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Discipline of Psychology

**Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients.**

By

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## **Declaration**


I, Ms Nonhlanhla Keswa, declare that the work described in this thesis has not been submitted to UKZN or any other tertiary institution for purposes of obtaining an academic qualification, whether by myself or any other party. I declare that this dissertation contains my own work and sources which have been used have been duly acknowledged.

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**Date.....9<sup>th</sup> February 2017.....**

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## **Abstract**

Over the years there has been an increasing interest in the collection, storage and use of human biological samples for current and future research purposes (biomedical research). Human biological samples are defined as any component of the human body or human biological material. They are useful media for research into developing better means of preventing, diagnosing and treating human diseases. Growth in biomedical research has led to increased efforts in developing and revising laws, policies and regulations pertaining to the donation, use and storage of human biological samples. When making these laws, it is necessary to take into consideration the views and attitudes of the public as they are important in informing and guiding legislature which is in line with people's views, beliefs and needs. This study sought to explore the views of 200 Pietermaritzburg out-patients currently being seen at Grey's Hospital and Edendale Hospital. Data was obtained through a cross-sectional survey which was analysed quantitatively using SPSS. Results showed that over 50% of participants thought that consent was necessary for research on stored samples whether samples were identifiable or unidentifiable; and whether they were research derived, clinically derived or intended for research studying a disease other than what they were collected for. More than half of the participants thought that consent ought to be obtained when samples were initially collected and that it was the responsibility of the initial clinician or researcher to obtain consent for future research. An equal split was observed between participants who felt that one-time general consent was sufficient and those who thought it was necessary to impose limits to the use of their samples. Most participants wanted to be informed about clinically significant results and they wanted their doctors to be informed too. Participants regarded medical information as most sensitive and most likely to be misused. They regarded all types of medical information as important.

**Key words:** Biomedical research, human biological samples, research ethics, biobanks

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# **Chapter 1: Introduction**

## **1.1 Background**

There has been increasing interest in human biological samples that may be used for present, or stored for future research purposes (Kapp, 2006). Research on human biological samples has played an important role in providing a vast amount of information pertaining to diagnosing, treating, and preventing certain human diseases (Elger & Caplan, 2006). Three strategies have been identified for the collection of these samples and obtaining consent for their use (Gefenas et al., 2012). The first strategy is where human biological samples are specifically sought for current research purposes and participants provide their consent for these (Gefenas et al., 2012). The second strategy involves requesting patients undergoing medical procedures or current research participants to donate biological samples and consent for their use in future research that is not yet known (Gefenas et al., 2012; Kapp, 2006).

The third strategy involves the utilisation of residual samples from medical procedures, and the storage of these for future research purposes (Elger & Caplan, 2006; Gefenas et al., 2012). These samples are typically collected from leftover biological samples obtained from medical visits, which were stored and used without the consent of the patients. This raised many ethical concerns (Elger & Caplan, 2006). Biomedical research involving human participants raises a variety of ethical concerns pertaining to values of dignity, bodily autonomy, autonomy, and privacy (Kapp, 2006). In recent years, biobanks have been established in order to enable willing donors to donate their biological materials; although this is a new alternative, ethical concerns still remain with regard to whether once-off consent is sufficient, and how consent should be given, and for the purposes of which research (Porter et al., 2000).

## **1.2 Structure of report**

This study aims to investigate the attitudes of Pietermaritzburg government hospital out-patients to the collection and storage of human biological samples for future research purposes. The main areas of investigation will include attitudes to the use of their human biological samples for

research purposes, with a particular focus on: (1) how consent should be obtained for research on stored samples; (2) whether people would desire to receive results of clinical significance; (3) people's perceptions of confidentiality, and (4) whether there are any significant differences based on participant demographics (race, gender, age).

This thesis begins with the theoretical framework. This provides an overview of the history of research ethics which focuses on how past research atrocities on human participants have led to the conceptualisation of ethical codes and specific ethical requirements to avoid the mistakes of the past (Emanuel, Wendler, & Grady, 2000). It will then discuss the four philosophical principles guiding ethical research, which will be followed by a more practical application of these, namely the eight ethical requirements for research (Emanuel, Wendler, Killen, & Grady, 2004). This will be followed by a literature review. Biomedical research will then be introduced, and the distinction will be made between samples collected for clinical purposes (then later used for research) and samples collected solely for research purposes.

