71.

South Africa. However, the general position is that a participant relinquishes his/her right of ownership, once their samples have been donated.

Apart from national legislation and guidelines related to health research, governance and management of human materials and data, most Australian biobanks have their own internal oversight policies which aim to promote confidence and trust by the public in biobank research. Nevertheless, continued funding and sustainability remain national issues.[732] Although the regulatory framework for biobank research is not contained in one specific piece of legislation or guideline document, the NHMRC has developed a detailed set of regulatory guidelines that have consolidated the issues (from a practical point of view) and have combined them as general principles into the National Statement and more specifically into the Biobanks Information Paper. The Australian framework relies heavily on the position adopted in the UK, in specific, the guidelines developed by UK Biobank. This could perhaps be construed as a step towards harmonising their legislative framework with that of a frontrunner in genomic research and data protection. Yet, the Australian guidelines seem to recognise the sensitivities of different cultures and communities, which the UK guidelines appear to gloss over. The strategies of two developed countries have been analysed in respect of the way in which they regulate biobanking. Both of these countries have well developed health care and research systems and are leaders in the field of medical research.

Having explored the UK position and that of Australia, the focus will next turn to a developing country on the African continent, one whose population groups, like South Africa, often form “participant bases” in the context of cross-border health research.

[732] Chalmers D *op cit* (2015) at 711.

5.4 Uganda

5.4.1 Background and Biobanking activities

Uganda has a total population of approximately 40 million people and spends around 7.2 % of its GDP on health.[733] It is resident to over 40 diverse ethnic groups[734] and was ranked number 149 out of 191 surveyed countries in respect of its health care systems.[735] According to the WHO, Uganda has been classified as a low income country with a poor health care system.[736] In comparison, South Africa was ranked a low 175 out of the 191 surveyed countries, with a lower life expectancy at birth than that of Uganda.[737] On the face of these statistics, Uganda seems to out-perform South Africa in terms of health care. These statistics are not surprising, as African populations in general tend to struggle with extreme poverty and harbour the bulk of the disease burden globally.[738] With this background in mind, it is reasonable to conclude that developing countries, such as Uganda and South Africa, should be involved in progressive health research projects that would ultimately lead to improving their health care systems. However, unlike the UK and Australia, government funding in Uganda and South Africa (in Africa in general) and long-term sustainability of research projects remain a serious problem.[739] Research tends to be sponsored from outside sources rather than being embraced as a national responsibility. This presents additional challenges as international collaborations in developing countries raise their own unique set of concerns.[740]

Uganda's healthcare system comprises a mix of both public and private sectors, however, high costs in the private sector, indicate that only the wealthy population benefits from private health care. Lower income earners have no choice but to use

[733] The World Health Organisation report on Uganda as at 2015, Accessed January 26, 2017. http://www.who.int/countries/uga/en/.
[734] Nnamuchi O. 2016. "Biobank and Genomic Research in Uganda: Are Extant Privacy and Confidentiality Regimes Adequate?" *Journal of Law, Medicine & Ethics*, 44(1): 85-95 at 86.
[735] The World Health Report 2000, Accessed January 26, 2017. http://www.who.int/whr/2000/en/.
[736] WHO Statistical Profile. Accessed January 26, 2017. http://www.who.int/gho/countries/uga.pdf?ua=1.
[737] *Ibid.*
[738] Nnamuchi O *op cit* (2016) at 85.
[739] Whitworth JAG, Kokwaro G, Kinyanjui S, Snewin VA et al. 2008. "Strengthening capacity for health research in Africa." *Lancet* 372(9649): 1590-1593.
[740] Nienaber A. 2011. "Consent to and authorisation of the export and use of human biological specimens for future research-perspectives from three African countries." XLIV *Cilsa* 225-254.

either traditional healers, whose practices remain unregulated, or the public sector, which is conventionally marred by a lack of basic facilities.[741] With regard to biobanking, Uganda has not lagged behind as genomic research offers the promise of hope to a nation struggling with an increasing disease burden and growing stigma associated with specific diseases.[742] The Integrated Biorepository of H3Africa Uganda, (IBRH3AU) is the most well-known biobank in the country. The H3Africa Initiative aims to facilitate the study of genomics and environmental determinants, in order to improve the health of African populations.[743] With over 50 000 samples in storage, the IBRH3AU has become an important database for research of an African population, both nationally and internationally.[744] In addition, the Ugandan Medical Informatics Centre (UMIC)[745] has the potential to collect, store and analyse data for genomic research purposes.

Most developing countries' ethico-legal systems are influenced by developed jurisdictions, in particular European countries and the United States.[746] One reason may be that funding for health research predominantly originates from organisations based in the western world. Though, developed world systems may not always work in developing countries where tradition and culture play a big part in determining an individual's or community's perception to and/or participation in research.

The discussion will next explore the ethico-legal framework with regard to health research in Uganda, with the regulation of biobanks as the focus.

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[741] *Ibid* at 87.

[742] Genomic research is as important as research into poverty and other social factors. Researchers in Uganda and South Africa and other parts of the continent have currently moved towards genomic research for diseases such as HIV/AIDS. According to Nnamuchi O *op cit* (2016): "HIV/AIDS prevalence in the country, although declining remains unacceptably high. Uganda leads the rest of East African countries in prevalence rate, and in 2013 accounted for 10 percent of all new infections in sub-Saharan Africa." at 87. See also: Chan BT, Weiser SD, Boum Y II, Siedner MJ et al. 2015. "Persistent HIV-Related Stigma in Rural Uganda during a Period of Increasing HIV Incidence despite Treatment Expansion." *AIDS (London, England)* 29:1: 83–90.

[743] See: The H3Africa, Human, Heredity & Health in Africa website. Accessed January 26, 2017. http://www.h3africa.org/.

[744] Nnamuchi O *op cit* (2016) at 88. See also: Intergraded Biorepository H3Africa Uganda website. Accessed January 26, 2017. http://www.ibru.mak.ac.ug/.

[745] A partnership between Makerere University and the Uganda Virus Research Institute and funded by the UK Medical Research Council and the Wellcome Trust. See: Nnamuchi O *op cit* (2016) at 85.

[746] Sathar MA & Dhai A. 2012. "Laws regulations and guidelines of developed countries, developing countries in Africa, and BRICS regions pertaining to the use of human biological material (HBM) in research." *SAJBL* 5(1): 51-54 at 51.

5.4.2 Ethico-legal framework and governance structures relevant to biobank research

The Constitution of Uganda[747] provides that the State shall take all practical measures to ensure the provision of basic medical services to the population; however, it remains silent on research. The Public Health Act[748] is also completely silent on any aspect related to health research. The National Guidelines for Research Involving Humans as Research Participants,[749] ("National Guidelines") developed by the National Council for Science and Technology[750] appears to be the only document which regulates health research in Uganda. The National Guidelines provide mechanisms for protecting the rights and welfare of research participants; provide ethical standards and procedures for the conduct of research involving humans as research participants; and ensure that researchers take into account social and cultural values of participating communities.[751] The National Guidelines apply to all research involving humans as research participants in Uganda; research conducted in or by public, private, inter-governmental and non-governmental organisations; and research conducted in a foreign country on human materials collected from Uganda.[752]

Therefore, the reach of the National Guidelines is quite broad and would include biobanks. It aims to apply both nationally and internationally, when human materials from Uganda are collected for research purposes and transferred across borders. The oversight functions of research involving human participants lies with RECs (at an organisational level); and the Uganda National Council for Science and Technology,

[747] The Constitution of the Republic of Uganda, 1995. Accessed January 26, 2017. http://www.usig.org/countryinfo/laws/Uganda/CONSTITUTION%20OF%20THE%20REPUBLIC%20OF%20UGANDA%201995.pdf.

[748] The Public Health Act 1935. Accessed January 26, 2017. http://www.ulii.org/ug/legislation/consolidated-act/281.

[749] Uganda's National Council for Science and Technology, National Guidelines for Research Involving Humans as Research Participants, July 2014. Accessed January 26, 2017. https://www.swarthmore.edu/sites/default/files/assets/documents/institutional-review-board/Human_Subjects_Protection_Guidelines_July_2014.pdf.

[750] In accordance with Research Ethics policies: "The Ugandan National Council for Science and Technology (UNCST) has a mandate to facilitate and coordinate the development and implementation of policies and strategies for integrating Science and Technology (S&T) into the national development process. The UNCST is also tasked with overseeing the appropriate application of research ethics policies and practices within Uganda." Accessed January 26, 2017. http://www.ccghr.ca/resources/harmonization/uganda/uganda-research-ethics/.

[751] National Guidelines at 1.

[752] *Ibid.*

(UNCST) in collaboration with the Ugandan National Health Research Organisation (UNHRO) for health research (at a national level).[753] The National Guidelines provide various protections to research participants,[754] significantly including that research should be conducted in a manner that does not violate the rights and welfare of participants *and their communities*. The concept of "community welfare" is not a concept that has been identified as a requirement for research in the UK and Australia. Although, in Australia, there is recognition of respect for different cultural values, this does not extend as far as ensuring that community rights and the welfare of the community are not violated, where health research is concerned.

Noteworthy, with respect to RECs, their role does not stop at the time the protocol is approved, but is rather a continuing function. An REC is required to conduct review of the research at intervals which are appropriate to the degree of risk, but not less than once a year.[755] This creates a responsibility on the REC to ensure continued oversight of the research project. Furthermore, an REC must have a plan for onsite monitoring of approved studies. This is an additional safeguard in order to monitor approved studies.[756] As the National Guidelines form the foundation for health research in Uganda, I will now analyse how consent and data sharing are approached in terms of these guidelines.

5.4.3 Informed consent, data sharing and privacy

The National Guidelines are stringent in their requirements for consent and meeting these requirements is paramount in order to obtain REC approval. In certain instances and for certain types of research, the REC may require that the researcher administer

[753] Nnamuchi O *op cit* (2016) at 88.

[754] Section 2.2.1 of the National Guidelines states that:

"Human Research Participants have a right to, inter alia:

a. Participate in research or not, or withdraw at any time without penalty;
b. Be respected, including the right of their autonomy, culture, beliefs and values;
c. Information about the research (it is important to ensure that information is communicated in understandable language, format and in a conducive environment at all stages of the research);
d. Protection against research related injuries, harm, exploitation, and any other forms of abuse;
e. Privacy and confidentiality of their participation, during and after the research;
f. The standard of health care that is established nationally;
g. Treatment and management of research related injuries; and
h. Reimbursement for costs associated with their participation in the research." at 2.

[755] Section 4.5.1 at 11.

[756] *Ibid.*

a comprehension test in order to ascertain whether the participant has a full understanding of the facts and any associated consequences to participating in the research.[757] Informed consent may be provided in an oral or written form and should not contain any language which insinuates that the participant waives any of his/her rights; or releases the organisation or its agents from liability.[758] The onus to ensure re-consent of the participant, should the project change, or if new information becomes available which could affect the participant's willingness to participate in the project, lies on both the researcher *and the REC*.[759] This requirement reiterates the continuing nature of consent and REC participation throughout the consent process.

Informed consent may be waived by an REC if it determines that: the project carries no more than minimal risk;[760] the project could not be carried out practicably without such waiver; where deception needs to be applied in order to achieve the study objectives; where the risk to the participant would be potentially harmful as a result of a breach of confidentiality, where the informed consent document is the only record linking the participant to the project; and when the participant presents in an emergency situation and informed consent cannot be reasonably obtained from the individual or his/her representative.[761] Future uses of identifiable human materials[762] are allowed in terms of the National Guidelines, as long as appropriate consent has been obtained, including consent to (possible) future uses. In addition, a study conducted in Uganda[763] indicated the willingness of participants to contribute their samples for re-use, with future REC approval being a pre-requisite. A separate consent form (apart from the consent form which is required for enrolment in the study)

[757] Section 5.2 at 16.
[758] *Ibid.*
[759] *Ibid.*
[760] According to section 5.5 of the National Guidelines: "risk that is no more than the risks encountered in normal daily life in a stable society." at 19.
[761] *Ibid.*
[762] According to section 10 of the National Guidelines: "Human materials are substances including, but not limited to, blood, urine, stool, saliva, hair, nail clippings, skin and any other associated bio-products obtained from participants…" at 28.
[763] Wendler D, Pace C, Talisuna A, Maiso F et al. 2005. "Research on stored biological samples: the views of Ugandans." *IRB Ethics & Human Res*. 27: 1-5. See also: Staunton C & Moodley K. 2013. "Challenges in biobank governance in Sub-Saharan Africa." *BMC Medical Ethics* 14-35.

is required for samples that are stored with the intention of being used for future purposes.[764]

Significantly, the National Guidelines provide that a Ugandan scientist *must be included as a co-investigator in all future studies* using human materials collected from Uganda.[765] This will allow for the development of the local researcher as well as continued participation in the project. If identifiable samples have been collected for uses other than for research purposes,[766] consent must be obtained for the use of those samples in any future research projects. Unlike the situation in South Africa regarding ownership, in Uganda it is made quite clear that *ownership of samples remains with the participant*. A participant may withdraw their sample where their samples are linked and where samples are held "in trust on behalf of the sample source by a duly registered and recognised organisation in Uganda."[767] The entity holding the samples in trust acts as custodian of the samples and is entrusted with the authority to decide on matters such as use, transfer, storage and future uses taking into consideration the rights and welfare of the participants.