The ethical, legal and social considerations of research using stored human biological samples will be discussed, and arguments from different authors will be presented. Biomedical research in the African context will then be introduced and the ethical considerations of this will be discussed. This literature review will end by discussing public attitudes to the use of their human biological samples for research purposes

The researcher will then discuss the aims and rationale of this study, followed by the methodologies used to carry out the aims of the study. Results of the study will then be presented, followed by a discussion which will incorporate the theoretical framework and the literature review. This study will end with a conclusion and recommendations.

## **Chapter 2: Theoretical framework**

### **2.1 Research ethics**

An ethically sound research study is one that is scientifically valid and justifiable, and one which does good and avoids harm (Orb, Eisenhauer, & Wynaden, 2000). One of the main aims and functions of research ethics is to ensure that the welfare of research participants is protected throughout the research process (Wassenaar, 2006; Wassenaar & Mamotte, 2012). This research process with human participants involves various stages of the research, namely the planning, designing, implementing, and reporting of research (Wassenaar, 2006). In any research study, it is vital to protect the dignity and rights of human beings and efforts need to be made to reduce any potential harm that could be sustained by participants as a result of participation in a particular research study (Orb et al., 2000). Under no circumstances should participants be treated as a simple means to the researcher's ends, and it is the obligation of the researcher to treat all participants ethically (Wassenaar, 2006).

#### *2.1.1 The history of research ethics*

In the past few decades, the main foundations of guidance for the ethical conduct of clinical research have been the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, the International Ethical Guidelines for Biomedical Research Involving Human Subjects, and similar documents (Emanuel et al., 2000). Several of these ethical guidance documents were written in reaction to particular events that happened and were hence intended to serve as a means to avoid recurrence of earlier research mistakes (Emanuel et al., 2000). Hence, these guidelines often tend to incline towards more particular ethical considerations associated with particular events, while relegating other important ethical considerations (Emanuel et al., 2000).

The Nuremberg Code, published in 1948, was written in response to the atrocities committed by the Nazi medical researchers in Germany during World War 2 (Emanuel et al., 2000; Wassenaar, 2006; Wassenaar & Mamotte, 2012). Some experiments involving hypothermia were conducted on prisoners between 1942 and 1943 in the Dachau concentration camp and, while these

experiments were disguised as medical research, they were brutal crimes (Berger, 1990). The Dachau human hypothermia study aimed at establishing the most effective treatment for victims of hypothermia (Berger, 1990). The study involved the immersion of prisoners into a tank of iced water, with some subjects dressed, others naked, and some anaesthetised, while others were conscious (Berger, 1990). Most of the subjects' participation in this study was coerced, with some participating 'voluntarily' in response to rarely fulfilled promises of release from the concentration camps (Berger, 1990).

The Nuremberg Code was part of the judicial decision formed in response to the atrocities of the Nazi era (Emanuel et al., 2000) and various other brutal crimes against individuals disguised as research. It focused on the need for individual informed consent and a favourable risk/benefit ratio in research for participants; however, it failed to speak about fair subject selection or independent review (Emanuel et al., 2000; Wassenaar & Mamotte, 2012).

After the Nuremberg Code, the Declaration of Helsinki was first developed in 1964 by the World Medical Association to remedy omissions that were believed to have been made in the Nuremberg Code (Emanuel et al., 2000). The Declaration of Helsinki focused on physicians conducting research with human participants, and particularly focused on favourable risk/benefit ratio and independent ethics review (Emanuel et al., 2000). It also emphasised the distinction between therapeutic and non-therapeutic research (Emanuel et al., 2000).

The Belmont Report was written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research as a response to research atrocities such as the Tuskegee Syphilis Study and other research abuses committed between 1932 and 1972 (Emanuel et al., 2000; Isler, Odulana, & Corbie-Smith, 2011). Essentially, the Tuskegee Syphilis Study was used as a name to group all of the medical abuses and mistreatment of African Americans within the research context (Isler et al., 2011).

The Tuskegee Syphilis Study was an observational study comprised of over 400 African American share-croppers (men) with untreated syphilis (Corbie-Smith, 1999). It began in 1932 and was conducted by the United States Public Health Service as they aimed to document the course of development of syphilis (in blacks), and whether there were any significant clinical differences in its manifestations (Corbie-Smith, 1999). The men were allegedly not informed that they had syphilis, nor were they counselled on how to avoid the spread of the disease (Corbie-Smith, 1999). Treatment was not available when the study began, but when it became available, it was not given throughout the 40-year duration of the study (Corbie-Smith, 1999). This study was documented as the longest non-therapeutic experiment on humans in the history of medicine. By the end of the study, over 100 men had died from syphilis and other related illnesses (Corbie-Smith, 1999). The study finally came to an end in 1972 when ethical concerns about it were raised in the media (Corbie-Smith, 1999).

In the aftermath of such atrocities, the Belmont Report concentrated on informed consent, favourable risk/benefit ratio, as well as ensuring the fact that when research risk is high, vulnerable populations are not targeted (Emanuel et al., 2000). At institutions receiving federal grants, this report required that institutional review boards (IRBs) be established and that these federally funded grants be subject to review by IRBs, to regulate whether the selection process was fair and that rights and welfare of the intended human participants of any research were acknowledged and protected (Corbie-Smith, 1999).

Another outcome of the Tuskegee Syphilis Study was the emphasis placed on research being participant centred and community engaged (Isler et al., 2011). This meant that participants' needs and interests should be central to research, unlike previously when the professional needs of the researcher were the focus (Isler et al., 2011). This shift of focus to participants' needs and interests had the potential to influence a variety of factors within the context of research with human participants, including recruitment strategies, participation assignment to groups and the strategies of dissemination (Isler et al., 2011).

### *2.1.2 The four philosophical principles guiding ethical research*

Through the application of appropriate ethical principles, harm incurred by research participants can be prevented or at least reduced (Orb et al., 2000). There are four widely accepted philosophical principles, namely autonomy, beneficence, non-maleficence, and justice, and these four principles have been applied to research in various ways to determine whether or not research is ethical (Wassenaar, 2006; Wassenaar & Mamotte, 2012).

Autonomy is seen as the participant's right to be informed about the intended study, the right to freely decide whether they wish to participate, and the right to withdraw without penalty at any stage (Orb et al., 2000). Autonomy can be operationally expressed in the essential requirements for voluntariness, informed consent, and the protection of participants' confidentiality throughout the research process (Wassenaar, 2006).

The philosophical principle of beneficence states that researchers must take all possible measures to ensure that benefits are maximised and risks are minimised for research participants in the research study (Orb et al., 2000). This principle can be viewed in combination with the principle of non-maleficence (see below) and together they can be determinants of a favourable risk/benefit ratio (Wassenaar, 2006). A favourable risk/benefit ratio is determined by the weighing of possible risks/harms, that might be directly incurred by the participants, against the benefits that participants may gain as a result of participation, and ensuring that the benefits outweigh the risks (Wassenaar, 2006). It should be noted that monetary incentives given to research participants cannot be regarded as benefits, and benefits should be more direct (such as better access to health facilities, skills development, and so forth) (Wassenaar, 2006).

Researchers also need to ensure that no direct or indirect harm is incurred by the participant as a result of participation (Orb et al., 2000; Wassenaar, 2006). This refers to the philosophical principle of non-maleficence and means that researchers need to take necessary steps and

precautions to minimise and avoid anticipated harms (Wassenaar, 2006). Wrongs also fall under this principle and, although participants may not be harmed by research, they may be wronged in some way and this should also be avoided (Wassenaar, 2006).

The final philosophical principle guiding ethical research is that of justice and this requires that research participants be treated fairly throughout the duration of the research (Orb et al., 2000). This applies to all stages, including the initial stages of the research, where there should be a fair selection of participants, and to the course of the research where those who stand to benefit the most from a particular research, should consequently bear the most burdens (favourable risk/benefit ratio) (Orb et al., 2000; Wassenaar, 2006).