Therefore, it seems that broad consent is favoured by the National Guidelines as consent to future uses is permitted, with REC approval and an option to withdraw identifiable materials. There appears to be a growing acceptance of broad consent in certain African countries[768] as a favourable means for participants to consent to future uses of materials, whilst still ensuring REC oversight. An MTA must be in place when samples are transferred within the country and outside of the country and human materials cannot be transferred outside Uganda, unless it is demonstrated that in-country capacity to perform certain types of investigations/testing does not exist or is

[764] According to section 10.2 of the National Guidelines: The separate consent form must include the: purpose of sample storage, quantities of samples to be stored, place where samples will be stored, measures to protect confidentiality, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future research and any other information deemed necessary by the researcher or REC. After explaining the need to store the samples, the research participant shall be given the option to choose whether his/her sample should or should not be stored for future studies. at 28.

[765] Section 10.2 at 28.

[766] Section 10.2 of the National Guidelines at 28. E.g.: Routine surveillance, emergency procedures, laboratory quality control notifiable diseases, routine counselling or testing etc.

[767] Section 10.3 at 28.

[768] See: Igbe MA & Adebamowo CA. 2012. "Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria." *BMC Medical Ethics* 13-27; See also: Nnamuchi O *op cit* (2016) at 93; See also: Wendler D, Pace C, Talisuna A, Maiso F et al *op cit* (2005) at 5.

inadequate.[769] In this regard, researchers, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing to fulfil the objectives of the proposed research.[770] The stringent requirements of Uganda's national MTA outline will be discussed in detail in Chapter 6.

With respect to data; ownership, associated intellectual property rights, access thereof and usage must be discussed and agreed upon before the project commences.[771] Researchers must have confidentiality mechanisms in place to protect participants and their communities' confidentiality and a collaborating research partner may not transfer data to a third party without the written consent of the other research partner.[772] This requirement displays the additional mechanisms that the Ugandan framework implements in respect of data access and control. Furthermore, local researchers have unrestricted access rights to data sets collected through collaborative research.[773] The sharing of findings is emphasised in the National Guidelines and includes sharing with the host organisation; participants, key stakeholders; and the communities in which the research was carried out.[774] The National Guidelines stress the importance of maintaining the privacy and confidentiality of the participant, both during and after the research.[775] Privacy and confidentiality extend to the participants' samples and data for collection, storage, transfer and future uses and form a basic right of the participants and their communities in terms of the Guidelines.[776] However, the Guidelines are silent on the specific method of protections in respect of identifiable information. They do not specify whether identifiable information must be anonymised or de-identified in order to achieve privacy protections. This is an issue that requires clarity as silence on the method(s) of protection fails to fulfil the objectives of the Guidelines in respect of privacy and confidentiality.

[769] Section 10.4 at 28-29.
[770] *Ibid* at 29. See also: Staunton C & Moodley K *op cit* (2013) at 35.
[771] Section 11.0 at 32.
[772] *Ibid.*
[773] *Ibid.*
[774] *Ibid.*
[775] *Ibid* at 2.
[776] *Ibid* at 2; 17; 28 and 32.

The Guidelines dedicate a section to community engagement[777] and identify four principles of community engagement, namely respect; mutual understanding; integrity; and transparency.[778] In terms of respect, the Guidelines outline that this concept is demonstrated when stakeholders communicate and act in ways that value and honour each other's perspectives and realities. This extends to respect for local values, cultural beliefs and scientific process. Mutual understanding[779] should inform the study design in order to ensure that it is culturally appropriate. It is imperative that researchers understand the norms, practices and beliefs of relevant local cultures and local social stances and the diverse community stakeholder perspectives, priorities and research requirements.[780] Integrity includes both scientific and ethical integrity in the conduct of the research and is emphasised as being vital to achieving scientific goals and maximising benefits to the community and society.[781] In order to achieve transparency, feedback from stakeholders must be addressed and acknowledged. Stakeholders must also be clear on their respective roles and responsibilities, the constituents they represent, and the extent to which their input may influence research related decisions.[782] Consultation[783] with the community should take place before REC approval is sought and engaging with community members must be treated as an ongoing process until the research reaches completion.

Community engagement by researchers may take a variety of forms and include: community education to improve research literacy; community dialogues to promote understanding; and research participation. In addition, the Guidelines include a section on traditional and complementary medicine research which is subject to the same

[777] According to section 12 of the National Guidelines: "Engaging with the community is a process of building transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations, with the ultimate goal of shaping research collectively. Involvement of community stakeholders shall not override the rights of individuals to consent voluntarily for participation in a research project. Community stakeholders may include individuals and groups that are ultimately representing the interests of the people who would be recruited to or who participate in research as participants, as well as others who are locally affected by the study." at 33.

[778] Section 12 at 33.

[779] According to the National Guidelines are: "A common understanding about objectives and how to achieve them." at 33.

[780] *Ibid.*

[781] *Ibid.*

[782] *Ibid.*

[783] According to the National Guidelines: "Such consultation involves obtaining prior agreement from community gatekeepers such as local chiefs, local administration officials or heads of organisations where research is to be undertaken." at 34.

ethical standards as conventional research practices. There are steep penalties for non-compliance[784] with the National Guidelines and any person or stakeholder may report such non-compliance, which is then actioned by the UNCST. Therefore, the Ugandan system displays many similarities to the UK and Australia, with regard to consent and the secondary uses of samples, however, there are differences in its approach to ownership, community engagement; and the responsibility of REC functioning, which identify the priorities and requirements of a developing African country in comparison to developed frameworks.

The discussions above have examined the ethico-regulatory frameworks specific to biobank research in the UK, Australia and Uganda. An in-depth analysis of the South African position in regard to informed consent, ownership, privacy and confidentiality was highlighted in previous chapters. This current analysis has pointed out many similarities and stark differences between each ethico-legal system. It is now relevant to summarise and compare the positions of the UK, Australia, Uganda and South Africa in order to easily identify the similarities and differences of each system. The benefits of this comparison will place our own South African position in context and allow for our current framework to be challenged in light of these comparative findings.

5.5 Comparative analysis

Using the above discussion as a foundation, a comparison of each country specific ethico-legal framework may be summarised as follows: (only the most pertinent concepts have been summarised in the table below):

[784] According to section 14 of the National Guidelines: "Non-compliance with the guidelines may lead to: revocation of research approval for a study found to be non-compliant; withdrawing research registration permits of researchers involved in repeated non-compliance; suspension and eventual termination of ongoing studies at the site or organization; withholding approval of new studies to be conducted at the organization; disciplinary action by relevant professional bodies for cases of suspected negligence and malpractice; disqualifying a REC that has failed to take adequate measures to ensure compliance with these guidelines or that repeatedly fails to comply with these guidelines." at 36.

Table 5.1

Comparative analysis - UK, Australian, Ugandan and South African systems

Country	Legislation specific to biobanking	Approvals	Consent model	Ownership	Import/export	Community engagement	Privacy safeguards
United Kingdom	No formal law. HRA guidelines apply.	HTA license required. Biobank & REC approval.	Broad Consent.	Participants do not retain ownership. Ownership transferred to biobank.	Import: HTA license desirable. Export: No legal requirement for licensing or ethical approval. MTA required by UK Biobank.	Not specified.	Data requires security measures. Pseudonymi-sation/ coded.
Australia	No formal law. NHMRC guidelines apply.	HREC approval.	Growing support for broad consent.	Remains unsettled. General position: participant relinquishes ownership. Entity = custodian.	Import: Biospecimens must be obtained in a manner consistent with the Australian framework. Export: ethical approval required. MTA = best practice	Specifies community involvement	Data requires security measures. Samples are generally coded.
Uganda	No formal law. UNCST guidelines apply.	Two pronged: First, REC approval. (organisation level) Second, UNCST in collaboration with UNHRO approval. (national level)	Broad consent.	Ownership remains with the participant. Entity = Custodian.	Import: Clearance from UNCST for cross border transfers. Export: Clearance from UNCST. MTA required by national guidelines.	Specified in detail.	General data protection. Non-specific.
South Africa	No formal law. National ethics guidelines apply.	REC approval.	Different forms of consent, including broad consent are implicated.	Unsettled. General position: no one (including an entity) has ownership rights.	Import and export: permit required. MTA required by ethical guidelines.	Mentioned generally.	General data protection Non-specific. Usually: coded or anonymous data.

From Table 5.1 above, it is evident that none of the analysed countries, including South Africa, has laws specific to biobanking. The reason for this may be because many issues relating to biobanking are covered by different pieces of legislation that have an influence on biobank research. As this area of research falls under health research, relevant ethico-legal guidelines are applicable. In terms of the guidelines, all analysed countries require ethical approval for biobank research and view broad consent as an acceptable consent model. The general rule regarding ownership of human materials is that participants relinquish ownership rights in their samples once they have donated these for research purposes. Compared to the South African situation that remains unsettled, Uganda specifically outlines that ownership vests with the participant, although the biobank remains custodian of the materials and in a position of trust.

With regard to the import and export of human materials in the UK, it is desirable for imported tissues to be stored in an entity that has an HTA license. If the entity does not have an HTA license, each research project using the tissue will require NHS REC approval. With regard to export, there is no legal requirement for licensing or ethical approval; yet, voluntary applications for approval may be made to a NHS REC. The Australian position holds that there is an onus on the researcher to establish whether the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation when importing samples. If it cannot be established that the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation, then they should not be used for research purposes. Exporting samples for research is allowed in Australia provided that there is ethical approval, or that the exportation of the biospecimens is consistent with the original consent and ethical approval is provided by an HREC.

In Uganda, importing materials requires clearance from the UNCST, except for the exchange of human materials between organisations within the country. In respect of exporting materials, clearance from UNCST must be obtained and an MTA must be in place. It is important to note that human materials cannot be transferred outside Uganda, unless it is demonstrated that in-country capacity to perform certain types of investigations/testing does not exist or is inadequate. This requirement is similar to the

positions in Botswana and Kenya.[785] In South Africa, the import and export of human materials is governed by the Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes, and gametes.[786] The National Ethics Guidelines published in 2015 are silent on the processes regarding importing or exporting human material. According to the Regulations, a permit issued by the Department of Health is required before any human material may be imported or exported. With regard to community engagement, the UK guidelines are silent. The Australian guidelines specify community involvement under specific circumstances[787] and the Ugandan framework outlines a detailed process with regard to community engagement. The South African guidelines mention community engagement in a very general manner with no specific direction in terms of process. All countries provide that adequate measures should be in place to ensure privacy and confidentiality of participant samples and data. However, while the UK and Australia specify that data should be coded, the South African framework provides different options of data security methods, but leaves the determination of "risk" up to an individual REC. The Ugandan guidelines do not provide for methods of data protection and remain unspecific.

In light of the above comparison, it is evident that broad consent as a model is being embraced by different countries with varying social and economic backgrounds. Adequate governance of the biobank and oversight of research projects are a fundamental concept that cannot be overlooked and suitable methods to protect the privacy of participant information is paramount. These principles resonate with recently published international guidelines[788] as discussed in Chapters 2, 3 and 4. It is also

[785] De Vries, J, Munung SN, Matimba A, McCurdy S et al. 2017. "Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries." *BMC Medical Ethics* 18(8).

[786] *GN* R 182 in *Government Gazette* 35099 of 2 March 2012.

[787] According to section 3.5.11 of the National Statement: "Consent should be sought from appropriate community representatives as well as from the individuals concerned where:
(a) researchers propose to collect genetic material and information from individuals who are chosen because of their membership of a particular community;
(b) the research involves sensitivities for that community; and
(c) there is known to be a culturally relevant community structure involved in such matters." at 44.

[788] The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) Geneva 2016. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-

apparent that because the reach of biobank research penetrates into different aspects of a nation's legislative framework, adopting a singular Act, may not be the most appropriate method of regulating this terrain.

5.6 Conclusion

A Report by the Bioethics Advisory Committee of Singapore, Human Tissue Research[789] ("Singapore Report") states that:

> […] we do not think that it is appropriate to resort to hard-coding specific rules in legislative form for the regulation of research and commercial activity in the genetic and genomic sciences. Overly specific rules run the risk of rapid obsolescence, and of abuse by those minded to be seen to comply only with the letter but not the spirit of the law. In general, we recommend legislative intervention only in situations where it is clear that effective professional self-regulation and a fair balance of rights and interests between individuals and the public in encouraging research cannot be achieved without legislative teeth.

The Report however, does indicate that legislation must be enabling and that appropriate government agencies should exercise supervisory jurisdiction as gatekeepers.[790] It may be argued that that despite some differences, the UK, Australia, Uganda and South Africa have similar ethico-regulatory frameworks for biobank research. I believe that in order for the current South African framework to improve, we should adopt guidance from each specific country identified above, taking international guidelines into account, to the extent that they enhance protections and promote ethical research. The robust nature of the UK and Australian guidelines should be incorporated into South Africa's system, together with the strict requirements and participant protections as offered by the Ugandan framework. This would achieve a strengthened balance which our current "black and white" framework tends to lack. In my opinion, the development of a separate set of regulations to the

humans/; WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

[789] WHO Human Genomics in Global Health, Bioethics Advisory Committee (2002). Report: Human Tissue Research. Singapore. Accessed January 29, 2017. http://www.who.int/genomics/elsi/regulatory_data/region/wpro/096/en/ (Date accessed: 29 January 2017) Also see: Australia's NHMRC Biobank Information Paper at 54-55.

[790] Singapore report at 32.

NHA in South Africa will provide adequate governance for biobank research; have legal standing;[791] and be more flexible to amendment than an Act of Parliament. Harmonising frameworks for biobank research is currently a widely debated topic for discussion,[792] which I will deliberate on in more detail, together with providing my recommendations for South Africa, in Chapter 7.