### *2.1.3 Towards a more practical application of research ethics: The eight ethical requirements*

While there is no doubt that these four universally accepted philosophical principles are useful and important, their practical implications and applications as applied to research have been unclear (Emanuel et al., 2000; Emanuel, Wendler, Killen, & Grady, 2004; Wassenaar, 2006; Wassenaar & Mamotte, 2012). This is due to their abstract nature, and the difficulty in practically applying them to different people and in varied contexts (Wassenaar & Mamotte, 2012). Emanuel et al. (2004) provided eight requirements which attempted to outline a systematic and coherent framework for evaluating clinical studies that incorporate all relevant ethical considerations. These eight requirements are: (1) collaborative partnership, (2) social and scientific value, (3) scientific validity, (4) fair participant selection, (5) favourable risk/benefit ratio, (6) independent ethical review, (7) informed consent, and (8) ongoing respect for participants and study community (Emanuel et al., 2004; Wassenaar, 2006).

The eight ethical requirements for clinical research aim to minimise the possibility of exploitation mainly by ensuring that all human participants are treated with respect while they contribute to social good (Emanuel et al., 2000). The order in which the principles are listed



below is significant as it represents the chronological order from the conception of the research, to its formulation and its implementation, and they serve as the guideline to the ethical development, implementation, and review of individual clinical protocols (Emanuel et al., 2000).

A brief description of each of the ethical requirements follows:

- *Collaborative partnership* requires the development of equal partnerships with researchers, makers of health policies, and the target community (Emanuel et al., 2004). It involves partnership in sharing responsibilities for determining research as expressed by a community need, and assessing the value of research and its implementation (Emanuel et al., 2004). Communities should be involved in all research stages, from the planning of the study right through to the dissemination of the results (Wassenaar & Mamotte, 2012). Ensuring that researchers show respect for the community's values, culture, traditions, and social practices is also an important aspect pertaining to this requirement (Emanuel et al., 2004; Wassenaar 2006). Lastly, the benefits of the research should be shared with the recruited participants and the host communities (Emanuel et al., 2004; Wassenaar, 2006).
- *Social/scientific value* stresses the fact that research with human participants should pursue questions that are of value to society or particular communities in society (Wassenaar, 2006). Clinical research that imposes risk on human participants can only be justified if, firstly, it identifies who may benefit from the research directly or indirectly and, secondly, if society will gain knowledge or possible interventions that prove to be valuable (Emanuel et al., 2004; Wassenaar, 2006). This means that, in responding to the needs of the community, researchers need to include intervention studies, action research, or advocacy efforts in their research design (Nyambedha, 2008, in Wassenaar & Mamotte, 2012). Research that lacks social/scientific value is unethical as it wastes scarce resources that could be used for other beneficial studies, and because it imposes possible harm on participants without any social/scientific benefit (Emanuel et al., 2004).
- *Scientific validity* Researchers need to ensure that the design, methodology, and data analysis of their study is adequate and best suited to answer their research question (Wassenaar, 2006). Inappropriate or flawed methodology is unethical as it yields

inaccurate results, wastes scarce resources, and exploits participants without social benefits (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006).

- *Fair participant selection* requires that the participants selected for any particular research be those to whom the scientific goals of the study apply (Wassenaar, 2006). The exclusion of certain groups or people should be justified by valid social/scientific reasons (Emanuel et al., 2000). Vulnerability, privilege, easy accessibility, or any other factors that are unrelated to the study should not be used as a basis for selecting participants (Emanuel et al., 2000). The requirement of fairness also holds that those who stand to benefit the most from a study should bear most of its burdens (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006).
- *Favourable risk/benefit ratio* holds that researchers need to assess the potential risks/costs and benefits of the research to its participants and evaluate ways in which the risks/costs can be minimised in order to ensure a favourable risk/benefit ratio whereby the benefits outweigh the risks (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). Payment of research participants cannot be considered a fair benefit as it does not offset risks (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). However, research participants may be reimbursed for costs (e.g. travel money) incurred by them (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). While there may still be debate surrounding the payment of participants in South Africa, all South African ethical guidelines support reimbursement payments (Koen, Slack, Barsdorf & Essack, 2008)
- *Independent ethics review* is important for issues pertaining to social accountability, and for minimising conflicts among researchers and research teams regarding methodology (Emanuel et al., 2000). Ethics review should involve an independent and competent research ethics committee (REC) reviewing a proposed study prior to commencement of data collection. The main goals of this committee are to ensure the protection of human participants and to enhance the quality of the proposed research (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006).
- According to Wassenaar (2006), *informed consent* is made up of appropriate information, ensures participants' competence and understanding, and provides for voluntariness in