As mentioned previously, a characteristic feature of biobank research includes the extensive networking of human materials and cross border transfers of samples and data. While a regulatory framework will take time to develop, this aspect can be (and in some instances, is already) regulated by the use of MTAs. In the following chapter, I will discuss MTAs and, in specific, the development of an MTA template, currently being used by the University of Witwatersrand, including the ethico-legal analysis which led to its development and an examination of the processes involved.

[791] As opposed to the quasi-legal status of the current National Ethics Guidelines: National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Ethics Guidelines) *Second Edition.*

[792] Rothstein MA, Knoppers BM & Harrell HL. 2016. "Comparative approaches to Biobanks and privacy." *Journal of Law, Medicine & Ethics* 44(1): 161-172; See also: Dove ES. 2015. "Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework." *Journal of Law, Medicine & Ethics* 43(4): 675-689; See also: Thorogood A & Zawati MH. 2015. "International Guidelines for Privacy in Genomic Biobanking (or the Unexpected Virtue of Pluralism) *Journal of Law, Medicine & Ethics* 43(4): 690-702.

Chapter 6

The Regulation of Human Material Transfer through the use of Material Transfer Agreements[793]

6.1 Introduction

With biobank research on the increase and the history of exploitation in Africa a reality, it has become necessary to manage the transfer of human materials across national boundaries. An MTA is a contract governing the transfer of materials between organisations and/ or institutions, which sets out: what will be done with any material supplied; whether the material will be used in humans or not; the quality of the material; the terms and conditions under which the materials will be used; any modifications to the material; third party transfers; benefit sharing mechanisms; intellectual property rights; and other legal, regulatory guidelines or policies.[794] In South Africa, the HPCSA[795] and the National Department of Health Ethics Guidelines[796] make it a mandatory requirement for MTAs to be concluded before human materials are transferred out of the country. In particular, our National Ethics Guidelines [797] state that:

> Where data or materials are shared with researchers in other institutions, the recipient institution should agree to comply with the requirements of the donor institution. Furthermore, use of the data or material should comply also with any additional requirements of the recipient institution. *Inter-institutional sharing agreements should be confirmed in writing*. (*my emphasis*).

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[793] Two outcomes of this chapter are: Mahomed S, Behrens K, Slabbert MN, Sanne I. 2016. "Managing Human Tissue Transfer across National Boundaries: An approach from a South African Institution." *DWB* 16(1): 29-35; and The Material Transfer Agreement for Human Biological Materials and Data (May 2017 version) developed by Mahomed S.

[794] The Human Research Ethics Committee Medical: Material Transfer Agreement for Human Biological Materials, developed by Mahomed S through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand with support from the Wits Biobanks Ethics Committee and Wits Legal Office. Accessed July 02, 2017. https://www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/biobanks-ethics-committee/.

[795] HPCSA "Guidelines for Good Practice in Health Care Professions: General Ethical Guideline for Health Researchers." September 2016 Booklet 13.

[796] National Department of Health. 2015. "Ethics in Health Research: Principles, Processes and Structures." (National Ethics Guidelines) *Second Edition.*

[797] Section 3.5.2.3 at 53.

Although the National Ethics Guidelines only came into effect during 2015, making inter-institutional agreements mandatory, the HPCSA guidelines came into effect in 2008. Therefore, the requirement of having MTAs in place when cross border transfers of human materials are contemplated, is not something new. With regard to the complexities surrounding the transfer of human materials, there have not been many empirical studies undertaken to substantiate the anecdotal evidence that human materials are in fact leaving South Africa without the necessary ethico-regulatory requirements being satisfied. In the first empirical study to be conducted in South Africa on the issue, an examination was undertaken to establish whether or not researchers and a REC at a South African institution addressed the ethical issues and complied with legislature, regulations, national and/ or international guidelines with regard to the use, collection, storage, transfer and benefit-sharing relating to human materials in collaborative research. This study was specific to the transfer of human materials between South Africa and developed countries. The study was a retrospective, cross-sectional descriptive audit of research protocols submitted from January 2004 to December 2009 (inclusive) for ethical review to the particular institution's REC. Therefore, there were limitations in terms of disclosing incidental findings.[798] The results of the study found that human materials were unequivocally leaving South Africa without export permits and MTAs in place, during the process of international collaborative research.[799] This disturbing reality, if perpetuated, could result in a complete misuse of human materials by the recipient institution and/ or any third party institution to which the materials are subsequently transferred. It is therefore essential that a carefully drafted MTA, which incorporates very specific ethical and legal considerations to safeguard the donor, researcher and providing institute is concluded and approved by an REC before material transfer takes place.

There are many accepted templates of MTAs that currently exist internationally. However, these templates do not address the specific concerns of South Africa and even of Africa as a continent.[800] When drafting an MTA for biobank research, emphasis must be placed on protecting the participant from being exploited. It is their

[798] Sathar A, Dhai A & van der Linde S. 2013. "Collaborative International Research: Ethical and Regulatory Issues Pertaining to Human Biological Materials at a South African Institutional Research Ethics Committee" *DWB* 14(3): 150-7.
[799] *Ibid.*
[800] Mahomed S, Behrens K, Slabbert MN, Sanne I *op cit* (2016) at 29.

tissues that are being utilised for research purposes and which result in the breakthrough developments that we see in the scientific sphere, but more often than not, their value is not adequately recognised. It is also imperative that specific ethico-legal concepts, such as informed consent, secondary uses, benefit sharing and ownership, be included into the MTA and are adequately addressed, as these concepts are often the focus of participant concerns when their materials are transferred across borders. In addition, the concerns and complexities relevant to African communities are very different to those experienced in the West, given the disproportionate power imbalances in respect of international collaborative research relationships and the context of exploitation which historically defines the African context. When drafting regulatory documents, we must also be mindful of the fact that African communities attach a deep cultural significance to their blood and human materials in general.[801] In the preceding chapter, I canvassed the diverse ethico-regulatory systems with regard to biobank research in the United Kingdom, Australia and Uganda.[802] It will therefore be prudent at this stage to assess whether these countries require MTAs and if so, whether they have national requirements enforcing compliance in this regard.

6.2 MTAs in the United Kingdom, Australia and Uganda

6.2.1 United Kingdom

In the UK, the HRA SoPs are silent on the issue of MTAs,[803] however, they do specify a requirement for Data Sharing Agreements to be in place with researchers and that the Research Database team must have specific policies in respect of access and processes for de-identification of data extracts.[804] The ethical and governance

[801] Moodley K, Sibanda N, February K & Rossouw T. 2014. "It's my blood": ethical complexities in the use, storage and export of biological samples: perspectives from South African research participants." *BMC Medical Ethics* 15:4. See also: Moodley K & Singh S. 2016. "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa." *BMC Medical Ethics* 17:57.

[802] The justification for comparing the United Kingdom, Australia and Uganda in this regard, is a follow on from the preceding comparative chapter 5.

[803] However, the HRA website does refer to a toolkit created by the National Cancer Research Institute (NCRI) to assist organisations in developing a policy for access to collections of samples or data, including a template Material Transfer Agreement. This template, however, does not form part of the actual SoP document. Accessed July 02, 2017. http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/human-tissue-2/.

[804] Section 11.26 at 194.

framework established by UK Biobank stipulates that licences for specific uses of data and/or samples will be granted for research that has been scientifically and ethically approved and that is consistent with UK Biobank's purpose.[805] Licences will be granted for specific uses, under strict terms and conditions, in compliance with the consent provided, in "Standard Access Agreements."[806] MTAs are a requirement and are discussed in more detail in UK Biobank's Access Procedures,[807] the objective of which is to facilitate access to the samples and data in order for the broadest possible usage, while being consistent with participant consent and lawful and compatible with respect for human rights.

UK Biobank has a standard MTA for Applicant's and Collaborators. The MTA is an agreement between UK Biobank and the Applicant Institution and UK Biobank and the Collaborating Institution(s). The Applicant Principal Investigator (PI) is not a party to the agreement, however he/she must read and understand the MTA in order for him/ her to be aware of their Institutions' obligations to both the UK Biobank and to UK Biobanks participants. The same provision applies to Collaborating Institutions and Collaborating Investigators. UK Biobank requires that all Collaborating Institutions also execute standard MTAs and provide copies of same to UK Biobank, together with the Applicant MTA which must be signed by an authorised signatory of the Applicant Institution.[808] The MTA is broken up into two parts: first, an agreement to be signed by the Applicant Institution; and second, an agreement to be signed by the Collaborating Institution(s). The MTA stipulates specific terms and conditions for both the Applicant and Collaborating Institute(s). This includes information on: the supply of the materials[809] by UK Biobank; usage of materials for approved research projects only; the provision of samples and data (explicitly stating that UK Biobank is the owner of the property in the samples and the owner of the intellectual property rights in the data and that the Applicant/ Collaborator is granted a "limited, revocable, worldwide, royalty-free, non-exclusive licence"[810] only to use the samples and/or data); data

[805] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) at 13.
[806] *Ibid.*
[807] Access Procedures: Application and review procedures for access to the UK Biobank Resource, Version 1.0 (November 2011). Accessed February 27, 2017. http://www.ukbiobank.ac.uk/resources/.
[808] UK Biobank's Collaborator MTA v1.3. Accessed February 27, 2017. http://www.ukbiobank.a"c.uk/resources/.
[809] According to UK Biobank's standard MTA for Applicants, Materials are defined as: "the data and/or samples supplied by UK Biobank to the Applicant under this agreement."
[810] UK Biobank's Collaborator MTA v1.3.

results deriving from use of the samples and/or data which will belong to the Applicant/ Collaborator; the withdrawal of samples and/or data by participants; and the protection of the identity of participants (in specific, should the Applicant/ Collaborator inadvertently identify a participant(s), UK biobank must be notified immediately and the circumstances by which identification occurred must be explained in detail).

The MTA further outlines that: periodic updates must be provided to UK Biobank in the form of a report; the location of the samples must be disclosed and third party transfers may only occur with the written permission of UK Biobank; the samples must be destroyed on completion of the project (such destruction must be confirmed in writing by the Applicant/Collaborator); a summary of the project and details of the Applicant/Collaborator will be published on UK Biobank's website; there is a time period within which results should be published by the Applicant/ Collaborator; UK Biobank must be notified before any public presentation or publication is made in any format; UK Biobank must be provided with credit as the source of the material; and auditing of the premises of the Applicant/Collaborator will occur in order to review security. The MTA further specifies: storage or other arrangements in respect of the materials; confidentiality of the Applicant's/Collaborator's information; termination of the agreement and the conditions of termination; and dispute resolution processes (specifically that any unresolved dispute is to be mediated at the London Court of International Arbitration and that the medium of language used will be English). Therefore, in the UK, there appears to be no *prima facie* legal requirement for an MTA to be in place for cross border transfers of human materials, however, UK Biobank in its capacity as a national biobank does require such an agreement and has MTA templates with very specific terms and conditions for Applicant and Collaborator Institutions. In addition, the same MTA template is used for both samples and data. It can therefore be reasonably assumed that it is a national practice that MTAs are required for cross border transfers of human materials in the UK. I will now turn to discuss the position in Australia with regard to transfer agreements between local institutions and across borders.

6.2.2 Australia

The Australian Code for the Responsible Conduct of Researchers (the Code) indicates that when projects span over several institutions, an agreement (which should be developed at the outset) that covers the storage of research data and primary materials[811] within each institution must be instituted.[812] Section 8 of the Code deals with collaborative research across institutions. In specific, that should organisations become involved in a joint research project, such organisations must ensure that an agreement is reached on the management of the research.[813] The Code goes on to state that:

> The agreement should be in writing. It must cover intellectual property, confidentiality and copyright issues; sharing commercial returns, responsibility for ethics and safety clearances; and reporting to appropriate agencies. It should address the protocols to be followed by the partners when disseminating the research outcomes, and the management of primary research materials and research data.[814]

Such agreement may be concluded in a variety of formats, including, in the form of a legal contract, an exchange of letters, or a research management plan(s) signed by all parties or appropriate representatives.[815] Section 8.4 of the Code further cautions that researchers involved in joint research must be aware of and comply with all policies and written agreements affecting the project, in particular, those relating to the dissemination of research findings and the management of research data and primary materials.[816] The NHMRC Biobanks Information Paper[817] (Information Paper) stipulates that an MTA is an integral part of biobank research which ensures traceability of specimens and data, and provides for transparency and accountability

[811] Which includes biological materials. See: Section 2 of the Australian Government, NHMRC, Australian Research Council, Australian Code for the Responsible Conduct of Research. Accessed March 08, 2017. https://www.nhmrc.gov.au/_files_nhmrc/file/publications/r39_australian_code_responsible_conduct_research_150811.pdf.

[812] Section 2.2.3.

[813] Section 8.1.

[814] *Ibid*.

[815] *Ibid.*

[816] Section 8.4.