participation and freedom to decline or withdraw from the study, even after the latter has started. Formalisation of consent, which is mainly done in writing, also forms part of informed consent to participation (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). This ethical prerequisite demands that the researcher provides potential participants with comprehensive and truthful information with regard to the research and its methodology, as well as the potential risks and benefits that may directly or indirectly arise should they agree to participate in the research (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). The main purpose of informed consent is to ensure the voluntary, uncoerced nature of participation, and it gives the participants the choice in participating in studies that are consistent with their values, interests and preferences (Emanuel et al., 2000). It respects the autonomy of individuals' decisions.

- Finally, *ongoing respect* for participants and study communities requires that researchers develop and implement procedures to protect the confidentiality of recruited and enrolled participants throughout the study (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). Risks and benefits pertaining to participation in a study should be reassessed over time, and any new developments need to be explained to participants (Wassenaar, 2006). It is also necessary for researchers to ensure that participants know they can withdraw at any stage of the research without any penalties (Emanuel et al., 2000; Emanuel et al., 2004). It is also the responsibility of researchers to inform participants and the study community of the results of the research, in a language which they are able to understand, and in a format that is relevant and appropriate (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006).

## Chapter 3: Literature Review

### 3.1 Biomedical research: International context

#### *3.1.1 What is biomedical research?*

According to the Organisation for Economic Cooperation and Development (2007), biomedical research can be defined in three components. Biomedical research is:

... the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment, and rehabilitation of persons; the design of methods, drugs, and devices used to diagnose, support, and maintain the individual during and after treatment for specific diseases or conditions; and the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, and immunology. (Organisation for Economic Cooperation and Development, 2007, p. 70).

The main purpose of carrying out biomedical research is to facilitate the systematic collection and analysis of data from which ‘generalisable conclusions’ can be made (Kapp, 2006). This may consequently help in the improvement of future care of presently unknown beneficiaries (Kapp, 2006). Therefore, biomedical research relies on human participants as the primary source of data, and much of this data includes the use of human biological samples (Kapp, 2006; Porter et al., 2000). Although research on animals has proved beneficial, it sometimes provides only limited insight in relation to humans (Bathe & McGuire, 2009). Due to this limited insight, Bathe and McGuire (2009) also highlight the fact that it becomes difficult to ethically justify research on animals.

#### *3.1.2 Human biological samples*

Research with human biological samples has great scientific potential for combating severe illnesses like cardiovascular diseases, metabolic disorders, hormonal pathologies, cancer, diseases of the nervous system, infectious diseases, and diseases of the immune system (Simitis, 2004). Research with human biological samples is not only beneficial to the public, but individual donors may also benefit from the results (Simitis, 2004).

Human biological samples may be obtained in three different ways namely: (1) solely for specific research purposes, (2) for diagnostic or therapeutic procedures (clinical purposes) with no intention for them to be used in research, (3) or they may be sought for specific medical or research purposes with the intention of using them for future unspecified research purposes (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2010; Gefenas et al., 2012; Kapp, 2006; National Bioethics Advisory Committee, 1999). When individuals contribute their human biological samples solely for research purposes, the researcher is required to inform them fully of the study (by means of an information sheet) before they provide their consent (by means of a separate consent form) (Canadian Institutes of Health Research et al., 2010). The consent form needs to provide research participants with the option to withdraw their samples from the study with no penalties, and should they withdraw, they may decide whether already obtained data from their samples may be used (Canadian Institutes of Health Research et al., 2010).