[817] Australian Government, NHMRC, Biobanks Information Paper, 2010. Accessed January 21, 2017. https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e110_biobanks_information_paper_140520.pdf.

on the part of biobanks and their users.[818] According to the Information Paper, an MTA is:

> A binding legal agreement between a biobank and the researcher(s) who is/are to receive the biospecimens and data, setting out the conditions of transfer and use.[819]

The Information Paper further specifies that detailed care must be taken when samples are transferred and that many biobanks require a formal MTA to be concluded prior to transfer taking place.[820] Generally MTAs specify: relevant parties to the "transaction;" details of the samples; conditions of transfer; the destruction or return of residual samples after use; third party and trans-border restrictions on transfer; intellectual property rights; and the return of research results to the biobank within a specific time frame.[821] In addition, the following might also be considered for inclusion within the MTA: use should only be for an intended purpose; no attempt should be made to obtain identifying information; no third party transfers should take place without prior written permission of the repository; and any resulting publication must acknowledge the repository.[822]

The Information Paper's flexible language results in no solid requirements created for MTAs. An institution "may" or "might" consider for inclusion the abovementioned terms and conditions, however, failure to do so, will not result in digression of policy requirements as such terms and conditions do not appear to be mandatory. As most biobanks are members of the Australasian Biospecimens Network (ABN), and as the ABN Guidelines for Biorepository Protocols makes it mandatory for an MTA (or similar document) to be concluded before providing samples, it can be reasonably assumed that most biobanks in Australia require MTAs to be enforced when samples are transferred. I now turn to evaluate the position in Uganda.

[818] NHMRC, Biobanks Information Paper at 46.
[819] *Ibid.*
[820] *Ibid* at 66.
[821] *Ibid* at 66.
[822] *Ibid* at 67.

6.2.3 Uganda

The National Guidelines for Research Involving Humans as Research Participants,[823] (National Guidelines) which appears to be the only document which regulates health research in Uganda, specifically outlines certain requirements that must be met when human materials are transferred for storage or any other uses between organisations within the country and transferred outside the country. A mandatory requirement is that a contractual agreement, in the form of an MTA, must be in place when such transfer is contemplated.[824] Furthermore, the transfer of human materials outside the country must be qualified by researchers, sponsors and collaborators demonstrating that local capacity regarding certain types of investigations or testing is inadequate or does not exist. In addition, researchers, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing required to fulfil the objectives of the proposed research.[825]

Any transfers of human materials require clearance from UNCST with the exception of transfers that take place between organisations within the country. An application for permission to exchange or transfer human materials for research purposes is made to the UNCST and such application must be accompanied by an MTA before it will receive consideration.[826] The National Guidelines are stringent in not only the requirement for an MTA for the exchange or transfer of human materials, but also with regard to the details that should be included in the contractual agreement. The National Guidelines stipulate (as a guide) that the following clauses must be included in the MTA:[827] details of the parties (the provider and recipient organisations) to the agreement; a description of the materials being transferred including any derivative products; the quantity of materials and that materials are appropriately packaged; the purpose and usage of materials, including details regarding whether such materials will be used for research or commercial purposes or both; details of any authorised

[823] Uganda's National Council for Science and Technology, National Guidelines for Research Involving Humans as Research Participants, July 2014. Accessed January 26, 2017. https://www.swarthmore.edu/sites/default/files/assets/documents/institutional-review-board/Human_Subjects_Protection_Guidelines_July_2014.pdf.
[824] Section 10.4 at 28.
[825] Section 10.4 at 29.
[826] *Ibid.*
[827] *Ibid* at 29-30.

users of the materials and that such user(s) has agreed to the terms and conditions of the MTA; that third party transfers not mentioned within the MTA are prohibited without the written consent of the provider organisation or its assignees; the location of transfer, storage or use; and the period of use of the material.

In this regard the National Guidelines outline that a date for termination be specified in order to avoid any indefinite use of the materials by the recipient organisation, however, such date may be extended by written mutual consent of the parties. On termination, the provider organisation may request that the materials be returned or destroyed.[828] The MTA should also specify: if the materials will be used for any future unknown uses;[829] a disposal plan for the materials and documented proof of such disposal; restrictions of use of the materials as prescribed by the provider institute to the recipient institute; whether the recipient organisation may own any derivatives of the material developed over time;[830] and the details of who owns any new products discovered through the use of the material. It is critical to note at this juncture that should the MTA contain no details of who owns any new products discovered, then the provider organisation *automatically* assumes ownership.[831] This means that if an outside organisation discovers a new product from the use of human materials which have been sourced from Uganda, and that if no stipulation as to ownership is included in the MTA, then the provider institute based in Uganda can automatically lay claim to ownership of the new discovered product. This is a bold step by Uganda, which could be considered contrary to internationally accepted practices regarding intellectual property rights and patents in new discoveries. The requirements for commercialisation rights include that the MTA should indicate specific direction for handling commercialisable products, including the sharing of any royalties. A separate MTA may be negotiated should the need for commercialisation arise. The MTA must clearly state the technologies that will be transferred to the provider organisation or country and other collateral benefits to the provider organisation may be included.[832]

[828] *Ibid* at 29.

[829] According to section 10.4 of the National Guidelines: any future uses of stored samples will be subject to review and ethical approval by a REC in Uganda.

[830] According to section 10.4 of the National Guidelines: the provider organisation may allow the recipient organisation to retain the derivatives without any stipulations.

[831] Section 10.4 at 30.

[832] According to section 10.4 of the National Guidelines: such benefits include but are not limited to: building infrastructure, training and the provision of certain services.

The MTA must also stipulate that the provider organisation may place restrictions on the recipient organisation's publication rights in respect of data obtained from the material and should such allowance be granted by the provider organisation, acknowledgement of the providing organisation as the source of the material may be agreed upon and included. In addition, the MTA should be drafted taking into consideration the laws and regulations of both the provider and recipient organisation. Clauses regarding liability, warranty, amendment and termination of the MTA should also form part of the contract. Unfortunately, the MTA requirements are silent regarding a dispute resolution process, should a disagreement arise between the provider and/or recipient organisation, and/or any third party organisations. Therefore, the jurisdiction for dispute resolution is also not outlined. It can be assumed that in the absence of such requirement, the process and jurisdiction of such process is negotiated between the parties.

The process for exchange or transfer of human materials to a country outside Uganda is as follows:

1. The research project that involves and exchange or transfer must be registered by UNCST;
2. The applicant must be a legal resident of Uganda and be affiliated to a locally registered and recognised organisation in Uganda;
3. Such request for exchange or transfer shall be made in writing to the UNCST; and
4. The MTA and any other relevant documents shall accompany such request.[833]

It is evident that Uganda has stringent stipulations as to what should be included within an MTA for transfers or exchanges of materials outside the country. In addition, the repercussions of non-compliance with the Guidelines are equally as stringent and may even lead to the disqualification of an REC who has been non-compliant.[834] However,

[833] Section 10.5 at 31.

[834] According to section 14 of the National Guidelines: "Non-compliance with these guidelines may lead to: a. Revocation of research approval for a study found to be non-compliant; b. Withdrawing research registration permits of researchers involved in repeated non-compliance; c. Suspension and eventual termination of ongoing studies at the site or organisation; d. Withholding approval of new studies to be conducted at the organisation; e. Disciplinary action by relevant professional bodies for cases of suspected

as the Guidelines are fairly new,[835] the practical effects of implementing these provisions in collaborative research will be challenged as the requirements of the Guidelines are tested.

6.2.4 Conclusion

From the above discussion it is evident that although a requirement for MTAs does not fall within the ambit of a particular legislative prerequisite in the UK, Australia or Uganda, they do form part of national (ethical) guidelines. It is also evident that good practice requires an MTA to be enforced before the transfer of materials is contemplated. In this regard, UK Biobank has developed its own unique templates; Australian biobanks who are members of the ABN (and majority of Australian biobanks are members of the Network) must have MTAs in place; and the National Guidelines in Uganda outline stringent requirements for MTAs when cross border transfers are contemplated. These various positions echo the current South African situation where the requirement for an MTA is located in ethical guidelines only and not contained within an actual Act of Parliament or regulation thereto. Yet, any argument which attempts to discredit the requirement for an MTA to be enforced when cross border transfers of human materials are contemplated, is not justifiable. Although these requirements are predominately contained within so called "soft laws," the position of having an MTA in place when cross-border transfers are contemplated, has been accepted at a global level. The WMA Declaration of Taipei which came into effect in October 2016, requires an MTA to be enforced amongst one of its governance arrangements.[836] In addition, the CIOMS[837] Guidelines which were revised in 2016,

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negligence and malpractice; and f. Disqualifying a REC that has failed to take adequate measures to ensure compliance with these guidelines or that repeatedly fails to comply with these guidelines."

[835] The Ugandan National Guidelines came into effect in July 2014.

[836] WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Accessed November 08, 2017. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

[837] The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) Geneva 2016. Accessed November 08, 2017. https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/.

outlines that the transfer of biological materials must be covered by an MTA. According to the CIOMS Guidelines:

> This MTA must ensure that the biological materials are documented in such a way that they can be retrieved. The range and duration of use and what needs to happen at the end of the period of use must also be specified. All responsibilities concerning these elements of an MTA need to be clearly stated in the agreement. An MTA is also needed in multinational research projects in which one entity collects samples from persons in all participating countries and stores them in a single biobank.[838]

I have outlined the position regarding MTAs by conducting a comparative analysis of three, very different, ethico-legal systems. It has been established that a requirement for an MTA in South Africa forms part of our ethical guidelines only. Currently, unlike the UK, Australia and Uganda, no national MTA template or requirements for what should be contained in an MTA exists in our country. It has been left up to individual institutions to determine the content of this contractual agreement. I will now move on to discuss the provisions of an MTA template that was developed as part of my doctoral research and drafted with the South African ethical and regulatory perspective in mind.

6.3 A South African MTA Template[839] (The MTA template)

6.3.1 The process of development

South Africa currently does not have a national MTA template specific to the transfer of human materials, which addresses the concerns of the South African researcher and research participant. There are many different types of MTAs available, however, these templates usually originate from developed, Western countries, where perceptions and protections are viewed through a particular lens. This does not mean that these specific templates should not be regarded when considering a template unique to the South African context. However, it does mean that we require a template that speaks to the direct issues from our local context, that institutions, researchers and participants face on a daily basis, when collaborative research is contemplated. Having a workable template in use also provides for certain legislative and ethical

[838] Guideline 11 of the CIOMS Guidelines at 45.
[839] Please find a copy of the MTA Template, annexed hereto and marked as "**Annexure II**."

protections to be met with regard to biobank research, which is imperative when navigating around our current non-specific legal framework. Recognising this gap and in order to facilitate ethico-legal research, I developed an MTA template and presented the document to the Biobanks Ethics Committee (BEC) of the University of the Witwatersrand,[840] (Wits) of which I am a member. The template was initially considered by the Committee in 2014 and was subsequently ratified, with minor amendment, by the Wits legal office. The template is a living document which has been continually tested, reviewed and developed since its inception in 2014, as the need arises. The most recent developments to the template were made in May 2017[841] and the template is currently being used by Wits researchers, the South African Medical Association[842] and the Hospice Palliative Care Association.[843] According to the National Department of Health (NDoH) Export Permit Office, the MTA template is also used by most applicants who export biological substances.[844] The template is available for open access use by any other organisation/institution interested in utilising it. The BEC also developed a principles and policy document on biobanks,[845] which I contributed towards. This guideline document sets out amongst others: the objectives of a biobank; the importance of stakeholder consultation and ongoing information sharing; aspects of informed consent and withdrawal of samples; privacy measures and risks; benefits; governance; management; and biobank closure. I will now move on to discuss the most relevant considerations that have been incorporated into the MTA template.

[840] The Biobanks Ethics Committee is a sub-committee of the Wits HREC. It was established in 2013 and is currently the only committee in the country whose sole purpose is to review applications for the establishment of biobanks; and applications for storage, retrieval or transfer between biobanks and make recommendations to the HREC. The policy documents and application forms of the Biobanks Ethics Committee may be found at the following website: https://www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/biobanks-ethics-committee/ (Accessed July 02, 2017.)

[841] The University of the Witwatersrand Biobanks Ethics Committee MTA. Accessed July 02, 2017. https://www.wits.ac.za/ethics/biobanks-ethics-committee/.

[842] The South African Medical Association MTA. Accessed July 02, 2017. https://www.samedical.org/file/464.

[843] The Hospice Palliative Care Association MTA. Accessed July 02, 2017. http://www.hpca.co.za/item/material-transfer-agreement.html?category_id=23.

[844] Email correspondence from Motopi L, of the NDoH Export Permit Office attached hereto and marked as "**Annexure III.**"

[845] The Human Research Ethics Committee Medical: Principles and Policy on Biobanks, Faculty of Health Sciences, University of the Witwatersrand. Accessed October 21, 2017. https://www.wits.ac.za/media/wits-university/research/documents/HREC%20principles%20and%20policy%20on%20biobanking.pdf.

6.3.2 The content

After considering international and regional templates,[846] the South African MTA template was drafted with an emphasis on protecting the participant/ donor from being exploited. After all, it is their tissues that are being utilised for research purposes and which result in the breakthrough developments that we see in the scientific sphere, but more often than not, their value is not adequately recognised.[847] Importantly, the MTA template offers a definition of a biobank, which is also included within the BECs principles and policies on biobanks. The MTA defines a biobank as:

> an organised collection of Human Biological Material and associated data from different individuals, which are usually kept for an unlimited period of time, for the purposes of health research.

This definition is much broader than the definition contained within our National Ethical Guidelines. It also includes an unlimited storage period for materials, which serves the best interests of genetic research. The MTA template is quite different from traditional templates in that it includes specific clauses which safeguard the protections of participants/donors and researchers alike, and which are not customarily incorporated into legal contracts. In addition, there are three signatories to the agreement: the Providing Institute's representative (PI); the Recipient Institute's representative; and the Chair of the HREC (of the Providing Institute).

Traditionally, an MTA will require the providing and recipient institute as signatories only. However, as HREC oversight is emphasised throughout the MTA template, it is logical to include the Chair of the HREC as an additional signatory. Furthermore, the MTA emphasises that no materials may be transferred for purposes of a research project that has not been approved by the HREC. This provides additional safeguards in respect of secondary uses and third party transfers of materials which I will discuss

[846] Draft Material Transfer Agreement adapted for the National Health Research Ethics Council, developed by Glaudina Loots (Director: Health Innovation – Department of Science and Technology); Fred Hutchinson Material Transfer Agreement for Non Profit Organisations; South African National Botanical Institute Agreement (B) for the Supply of Biological Material; Uganda's Standard Material Transfer Agreement; UHN (Toronto) Technology, Development and Commercialisation Material Transfer Agreement; UW TechTransfer Invention Licensing UW CFAR HIV Specimen Repository Materials Transfer Agreement (Not-for-Profit); University College London Standard Material Transfer Agreement; WITS Health Consortium Standard Material Transfer Agreement.

[847] Mahomed S, Behrens K, Slabbert MN, Sanne I *op cit* (2016) at 31.

further on in this section. Additionally, the providing institute remains custodian[848] of the materials *even after transfer has taken place*. Therefore, not only does the providing institute act as "protector" of the materials within South African borders, but this right also extends to the materials once they are moved outside of our borders. This clause was inserted in order to prevent outside institutions from withholding (without agreement) a local researcher's samples after projects have come to an end. As a member of the BEC, this reality has been faced by us in the past,[849] where an outside institution claimed ownership of the researcher's samples after the project had reached completion. On challenging this incorrect perception of the outside institution, the Chair of the Wits HREC was able to negotiate for the return of the researcher's samples based on the principle that the parties' had signed the MTA and therefore agreed to the providing institute remaining custodian of the materials. I will now provide an overview of the MTA template as a whole by discussing certain concepts which are currently incorporated into the template.

6.4 Concepts incorporated into the MTA template

6.4.1 Benefit sharing

As the central theme of the MTA template centres on the protection of the participant/donor and the best interests of the researcher and participant/donor, benefit sharing was included within the template. This is not a concept which is usually incorporated into an MTA, which therefore makes the template unique in this regard. According to the template, a benefit is defined as:

> …the benefit that will be received by the Provider from the use of the Materials by the Recipient. Benefits may include, amongst others, the sharing of information, use of research results, royalties, acknowledgement of the Provider as the source of the Materials, publication rights, transfer of technology or materials, and capacity building.[850]

[848] According to the MTA template, a custodian means: "a person or entity entrusted by the Donor with safeguarding and protecting the Materials." at 7.
[849] Communication from Profs Cleaton-Jones and Dhai.
[850] MTA template at 6.

This definition is an adjusted one by the Wits legal office, to suit University requirements. However, my recommendation would be that this definition includes the donor and reads as follows:

> …the benefit that will be received by the Provider *and the Donor* from the use of the Materials by the Recipient… (*my emphasis)*

Capacity building, such as training and development of local researchers should also not be limited to the Provider only. This should be extended to the participant population as well. For example, capacity building could include building a clinic or contributing to the building of a clinic in the local participant area. The MTA contains a section on benefit sharing and stipulates that the sharing of benefits should be discussed and negotiated between the Provider and the Recipient before materials are transferred. The parties must also record any benefit sharing mechanisms within a benefit sharing arrangement. As the concept of benefit sharing is not yet a legal requirement in South Africa, albeit the HPCSAs requirement for benefits to be made available for the country when collaborative research is contemplated, this clause is particularly difficult to enforce.

6.4.2 Data

In the MTA template, materials include human biological materials and data. This is similar to the current stipulations of UK Biobank. This recent inclusion of data into the definition of materials was effected as protecting human biological materials only, without protecting the resultant data, will be counterproductive. As most genetic research includes the analysis and extraction of data, providing protections for the transfer of data is crucial to serve the best interests of the researcher and participant. Data has been defined as:

> …any information, including personal information in any form, derived directly or indirectly during the conduct of research or clinical care.[851]

As per the template, the same protections that are afforded to human biological materials are extended to any data derived directly or indirectly during the conduct of the research or clinical care of the participant. This incorporation of data into the MTA

[851] MTA template at 7.

template (where materials are defined to include data) causes the template to be all encompassing. The need for a separate data sharing agreement may even fall away depending on the extent and nature of the research.[852]

6.4.3 Secondary uses and HREC oversight

As secondary uses of materials remains undefined per the NHA and its regulations,[853] and since the secondary use of materials is key to biobanking, the MTA template defines secondary uses as:

> use of the Materials for health research purposes other than the uses determined in the approved protocol. Secondary uses must be approved by the HREC.[854]

This oversight is extended to any third party transfers as well.[855] The justification for the approval of secondary uses by the HREC is that as secondary uses of materials include health research as contemplated by section 1 of the NHA and as all HRECs are required to review and approve health research proposals and protocols, approval for secondary uses of material must be obtained from an HREC. With regard to third party transfers, it is in the best interests of the participant and the providing institution that the HREC approves any subsequent transfers of materials. Such approval will be in writing and contain conditions as the Provider may deem fit in its sole discretion and that will be agreed upon by the Recipient in writing.[856]

6.4.4 Identifiability and feedback

The MTA template also provides additional safeguards in respect of the identifiability of materials. It is a requirement that should the materials become identifiable for any reason, by the Recipient,[857] the Provider must be informed. The Provider then

[852] This is also in keeping with the UK Biobank's standard MTA for Applicants where Materials are defined as: "the data and/or samples supplied by UK Biobank to the Applicant under this agreement."
[853] According to the National Ethics Guidelines, Secondary Use means: "use in research of materials or data originally collected for other purposes." at 43.
[854] MTA template at 8.
[855] Clause 4.6 of the MTA template at 10.
[856] *Ibid.*
[857] Clause 4.7 of the MTA template at 10.

becomes responsible for informing the HREC, the donor/s and for obtaining approval from the HREC and consent from the donor/s (where reasonably possible) for any further uses of the materials. This requirement acts as an additional safeguard in respect of the identifiability of the materials. The MTA also contains a section on acknowledgements and obligations of the Recipient. In particular, it is an obligation of the Recipient to:

> …deliver feedback to the Provider on the development and progress made with regard to the Project by supplying the Provider with updated information where relevant and in terms of applicable ethical and legal requirements.

Oftentimes, once Materials are transferred, the Providing institute is no longer involved with the process or updated with regard to the development and progress made. This clause was inserted to ensure that the Providing institute is not overlooked after transfer occurs.

6.4.5 Termination

The MTA contains a termination clause, which is particularly relevant and oftentimes disregarded as an immediate concern when collaborative research is anticipated. A termination report is required from the Recipient should the Project terminate for any reason whatsoever.[858]

Termination of the Project will occur under one or more of the following circumstances:

- the Project reaches completion;
- the Project cannot be carried out by the Recipient for any reason whatsoever, including but not limited to the following:
    - the Donors withdraw consent for use as contemplated hereunder and in such numbers as to render continuation of the Project impracticable or impossible;
    - the Recipient entity dissolves, winds-up or ceases to continue operating for any reason whatsoever;
    - the HREC withdraws approval for the Project in its entirety;
    - either Party terminates the Agreement on reasonable notice;
    - a force majeure makes continuance of the Project impracticable or impossible.[859]

[858] Clause 8.1 of the MTA template at 11.
[859] Clause 8.2 of the MTA template at 11-12.

Should the Project terminate, the Recipient will immediately discontinue using the materials for any purpose whatsoever and either destroy, return to the Provider, transfer the materials, or any other arrangement made, as approved by the HREC.[860]

6.4.6 Informed consent

Informed consent is not traditionally included within an MTA, however, the MTA template contains specific information with regard to informed consent in order to explicitly ensure that participants have been informed of secondary uses, will be informed of any progress made in terms of the research project (where reasonably possible) and informed of third party transfers. According to the informed consent clause, in the event of secondary uses, the MTA template provides that the participants have consented thereto, insofar as the secondary uses have been approved by the HREC. In addition, where it is reasonably possible, the Provider will inform the participants of developments or progress made by the Recipient in the Project and which is relevant to the participants' informed consent. In addition, the participants must be informed and accept that on termination, the materials will be returned to the Provider, destroyed, or any other arrangement made as determined by the Provider and with the approval of the HREC. The participants must also be informed that should the Recipient wish to conduct studies or use the material for any other purpose than that approved by the HREC, the Provider must be notified in writing and HREC approval must first be obtained.

6.4.7 Dispute settlement

With regard to dispute settlement, the MTA states that: within a period of fourteen days after the date on which the dispute arose (the Dispute Date) the Parties will meet to discuss the dispute and will endeavour to resolve the dispute amicably. If the Parties are unable to resolve the dispute within thirty days from the Dispute Date the dispute will be referred to the Vice–Chancellor or a Deputy Vice-Chancellor of the University and the Chief Executive Officer of the Recipient or their duly appointed representative/s, who will use their best endeavours to resolve the dispute. Their determination will be final and binding and will be carried into effect by the Parties. If

[860] Clauses 8.3 and 8.4 of the MTA template at 12.

the dispute still remains unresolved within a period of thirty days after it has been referred, either Party may institute action in the South Gauteng High Court, Johannesburg, unless the Parties agree to resolve such dispute by arbitration in terms of a separate arbitration agreement.[861] It was decided that jurisdiction for resolving the dispute should remain within Gauteng province as this serves the best interests of the Wits researcher who is based in the region. In addition, should any dispute arise and jurisdiction be outside South Africa, our local researchers and institutions may not be able to afford to attend the proceedings. This requirement, although challenged by international collaborators,[862] is in keeping with Western standards. In terms of its dispute resolution processes, UK Biobank specifically outlines that any unresolved dispute is to be mediated at the London Court of International Arbitration and that the medium of language used will be English.[863]

6.4.8 Additional pertinent concepts

The MTA does not specify ownership of materials as this concept causes unnecessary confusion. It has chosen to confer custodianship of materials on the Provider, and as explained, such custodianship remains with the Provider even after transfer of the materials takes place. The MTA does stipulate that intellectual property will be dealt with through relevant laws related to the applicable protocol and underlying third party agreements, such as a benefit sharing agreement, in so far as there are any.[864] Clause 12 outlines the confidentiality provisions that must be respected with regard to the materials and the participants' privacy. With regard to publications and publicity, the MTA provides that:

> Where the Recipient wishes to publish any information concerning the Project (in either oral or written form), the Provider must be notified and provided with a copy of the publication at least ten (10) days prior to submission of the proposed publication. The Provider must inform the Recipient whether any information related to the publication must be removed or included and provide reasons to substantiate the removal or addition of such information.

[861] Clause 10 of the MTA template at 13-14.
[862] This is a challenge that the Committee and the Wits legal Office has faced.
[863] UK Biobank's Collaborator MTA v1.3.
[864] Clause 11 of the MTA template at 14.

> The Provider must be supplied with a final copy of the publication before publication by the Recipient. The Recipient must acknowledge the Provider's contribution of the Material unless otherwise requested by the Provider.[865]

This clause was inserted to ensure that local researchers are involved in the publication process and are awarded the necessary credit where so due. The MTA template is quite comprehensive and consists of two annexures. Annexure A contains information on the use of the materials and Annexure B is the benefit sharing arrangement which both parties must agree to before transfer takes place. It includes safeguards in terms of secondary uses of materials and third party transfers. It provides that the Provider is custodian of the Materials and remains as such even after transfer. It defines and provides information on benefit sharing and it reiterates the oversight function of the HREC throughout the document. The MTA is in fact null and void and of no force and effect unless and until the HREC has approved the research of which the MTA forms a part *and* approved the MTA. This responds, in part, to the HPCSA requirement for the MTA to be submitted to the HREC. For the submission to be accepted by the HREC, it will be necessary for the MTA to be reviewed and signed off. No review by the HREC, will reduce the MTA submission process, to a "rubber-stamping" exercise. I submit that a comprehensive MTA template which speaks to the concerns that are specific to a particular participant base and that attempts to balance the protections of participants, whilst ensuring that research progresses, is one effective way to regulate the transfer of human materials across our boarders.

6.5 Conclusion

From the above discussion it is evident that both the developed and the developing world consider the MTA an effective tool to regulate the transfer of human materials across borders. As developing countries, where our populace largely forms the participant base for research carried out outside our borders, we must develop unique frameworks which include MTAs that speak to the direct concerns of the majority of our citizens. The complexities that result when biobank research is considered, in

[865] Clauses 13.2 & 13.3 of the MTA template at 14-15.

particular the transfer of human materials, are immense. Individuals and communities are becoming increasingly aware of their rights. A balance between the protection of the participant and the progressive nature of research needs to be recognised in order for effective research to take place. It is the hope that in developing this MTA, we are one step closer to achieving this balance. Apart from including a comprehensive MTA into an ethico-legal framework, there are other pertinent recommendations that should be incorporated with regard to biobanking. I shall now collate these recommendations in the following chapter, by drawing from preceding analysis.

Chapter 7
Recommendations and Conclusion

7.1 Introduction

The complexities that biobank research present are diverse. These range from social and ethical to legal issues. In addition, there appears to be more questions raised when one attempts to find solutions to these difficulties. The key areas of concern involve uncertainties with regard to: what type of informed consent should be used; how secondary uses of materials should be approached; who in fact owns the materials after they are obtained; how far privacy and confidentiality measures should extend; to what degree benefit sharing should be implemented; and what provisions an MTA should contain. These so called hurdles should not be viewed as obstacles to the research process, but rather as a means to put forward a solid ethico-legal framework to address the areas of concern.