Human biological samples that are obtained from diagnostic or therapeutic procedures (clinical purposes) with no intention for them to be used in research, and samples that are obtained from specific medical or research purposes with the intention of using them for future unspecified research purposes, are referred to as residual human biological materials (Gefenas et al., 2012; Kapp, 2006; National Bioethics Advisory Committee, 1999). Residual human biological samples can also be obtained after death if the relatives of the deceased are willing to consent (Al-Jumah et al., 2011).

These samples are referred to as residual because of their potential secondary use which may or may not have been apparent when the tissue was obtained (Canadian Institutes of Health Research et al., 2010). Previously, researchers kept these residual samples and they were used without informed consent, as research with them was associated with little or no risk (Porter et al., 2000). However, as a result of this, ethical questions began to emerge, such as

- Is it appropriate to use stored biological materials in ways originally not contemplated, either by the people from whom the materials came or by those who collected the materials:
- Does such use harm anyone's interest?
- Does it matter whether the material is identified or identifiable as to its source, or linked or linkable to other medical or personal data regarding the source? (National Bioethics Advisory Committee, 1999)

Gefenas et al. (2012) refer to three models of consent when using residual human biological materials, namely: the precautionary consent model, the presumed consent model, and the no consent model. The precautionary consent model refers to consent that is obtained for research use of residual materials in future unspecified research (Gefenas et al., 2012). This consent is usually sought from patients undergoing diagnostic or therapeutic procedures, or current research participants, and the material may be stored in the absence of any concrete future research plans, in order to avoid the need to re-contact individuals for consent (Gefenas et al., 2012).

The presumed consent model, which is only applicable in some countries such as Belgium, and the Netherlands, refers to identifiable human biological samples collected during diagnostic or therapeutic procedures and stored without the individuals' consent for future research use (Gefenas et al., 2012). These residual materials are then treated as already-existing research collections and this relies on the assumption that members of society are aware of the fact that such residual samples are routinely stored for biomedical research (Gefenas et al., 2012). In hospitals in these countries, individuals may be informed at hospital admission of the storage of samples, through posters or through brochures, and an opt-out option made available to them (Gefenas et al., 2012).

The no consent model refers to not requiring consent for research use of identifiable human biological samples (Gefenas et al., 2012). For example, in the US Office for Human Research Protections at the Department of Health and Human Services, a guideline was issued which

disregarded research on anonymous residual materials as human research, thus making it exempt from ethics review and consent requirements (Gefenas et al., 2012).

### *3.1.3 Types of human biological materials*

Human biological samples may be categorised in one of four categories according to the amount of information that is conveyed to the researcher about the person (Canadian Institutes of Health Research et al., 2010; National Bioethics Advisory Committee, 1999). Samples can be categorised as follows (Canadian Institutes of Health Research et al., 2010; National Bioethics Advisory Committee, 1999):

- *Identified human biological samples:* These samples are labelled with the personal details of the individual, such as their name and their patient numbers. This enables researchers to make associations between the data obtained from the research and the specific individual.
- *Coded human biological samples:* With these samples, personal and identifying details are replaced with codes. Accessibility to these codes is often kept by principal investigators (or similar authorities), in case it becomes necessary to re-link the sample and the identity of the individual.
- *Anonymised/unlinked human biological samples:* Samples which have had all possible identifiers removed but these have not been replaced with any codes. This makes future re-identification and re-linkage extremely difficult.
- *Anonymous/unidentified human biological samples:* These samples are ones which have never had any personal or identifying details attached to them.

### *3.1.4 What are biobanks?*

The rapid growth and development of biotechnological research has led to the use of biobanks as a means managing biological samples (Kettis-Linblad, Ring, Viberth, & Hanson, 2005). The American Society of Human Genetics (ASHG) has defined DNA banking as a facility that stores DNA for future analysis (Godard, Schmidtke, Cassiman, & Ayme 2003). Simitis has defined biobanks as “collections of samples of human bodily substances that are, or can be, associated

with personal data and information on their donors” (Simitis, 2004, p. 21). Cells, tissues, blood, and DNA are examples of bodily samples and these contain genetic information about a person (Simitis, 2004). Similarly, the Biobank Ethics Committee of the University of Witwatersrand (Wits) Human Research Ethics Committee (HREC) (Medical) has defined biobanks as “repositories where organised collections of human biological materials (HMBs) and associated data from large numbers of individuals are collected, stored, and distributed for the purpose of health research” (2013, p. 1).