In this chapter, I will discuss proposed recommendations to each question raised, by the analysis in this research. In addition, I propose a draft Regulation for Human Biobanks, which I believe should be incorporated under the NHA.[866] This draft Regulation is a culmination of the outcomes of my research, which could be considered a starting point to standardise biobank research in South Africa. At this juncture, I would like to reiterate that the foundation of all my recommendations are entrenched in the fundamental principle of human dignity, which cannot be separated from human participant research under any circumstances.

7.2 Recommendations

7.2.1 What type of informed consent should be used for biobank research and how should secondary uses be treated?

It is prudent to begin the answer to this question by recollecting that classical research ethics focuses on individual consent which can only be obtained after the research

[866] The draft Regulation is attached hereto and marked as "**Annexure IV**."

has been approved by an REC. However, informed consent with regard to biobank research has become a complicated area of debate as traditional principles can no longer apply. Biobank research introduces a new paradigm which separates the sample collection process i.e.: the informed consent process from the actual research. Therefore, the complexities that biobank research presents with regard to informed consent, challenges traditional models. The right to informed consent is emphasised in South Africa's Bill of Rights. It is a fundamental, non-derogable right that cannot be limited. In addition, current ethical guidelines, legislation and case law point out specific information that an individual must consent to and further highlight the significance of a participant understanding an informed consent document and further understanding the implications of being bound by such a consent. With regard to secondary uses of materials, our legislative framework offers conflicting stipulations. Our National Ethics Guidelines is the only ethico-legal document that attempts to regulate biobank research in the country. It is also the first document that attempts to regulate, on a national level, the secondary uses of materials. It does not recommend a blanket or unrestricted consent for secondary uses and states that with this type of unrestricted consent, it is difficult to implement fundamental ethical principles, especially that of respect for persons. Broad consent allows for the intervention and approval of an HREC when secondary uses are contemplated and where re-consent of the participant becomes impracticable or impossible to obtain.

Even though the Guidelines do allude to broad consent, they do not promote a particular preferred type of consent *per se*, but rather provide for different options of consent mechanisms that could potentially be used by researchers. (i.e.: narrow, tiered and broad). From an analysis of international instruments, it is apparent that there is a shift (either directly or indirectly) towards the acceptance of broad consent as a suitable mechanism for biobank research. Therefore, although our legislative framework is unclear, our ethical framework provides for broad consent as an option for biobank research. In addition, while international instruments may not all explicitly promote the use of broad consent, the complete rejection of blanket consent, as well as the extensive list of requirements that all participants should be made aware of, including review and approval by a competent ethics committee for future and/or secondary uses where consent is impossible or impractical to obtain, leans towards the acceptance of broad consent as a viable option. In addition, a comparative

analysis of the ethico-legal frameworks of the UK, Australia and Uganda showed that broad consent is currently being implemented in both the UK and Uganda, and that there is a growing support for the implementation of broad consent in Australia. My recommendation is therefore, that a model of broad consent, combined with skilled and regular ethics review, together with active information sharing, in a language and at a level that all participants understand, is implemented for biobank research in South Africa.

7.2.2 Who owns the materials? A paradigm shift towards custodianship

Perhaps the most contentious of issues when it comes to human participant research is ownership of materials. Whether an institution or the participant retains ownership of the materials after it is obtained/provided, will determine how and to what extent the materials may be used within the ambit of the research project, and for future unspecified uses. The law has traditionally regarded separated bodily materials as *res nullius,* belonging to no one, until brought under the control the first person who obtains possession of the separated human tissue. However, developments in science and medicine have tested general traditional concepts. This is no different when it comes to the issue of ownership. There are stringent requirements that researchers must adhere to when it comes to informing participants about how their materials will be used, including in the case of secondary uses. In addition, participants have the option to withdraw their materials should they wish to do so at any time during the research process. With such stipulations on use, one may question if an institution could in fact "own" materials in the true legal sense.

Currently, there is uncertainty around exactly "who owns what" from a health research perspective and whether "ownership" is even the correct term to use. Our ethico-legal framework is particularly silent on this issue. The IPR Act does promote the notion that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of South Africa. Though, this is neither here nor there when it comes to actual ownership rights of materials and only applies to intellectual property emanating from publicly financed research and development. The NHA Regulations Relating to the Artificial Fertilisation of Persons attempts to clarify the issue of ownership with regard to donated gametes

used for artificial fertilisation. However, it is specific to artificial fertilisation only and does not apply to health research *per se*. Case law is also unclear in this regard, yet, what recent case law developments may point towards, is that although the position that all human biological material is not property remains the *status quo*, some courts seem willing to deal with novel cases on an *ad hoc* basis, which over time, may extend the circumstances under which human biological material could be viewed as legal property. International guidance documents have attempted to provide protections for ownership from an intellectual property perspective, but do not address the issue of ownership directly.

In my opinion, public health interests should always take precedence over the "exclusivity of rights" argument that institutions may put forward when it comes to human materials. The term "ownership" of human materials in a legal sense is in itself problematic. The holder of the human materials should rather be regarded as a custodian and not an owner *per se*. The research process is ultimately based on trust. Participants trust the researcher with their materials and provide their informed consent for their use and/ or subsequent future use. Having the notion of custodianship as an overarching concept, under which ownership rights are controlled, will allow for the most important aspect of research to be fulfilled – which is, for the common good of human kind. Custodianship allows for the obligation of caretaking which fits the principle of respect and dignity towards participant materials more appropriately than the rigid rules of ownership. From my comparative country analysis in Chapter 5, it is evident that participants relinquish ownership rights and ownership then vests with the Biobank, in the case of UK Biobank. Australia's position appears to be somewhat unsettled, however, the general position is that the entity is custodian of the materials and the participants relinquish ownership rights. In Uganda, ownership remains with the participant and the entity becomes custodian of the materials. It is my submission that "ownership" of human materials in the context of biobank research is inappropriate. We should shift the paradigm to include custodianship as the umbrella under which ownership rights vest.

7.2.3 Should benefit sharing be a requirement?

Trust should form the cornerstone of the researcher-participant relationship. The historical exploitation of African participants is a (not too distant) reality which still

causes apprehension on the part of participants when health research is contemplated. The concept of benefit sharing must be balanced with the idea of public interests and population health that are central to the purpose of biobanks. The philosophical principle behind the concept of benefit sharing is simple and is a matter of justice. Those who contribute to scientific research ought to share in its benefits. There is argument that participation in scientific research should always be altruistic in nature. This is how access to human genetic resources has been governed historically in prosperous nations. However, exporting this notion into developing countries could lead to the emergence of serious concerns around exploitation. In addition, participants from the developing world with varying cultural backgrounds, often attach a significance to their blood and related materials derived from their blood, that participants from the developed world may not. In South Africa we do not have a firm legal position on the concept of benefit sharing with regard to human biological materials. One reason may be that, as research is predominantly funded by outside sources, local researchers may find it difficult to negotiate benefit sharing mechanisms adequately without risking the loss of these potential funds. Another reason may be that, researchers need to become more sensitised to the importance of benefit sharing and the effect it will have on long term sustainable research. Researchers and institutions seem to be removed from the actual communities, without whom no scientific progress could be made. Our HPCSA guidelines make it quite clear that with regard to data and specimen storage and transfer, there must be justifiable reasons and benefits for the country, which should be provided to RECs for data and specimens to leave the country. International guideline documents are also moving in the direction of explicitly making benefit sharing a requirement. In addition, the comparative analysis of the positions in the UK, Australia and Uganda, all allude to some form of benefit to communities involved. It is therefore my submission that a properly regulated benefit sharing arrangement, which should be included within an MTA, may reinforce the trust relationship, bring researchers, institutions and communities closer and allow for sustainable, long term future research. It is essential that developing world countries, local researchers and communities benefit from the research process in some way.

7.2.4 To what extent should privacy and confidentiality be protected?

The right to privacy is enshrined in our Bill of Rights and within various pieces of legislation. However, in the context of health research, there is debate around the extent to which such privacy should be protected, specifically with regard to secondary uses of human materials and generated data. It must be emphasised that when attempting to draw the line between privacy and confidentiality of the participant/s on the one hand and promoting health research for the common good of mankind on the other, it is difficult to provide exact boundaries, as the nature of technologies are always developing and changing. Nevertheless, this should not be an excuse not to provide adequate protections for these principles. There have been great strides made towards the ultimate protection of participants' privacy both internationally as well as nationally. A breach of private information could cause disorder and disrupt research critically in that participants may develop a distrust of researchers and may institute litigious proceedings against the institution/biobank concerned. Yet, it has been traditionally difficult to envision a practical balance between privacy, confidentiality and the research participant, when the question of ownership remained unanswered. The model of custodianship will therefore work well as an effective alternative, in providing this balance. Respect for the participants' samples and data must form the framework to any ethico-legislative framework. The issue of identifiability speaks to the heart of confidentiality. It is essential that data subjects understand the notion of identifiability and the different levels of anonymisation in order to assess the individual consequences of participation. In addition, biobank research implies risks for identifiable groups and communities because anonymity of the individual does not necessarily translate to anonymity of the group.

Furthermore, confusion arises when the same terms used in different guidelines have different meanings. With regard to privacy protections in the UK and Australia, specific reference is made to coded data, the South African framework provides different options of security methods, but leaves the determination of "risk" up to an individual REC. The general position is that data is either coded or anonymised. The Ugandan guidelines do not provide for methods of privacy protections and currently remain unspecific. It is recognised that the possibility of complete anonymisation is becoming increasingly "illusionary" as the possibility of cross-matching large datasets improves.

In addition, should the data contain genetic information (such as DNA), complete anonymisation is impossible. Furthermore, there may be a need to trace the data back to an individual/ groups of individuals in the case of an adverse event or should a peculiar/ life altering genetic disposition be found. It is therefore my recommendation that privacy measures should include de-identified and coded rather than anonymised data.

7.2.5 What provisions should an MTA contain?

One way in which to consolidate all the questions raised above, is to incorporate them into an MTA. Internationally, there is a move towards specific ethico-legal MTA's which incorporate both ethical and legal norms and standards. Chapter 6 provided an in depth analysis of the specific provisions that an MTA should contain. In addition, annexed to this thesis, is a template MTA which I developed and which is currently being used by Wits researchers, the South African Medical Association, the Hospice Palliative Care Association and others. The template applies to both human biological materials and data. It includes many different provisions and incorporates broad consent into its application. It also provides that the providing institute remains custodian of the materials, even after transfer. It incorporates benefit sharing mechanisms and provides examples of different types of benefit sharing for consideration. HREC oversight is emphasised throughout the document and all uses of the materials must be approved by an HREC. With regard to privacy and confidentiality, the MTA provides specific safeguards should the materials become identifiable for any reason. There are also provisions on termination, dispute settlement and publication rights. In our current situation, where we operate in a largely unregulated manner, an MTA is one way to ensure that all the salient ethico-legal principles which speak to the heart of biobank research, are addressed. However, when an ethico-legal framework is established, this MTA template should be incorporated as part of the process at a national level.

During October 2017, the NDoH requested that the MTA template and draft Regulations, which I developed as part of my research, be considered by them, to

inform future work.[867] With permission from my supervisors, I acceded to their request, on condition that the draft Regulations (which are not in the public domain, unlike the MTA) remain confidential and are not disseminated until the examination of this thesis has been finalised.[868]

7.3 Conclusion

Biobank research has global reach and therefore global implications. One may argue that in the absence of a concise ethico-legal framework, we have very few options regarding regulating this type of research. Currently, institutions and biobanks function in a fragmented way, with their own specific procedural and policy requirements. Although our National Ethics Guidelines do provide some direction in terms of biobank research, their guidance requires a more instructive, solid basis. An MTA may be used as an effective means of regulation until our ethico-legal framework is in order. Once our framework is in place, the MTA should run parallel to the legislative process. It is my opinion that we require a national set of regulations for biobank research, in conjunction with a move towards harmonising global frameworks. Currently, we are operating at a global level within a network of fragmented frameworks. Yet, all these frameworks are focussed towards solving the same ethical and legal dilemmas. With respect to biobank research, one cannot separate the ethics from the law, for the reasons discussed in Chapters 1 to 6 above. There are key areas included within the complexities of biobank research, where ethics and the law clearly overlap. It is my final submission that our narrative needs to shift in respect of health research, where the human aspect is placed first, rather than monetary interests. If we are able to appreciate the contributions of participants and afford them the protectionism that they do undoubtedly deserve, the aims of research will ultimately transform to include participant protection as a key focus area, rather than as an afterthought. In addition, this approach will enhance the trust relationship between participant and researcher, breaking down the barriers that currently exist, allowing for biobank research to achieve its ultimate objective – to foster research that generates new science with the intention of benefiting human wellbeing and health.

[867] A copy of the email correspondence from the NDoH requesting use of the MTA and draft Regulations is attached hereto, marked "**Annexure V**."

[868] A copy of my email correspondence addressed to the NDoH is attached hereto, marked "**Annexure VI**."

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Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH 10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: Medical School Room 10M07, 10th Floor. Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265

Ref: W-CJ-140226-1

26/02/2014

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: Safia Mahomed (Student No. 0315905G).

Project title: An ethico-legal framework for the regulation of biobanks in South Africa

Reason: This is a study using information in the public domain. There are no human participants

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON - JONES
HREC (MEDICAL)
2014 -02- 26
JOHANNESBURG

Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy - HREC(Medical) Secretariat : Anisa Keshav, Zanele Ndlovu.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

MATERIAL TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS[1]

(hereinafter, "the Agreement")

Signature Date ----------

[1] This MTA has been approved by the Biobanks Ethics Committee of the University of the Witwatersrand Johannesburg. This document is an adaptation of one of the outcomes of Safia Mahomed's PhD through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand, with support from the Wits Biobanks Ethics Committee and Legal Office. This document may be used but sources must be duly acknowledged. Version 1. January 2018.

Entered into by and between:

(Hereinafter, “the Provider”)

Registered physical and postal address of Principal Investigator: _____ _____ _____ _____	Tel: Fax: Cell: Email:

and

(Hereinafter, "the Recipient")

Registered physical and postal address of Recipient: _____ _____ _____ _____	Tel: Fax: Cell: Email:

and

(Hereinafter, the Human Research Ethics Committee)

Registered physical and postal address of Human Research Ethics Committee: _____ _____ _____ _____	Tel: Fax: Cell: Email:

PREAMBLE[2]

WHEREAS

A. the Provider remains custodian of the Materials; and

B. the Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials subject to the terms and conditions below; and

C. each Party undertakes to engage with the other in the utmost good faith and to conduct itself with the highest ethical standards and comply with all applicable legislation, including but not limited to the legislative ban on the sale of or trade in tissues, gametes, blood or blood products; and

D. the Parties agree to conduct themselves hereunder in compliance with the Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg (HREC) protocols and policies on research on human biological materials; and

E. understanding, therefore, that no Materials can be transferred for purposes of a research[3] project that has not been approved by the HREC

[2] A Material Transfer Agreement is a contract governing the transfer of materials between organisations and/or institutions, which sets out: what will be done with any material supplied; whether the material will be used in humans or not; the quality of the material; the terms and conditions under which the materials will be used; any modifications to the material; third party transfers; benefit sharing; intellectual property rights; and other legal requirements and/or regulatory guidelines or policies.

[3] According to section 1 of the National Health Act 61 of 2003 (NHA):
"health research includes: any research which contributes to knowledge of –
(a) The biological, clinical, psychological or social processes in human beings;
(b) Improved methods for the provision of health services;
(c) Human pathology;
(d) The causes of disease;
(e) The effects of the environment on the human body;
(f) The development or new application of pharmaceuticals, medicines and related substances; and

NOW THEREFORE, THE PARTIES AGREE AS FOLLOWS

1. OBJECTIVE

The objective of this Agreement is to set out a framework within which the Parties will engage in the transfer, use and other processing of the Materials, and to provide for matters connected therewith.

2. DEFINITIONS

2.1	Agreement:	-	means this Agreement and all annexures thereto
2.2	Benefit:	-	means the benefit that will be received by the Provider from the use of the Materials by the Recipient. Benefits may include, amongst others: the sharing of information; use of research results; royalties; acknowledgement of the Provider as the source of the Materials; publication rights; transfer of technology or materials; and capacity building
2.3	Benefit sharing:	-	means the process or act of sharing in the benefits that derive from the Project in a manner that is fair and equitable
2.4	Biobank:	-	means an organised collection of Human Biological Material and associated data from different individuals , which are usually kept for an unlimited period of time, for the purposes of health research.

(g) The development of new applications of health technology."

2.5	Country:	-	means the Republic of South Africa
2.6	Custodian:	-	means a person or entity entrusted by the Donor with safeguarding and protecting the Materials
2.7	Data	-	means any information, including personal information in any form, derived directly or indirectly during the conduct of research or clinical care
2.8	Donor:	-	means a person who has donated Materials to be used for health research purposes and / or teaching.
2.9	Human Biological Materials:	-	means material from a human being including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof
2.10	Human Research Ethics Committee (Medical) University of the Witwatersrand, Johannesburg (HREC):	-	means the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg which is registered with the South African National Health Research Ethics Council, whose purpose is to review and, where the proposals meet the ethical standards of the committee, approve all health research protocols[4]

[4] Section 73(1)&(2) of the NHA stipulates that:

"(1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

(2) A health research ethics committee must-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable

2.11	Intellectual Property Rights:	- means statutory and other proprietary rights resulting from creations of the human mind such as copyright, patents, scientific works, discoveries and trademarks
2.12	Informed Consent:	- means an on-going information sharing process which allows a Donor to consent to participate and determine whether and how their Materials will be utilised in the Project, as approved by the HREC from time to time
2.13	Materials	- means Human Biological Materials and Data
2.14	Parties:	- means the Provider and the Recipient in this Agreement
2.15	Project:	- means the health research project for which the Materials will be used hereunder
2.16	Research Results:	- means all products of the research, whether tangible or intangible
2.17	Secondary Use:	- means use of the Materials for health research purposes other than the uses determined in the approved protocol. Secondary uses must be approved by the HREC[5]

diseases or disability or result in cures for communicable or non-communicable diseases; and
(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee."

[5] As secondary uses of Materials include health research as contemplated by section 1 of the NHA (footnote 3) and as all health research ethics committees are required to review and approve health research proposals and protocols (footnote 4), approval for secondary uses of Material must be obtained from a health research ethics committee.

2.18 Signature Date: - means the effective date subject to clause 7

2.19 Termination Report: - means a report prepared by the Recipient and submitted to the Provider on termination of the Project. The Termination Report will include, inter alia, reason for termination, status of Project at termination and current state of Materials

3. OBLIGATIONS OF THE PROVIDER

3.1 The Provider agrees to transfer to the Recipient the Materials more fully described in **Annexure A** in the quantity, packaging and by mode of transport as more fully described in **Annexure A**.

3.2 Should the Provider be informed that the Materials have become identifiable for any reason whatsoever, the Provider is responsible for informing the HREC and the relevant Donor(s) of same and for obtaining approval from the HREC and consent from the Donor(s), where reasonably possible, for any further uses of the Material.

3.3 This Agreement is subject to the suspensive condition that, and is of no force or effect unless and until, the HREC has approved the study of which the MTA forms a part of and the HREC has approved the MTA.

4. ACKNOWLEDGEMENTS BY AND OBLIGATIONS OF THE RECIPIENT

4.1 The Recipient acknowledges that the Materials have been obtained and/or developed by the Provider, where applicable.

4.2 The Recipient acknowledges that the Materials are of health research value.

4.3 The Recipient may only carry out research according to the protocol approved by the HREC.

4.4 The Recipient will be responsible for obtaining the necessary permits and authorisations, and for arranging and bearing the costs of the appropriate transport for the Material to be transferred to the Recipient.

4.5 The Recipient acknowledges that the Materials may contain sensitive and confidential information, which information the Recipient undertakes to protect and keep confidential.

4.6 Other than those parties stipulated in **Annexure A**, the Recipient may not transfer or otherwise provide the Material to any party without approval of the HREC. Such approval will be on such written conditions as the Provider may deem fit in its sole discretion and will be agreed by the Recipient in writing.

4.7 Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider without delay.

4.8 The Recipient agrees to deliver feedback to the Provider on the development and progress made with regard to the Project by supplying the Provider with updated information where relevant and in terms of applicable ethical and legal requirements.

5. USE AND PURPOSE OF MATERIAL

5.1 The Recipient warrants that the Materials will be used only for the purposes of the Project, as more fully described in **Annexure A**.

5.2 The Recipient agrees that the Material will be located at:

(entity details)

5.3 The Recipient shall not, without the written permission of the Provider, use the Materials for any purpose other than that permitted in terms of this Agreement.

6. BENEFIT SHARING

The sharing of benefits should be discussed and negotiated between the Provider and Recipient before Materials are transferred to the Recipient. The Parties agree to Benefit Sharing as detailed in **Annexure B**.

7. DURATION OF AGREEMENT

This Agreement will commence on the effective date and shall continue until the termination date.

8. TERMINATION OF PROJECT

8.1 In the event that the Project terminates, for any reason whatsoever, the Recipient will provide the Provider and the HREC with a Termination Report.

8.2 Termination of the Project will occur under one or more of the following circumstances:

8.2.1 the Project reaches completion;

8.2.2 the Project cannot be carried out by the Recipient for any reason whatsoever, including but not limited to the following:

8.2.2.1 the Donors withdraw consent for use as contemplated hereunder and in such numbers as to render continuation of the Project impracticable or impossible;

8.2.2.2 the Recipient entity dissolves, winds-up or ceases to continue operating for any reason whatsoever;

8.2.2.3 the HREC withdraws approval for the Project in its entirety;

8.2.2.4 either Party terminates the Agreement on reasonable notice; and/or

8.2.2.5 a force majeure makes continuance of the Project impracticable or impossible.

8.3 On termination, the Recipient will immediately discontinue using the Material for any purpose whatsoever.

8.4 Destruction, return to the Provider or transfer of Materials will be undertaken, or any other arrangements made, with the express approval of the HREC.

9. INFORMED CONSENT

Informed Consent requires that:

9.1 the Provider has obtained informed consent from the Donor(s) to provide Materials to the Recipient to undertake the Project as contemplated. In the event of Secondary Use of the Materials, the Donor(s) have consented thereto insofar as the Secondary Uses have been approved by the HREC.

9.2 the Donor(s) have been informed that, where reasonably possible, the Provider will inform them of developments or progress made by the Recipient in the Project and which is relevant to the Donor(s) Informed Consent.

9.3 the Donor(s) have been informed and have accepted that on termination of this agreement, the Material will be returned to the Provider or destroyed, or any other arrangements made, as determined by the Provider under clause 8.

9.4 the Donor(s) are aware that all Materials and associated data are de-identified.

9.5 Disclosure to Donor(s) has been made in the event that Materials will be released into the public domain.

9.6 should the Recipient wish to conduct studies or use the Material for any other purpose than that approved by the HREC, the Provider must be notified in writing and HREC approval must first be obtained.

10. DISPUTE SETTLEMENT

10.1 All disputes between the Parties will be determined in accordance with the provisions of this clause 10.

10.2 Within a period of fourteen (14) days after the date on which the dispute arose (the Dispute Date) the Parties will meet to discuss the dispute and will endeavour to resolve the dispute amicably.

10.3 If the Parties are unable to resolve the dispute in terms of 10.2 within thirty (30) days from the Dispute Date the dispute will be referred to the Vice–Chancellor or a Deputy Vice-Chancellor of the University and the Chief Executive Officer of the Recipient or their duly appointed representative/s, who will use their best endeavours to resolve the dispute. Their determination will be final and binding and will be carried into effect by the Parties.

10.4 If the individuals described in 10.3 are unable to resolve the dispute within a period of thirty (30) days after it has been referred to them, either Party may institute action in the South Gauteng High Court, Johannesburg, unless the Parties agree to resolve such dispute by arbitration in terms of a separate arbitration Agreement.

11. INTELLECTUAL PROPERTY

Intellectual property will be dealt with through relevant laws related to the applicable protocol and underlying third party agreements in so far as there are any.

12. CONFIDENTIALITY

The Recipient agrees to keep the Materials secure and confidential at all times. Confidentiality includes, but is not limited to: the properties; characteristics; content; composition; potential secondary uses; and methods of use of the Material. All information relating to the nature and processes of the research in whatever form must also be treated as confidential. The identity of the Donor(s) must be protected and kept confidential at all times. Any publications, newsletters or oral presentations must not divulge any details of the Donor(s) unless consent has been obtained for such use from the Donor(s).

13. PUBLICATIONS & PUBLICITY

13.1 Authorship of publications emanating from the use of the Materials hereunder must be in keeping with the International Committee of Medical Journal Editors Authorship Guidelines (http://www.icmje.org/icmje-recommendations.pdf) as amended from time to time.

13.2 Where the Recipient wishes to publish any information concerning the Project (in either oral or written form), the Provider must be notified and provided with a copy of the publication at least ten (10) days prior to submission of the proposed publication. The Provider must inform the

Recipient whether any information related to the publication must be removed or included and provide reasons to substantiate the removal or addition of such information.

13.3 The Provider must be supplied with a final copy of the publication before publication by the Recipient. The Recipient must acknowledge the Provider's contribution of the Material unless otherwise requested by the Provider.

13.4 Neither Party shall use the name of the other Party or its employees in any advertisement, press release or other publicity without prior written approval of the other Party.

13.5 Notwithstanding the above, and where relevant, publications must be subjected to the applicable protocol and relevant third party agreements.

14. LIABILITY

14.1 The Provider gives no warranty that the Materials are fit for the use and purpose for which they are transferred hereunder, or that they have any particular qualities or characteristics.

14.2 The Provider will not be liable to the Recipient for any claims or damages arising from the Recipient's use of the Material.

14.3 Should either Party breach the terms of this Agreement, notwithstanding 7 (seven) days written notice to rectify the breach, this Agreement may be terminated by the aggrieved Party by written notice.

15. GENERAL

15.1 This Agreement embodies the entire agreement between the Parties and no provision hereof may be altered or amended without the written mutual consent of both Parties.

15.2 Neither Party may assign or cede any benefit, obligation or interest it may have in this Agreement to any other person without the prior written consent of the other Party and the approval of the HREC.

15.3 Neither Party is regarded as having waived, or is precluded in any way from exercising any right under or arising out of this Agreement by reason of such Party having at any time extended any extension of time for, or having shown any indulgency to, the other Party with reference to any performance of any obligation under this Agreement, or having failed to enforce, or delayed in enforcing any right of action against the other Party.

15.4 This Agreement constitutes the sole record of the Agreement between the Parties in regard to the subject matter hereof and replaces any prior Agreement, which may exist between the Parties. No Party will be bound by any representation, express or implied term, warranty, promise or the like not recorded in this Agreement.

15.5 Any amendments to this contract are of no force and effect unless reduced to writing and signed by both Parties.

15.6 No extension of time or indulgence by any Party will be deemed in any way to affect, prejudice or derogate from the rights of the Party in any respect under this Agreement nor will it in any way be regarded as a waiver of any rights hereunder or a novation of this Agreement.

15.7 The rule that an Agreement will be interpreted against the Party that drafted it shall not apply to this Agreement.

15.8 In the event of any one or more of the provisions of this Agreement being held for any reason to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision was not a part of this Agreement, and the Agreement shall be carried out as nearly as possible in accordance with its original terms and intent.

15.9 The Recipient receives only the rights as set out in this agreement and these rights are not exclusive to the Recipient.

16. This MTA is null and void and of no force and effect unless and until the HREC has approved the research of which the MTA forms a part *and* the HREC has approved the MTA.

Duly authorised and on behalf of the Provider
Full name:
Designation:
Signature:
Signed at _____ on this the _____ day of _____ 2018.
Witness 1: _____ Witness 2: _____

Duly authorised and on behalf of the Recipient
Full name:
Designation:
Signature:
Signed at _____ on this the _____ day of _____ 2018.
Witness 1: _____ Witness 2: _____

Duly authorised and on behalf of the Human Research Ethics Committee
Full name:
Designation:
Signature:
Signed at _____ on this the _____ day of _____ 2018.
Witness 1: _____ Witness 2: _____

Annexure A

To be completed by the Provider and/or Recipient

The Responsible Party who will obtain the necessary permits and authorisations and arrange appropriate transport for the Material to be transferred is:

Description of health research project under which the Materials will be used on transfer:

Specific experimental tests that the Materials will be subjected to on transfer:

Parties other than the Recipient to whom the Materials might be transferred as required by the Project:

Quantity of Materials required to be transferred:

Preferred method of transfer of Materials:

Period within which Materials will be transferred:

Frequency of exporting of Materials:

Process of destruction of Materials:

How confidentiality will be maintained should Materials be released into the public domain:

Annexure B

Benefit Sharing Arrangement between the Recipient and Provider

Tebogo Dithung

From: Ames Dhai
Sent: Friday, 15 December 2017 3:06 PM
To: Tebogo Dithung
Subject: RE: Letter on MTA & draft Biobanks regulations

From: Lineo Motopi [mailto:Lineo.Motopi@health.gov.za]
Sent: 30 October 2017 12:50 PM
To: Ames Dhai
Cc: Safia Mahomed; Safia(mahoms1@unisa.ac.za) Mahomed; Kevin Behrens; Tebogo Dithung
Subject: RE: Letter on MTA & draft Biobanks regulations

Dear Prof Dhai,
Thank you so much for the documents.

I would like to take this opportunity to thank Ms Mahomed & Prof Behrens for their generosity in allowing the Department to use this work to advance what we do on behalf of South Africa.

It has been my observation that most of the applicants to export biological substances use your MTA and thus thank you for the wonderful MTA. As the letter from the Director-General indicated, we will adapt the documents into the Departmental format. We will only start the work on biobanks next year - so rest assured there will be no conflict with your academic work.

Thank you again

Warm regards
Lineo

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

A long and healthy life for all South Africans

Draft Regulations for Human Biobank Research in South Africa

Acknowledgement: Excerpts from the University of the Witwatersrand's HREC MTA[1] and Principles and Policies for Biobanks,[2] which I have contributed towards have been included in this Draft Regulation.

[1] The Human Research Ethics Committee Medical: Material Transfer Agreement for Human Biological Materials, developed by S Mahomed through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand with support from the Wits Biobanks Ethics Committee and Wits Legal Office available at: https://www.wits.ac.za/ethics/biobanks-ethics-committee/ (Date accessed: 21 October 2017).
[2] The Human Research Ethics Committee Medical: Principles and Policy on Biobanks, Faculty of Health Sciences, University of the Witwatersrand available at: https://www.wits.ac.za/media/wits-university/research/documents/HREC%20principles%20and%20policy%20on%20biobanking.pdf (Date accessed: 21 October 2017)

National Health Act, 2003

Draft Regulations for Human Biobank Research in South Africa

The Minister of Health has, in terms of section 68 of the National Health Act 2003 (Act No.61 of 2003), made the following regulations in the Schedule.

SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context otherwise indicates –

"Act"	means the National Health Act, 2003 (Act No. 61 of 2003).
"Benefit sharing"	means the process or act of sharing in benefits in a manner that is fair and equitable.
"Biobank"	means an organised collection of Human Biological Material and associated data from different individuals, which are usually kept for an unlimited period of time, for the purposes of health research.
"Broad consent"	means consenting to a specific framework for future health related research. It includes strategies to update the research participant regularly and provides for ongoing withdrawal opportunities. Should the framework change, the research participant should re-consent. It further allows research participants to choose the different fields of studies to which they would like to contribute their Materials.

"Custodian" means a person or entity/ institution entrusted by the research participant with safeguarding and protecting the Materials.

"Data" means any information, including personal information in any form, derived directly or indirectly during the conduct of research.

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

"Human Biological Materials" means material from a human being including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof.

"Human Research Ethics Committee" means a Human Research Ethics Committee which is registered with the South African National Health Research Ethics Council, whose purpose is to review and, where the proposals meet the ethical standards of the

committee, approve all health research protocols and Biobanks.

"Institution" in the case of donated Materials: a hospital; a university; a Biobank or any other entity authorised by the Minister of Health to store these Materials.

"Materials" means Human Biological Materials and Data.

"Material Transfer Agreement (MTA)" means a contract governing the transfer of materials between Institutions, which sets out what will be done with any Material supplied, whether the Material will be used in humans or not, the quality of the Material, the terms and conditions under which the Materials will be used, any modifications to the Material, third party transfers, benefit sharing, intellectual property rights and any other legal and/ or regulatory requirements including guideline and/ or policy requirements.

"Research participant" means a person who has donated Materials to be used for Health Research purposes.

"Secondary uses" means use of the Materials for health research purposes other than the uses determined in the approved protocol. Secondary uses must be approved by the HREC.

"Stakeholders" include but are not limited to research participants and / or their communities, researchers, policy makers and Institutions.

Objectives

2. The objectives of biobank research must be to foster research that generates new science with the intention of benefiting human wellbeing and health; to make Materials ethically accessible to researchers in order to advance knowledge and understanding; and to ensure the integrity of samples in perpetuity.

Principles

3. **Stakeholder consultation and community engagement**
   a. Consultation with all relevant stakeholders as well as the involvement of the community in the decision making process is key to the success of biobanking.
   b. Public trust must be promoted to maintain and encourage participation by local communities.
   c. Evidence of stakeholder consultation and community engagement by the biobank must be presented to the HREC.

4. **Informed consent**
   a. The principle of informed consent is entrenched within our legislative and ethical framework. It is an on-going information sharing process which allows the research participant to participate and determine whether and how their Materials will be used in biobank research, as approved by the HREC from time to time.
   b. The most appropriate form of informed consent to employ when biobank research is considered is broad consent as defined in these Regulations.
   c. In the event of secondary uses, or should the research framework change and should re-consent become impracticable or impossible, an HREC may make a considered determination in this regard.

d. Secondary uses or any changes to the research framework must be approved by the HREC.
e. Research participants must be provided with on-going withdrawal opportunities, however they should be made aware of the implications and limitations to exercising this right.

5. **Privacy and confidentiality**
   a. Privacy is concerned with who has access to personal information and records about the participant; including clinical health care records. Confidentiality is about ensuring that appropriate measures will be implemented to prevent disclosure of information that might identify the participant (inadvertently or not) either during the course of the research or afterwards.
   b. Reasonable steps must be taken to ensure that participants' privacy and the confidentiality of their Material is protected and secured.
   c. Materials must be de-identified and coded. Should the Materials become identifiable for any reason whatsoever, the relevant Institution must inform the HREC and the research participants and obtain approval from the HREC and informed consent from the research participants, where reasonably possible, for any further uses of the Materials.

6. **Custodianship**
   a. Public health interests should always take precedence over the exclusivity of ownership rights.
   b. The Biobank or any other Institution may not lay claim to ownership rights in the Materials. The Biobank or any other Institution must act as Custodian of the materials and safeguard and protect the Materials.
   c. The Biobank and/or any other Institution who has possession of the Materials must act in the best interests of the research participant(s) and public health.

7. **Transfer of Materials outside South African borders**
    a. An MTA must be completed when the transfer of Materials is contemplated. The national MTA template, annexed hereto, must be completed and the principles therein must be respected.
    b. The MTA as well as the informed consent document must be approved by the Department of Health, before the Materials are transferred outside of South Africa.
    c. Should the laws and regulations of the country to which the Materials are being transferred be more lenient than those found within South Africa, South African ethical principles will apply.

8. **Benefit sharing**
    a. The process of benefit sharing must be negotiated and consolidated before any Materials are transferred from one country to another and be included within the MTA.
    b. A benefit may include amongst others, the sharing of information, use of research results, royalties, acknowledgement of the Biobank as the source of the Materials, publication rights for local researchers, transfer of technology or materials, and capacity building.
    c. Biobanks must strive to benefit participant communities whose contributions add to the scientific value of health research.

9. **Governance**
    a. Governance of a biobank from establishment to dissolution must be in accordance with the principles of accountability and transparency and must take into consideration applicable legal frameworks and ethical principles.
    b. The purpose of the biobank and nature of the Materials that will be contained in the biobank must form part of the governance arrangements.
    c. Governance arrangements must include measures to protect the dignity, autonomy and privacy of research participants.
    d. Biobanks must be approved by an HREC.

e. Governance arrangements must include the contact details of the person/s who are responsible for the governance.
f. Biobanks must obtain Good Clinical Laboratory Practice (GCLP) Accreditation.
g. Relevant staff in the biobank must be certified with the International Aviation and Transport Authority (IATA).
h. Materials are to be transferred to other biobanks only for specific research projects.
i. In the event of temporary closure of the biobank, Materials are to be transferred to other HREC approved Institutions.
j. All storage, retrieval and transfers must be approved by the HREC.
k. Each collaborative project must have a MTA.
l. Governance arrangements must include how the Materials will be documented and traceable in accordance with the consent of the research participants.
m. Clearly documented operating procedures and policies for the procurement, collection, labelling, registration, storage (including durations of storage), processing, tracking, retrieval, transfer, use, access, re-contact, disposal and destruction of human biological materials, data and/or information must be written up and implemented.
n. Arrangement for how the Materials will be dealt with in the event of change of custodianship or closure must be provided for.
o. Security measures must be in place to prevent unauthorised access or inappropriate sharing of Materials.
p. The procedures for receiving and addressing enquiries and complaints must be included within governance arrangements.
q. There must be transparency about the nature and source of the Biobank's financing/funding.
r. Materials must not be sold for private gain.

10. **Closure**

a. Should the biobank dissolve, wind-up or cease to continue operating for any reason whatsoever, the entire net asset value together with any stored Materials, must be distributed in whole or in part, after obtaining HREC approval, to one or more organisations or Institutions carrying on biobank

activities in South Africa or, a non-profit trust; or voluntary association having objectives similar to the Biobank's main objective.

11. **Compliance checklist**
    a. A Biobank must have available and on hand, a compliance checklist for purposes of auditing and/ or inspection.
    b. Compliance checklists must include all the above considerations.

References:

1. National Health Act 61 of 2003.
2. National Department of Health Ethics Guidelines: Principles, Processes and Structures, 2015.
3. Organisation for Economic Co-operation and Development on Human Biobanks and Genetic Research Databases Guidelines, 2009.
4. WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks, 2016.

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NATIONAL DEPARTMENT OF HEALTH
CHAPTER 8 OF THE NATIONAL HEALTH ACT, 2003

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Prof Ames Dhai
Director: Steve Biko Centre for Bioethics
Faculty of Health Sciences
University of the Witwatersrand
Johannesburg
2000

Dear Prof Dhai,

COPY OF WITS MTA AND DRAFT REGULATIONS ON BIOBANK FOR CONSIDERATION BY THE NATIONAL DEPARTMENT OF HEALTH FOR FUTURE WORK

The above matter refers.

Following the meeting on export of biological substances held at the National Department of Health on 23 October 2017. We expressed the desire for the National Department of Health to consider using the current Wits MTA as well as the draft regulations on Biobank to inform future work. To this effect, I write to request that you kindly forward copies of the documents.

The documents will be reviewed by the relevant unit including Legal Services, to ascertain whether the documents could be adopted or adapted to suit the mandate of the National Department of Health.

We look forward to your prompt response

Kind regards

MS P NETSHIDZIVHANI
DIRECTOR-GENERAL: HEALTH
DATE: 24/10/2017

30 October 2017
National Department of Health
Ms P Netshidzivhani
Director General: Health

Dear Madam

Copy of Material Transfer Agreement and Draft Regulations on Human Biobanks for consideration by the National Department of Health

Your correspondence dated 24 October 2017, refers.

I, Safia Mahomed, agree to share the Material Transfer Agreement (MTA) and Draft Regulations, attached hereto, that form the outcomes of my PhD titled: "An ethico-legal framework for the regulation of biobanks in South Africa."

The MTA is already in the public domain; however, the Draft Regulations are not. Therefore, the Department of Health is allowed to use the Draft Regulations towards country needs, although it is not for circulation and should be treated as a confidential document until my PhD has been examined, which is envisaged to be in the next few months. I will inform the Department of Health as soon as I receive the outcomes of examination.

My supervisors have agreed to the above conditions.

Sincerely,

Ms S Mahomed
PhD Candidate, Steve Biko Centre for Bioethics
Faculty of Health Sciences
University of the Witwatersrand

Senior lecturer
College of Law
University of South Africa