The use of biobanks allows for identification of diseases, which is hoped to lead to personalised prevention programmes and treatments (Kettis-Linblad et al., 2005). Being able to identify relationships between genes, lifestyle, environmental factors and susceptibility to illness may serve as a useful therapeutic tool (Simitis, 2004). Biobanks also have the potential to contribute to the development of certain drugs tailored specifically to particular individual patients or specific diseases (Simitis, 2004). Biobanks can either be public or private, with public biobanks often referred to as population banks (Biobank Ethics Committee of the Wits HREC (Medical), 2013). Human biological samples stored in population biobanks are used for the benefit of the health of the population (Biobank Ethics Committee of the Wits HREC (Medical), 2013).

Biobanks are those facilities that are established and used solely for the purpose of research (Simitis, 2004). Facilities such as laboratories are not classified as biobanks because they merely record and store personal data from bodily samples (Simitis, 2004). Biobanks are seen as a vital resource for biomedical research, and more broadly, public health; therefore, their establishment can be seen as meeting the public interest (Kettis-Linblad et al., 2005). In order for biobanks to succeed, sample donors need to allow access to their personal data which touches private aspects of their life, without revealing their identity (Godard, 2003; Simitis, 2004). The efficiency and resourcefulness of these biobanks, therefore, is highly dependent on people’s willingness to contribute samples for both research and storage (Kettis-Linblad et al., 2005). Public support is thus seen as an essential component in securing the long-term viability and sustainability of biobanks (Kettis-Linblad et al., 2005).



### **3.2 Ethical considerations in biomedical research using human biological samples**

According to Porter et al. (2000), there are various legal, ethical, and social consequences of creating and storing human biological samples. Working around the issue of consent to use these samples comes with its own sets of difficulties (Porter et al., 2000). According to Gibbons and Kaye (2007), the considerable growth in research on stored biological samples and genetic research has led to the increasing need to devise a suitable and efficient framework that will help in the appropriate management of genetic databases, both nationally and internationally. These frameworks should not solely serve the purpose of safeguarding vital rights, principles, and values but should also seek to promote beneficial research for the good of the public and to preserve public confidence and support. This section will review the ethical considerations of biomedical research using the eight ethical requirements of research ethics as outlined in Section 2.2.3 above. Since there is a great deal of overlap within these and biomedical research, only the following five will be discussed: independent review, social and scientific value, favourable risk/benefit ratio, informed consent, and ongoing respect for participants and study communities.

#### *3.2.1 Independent review*

According to Simitis (2004), it is important for regulatory provisions to be put in place in order to protect participants, their relatives, and their population groups from genetic discrimination and stigmatisation. These regulatory provisions need to ensure that all research respects the autonomy of participants, and that no unacceptable risks are incurred by participants, their relatives, or their population group (Simitis, 2004). The National Bioethics Advisory Committee (1999) states that institutional review boards (IRBs) need to ensure that regulations are applied sensitively for participants whose human biological samples are used for research purposes. These regulations include the right of protection from harm, and the ongoing well-being of participants, their relatives, and related populations (National Bioethics Advisory Committee, 1999).

Along with the regulations pertaining to participants, institutional review boards also need to ensure that the interests of researchers and research teams are not overlooked (National Bioethics Advisory Committee, 1999). This means that research on stored biological samples, or on newly collected samples, should be permitted if scientifically and socially justifiable and if there is a sound methodology (National Bioethics Advisory Committee, 1999). Research ethics committees (RECs) or IRBs need to ensure that both the genetic privacy laws and the values of medical research are respected (Gibbons & Kaye, 2007). Bathe and McGuire (2009) make a distinction between ‘genetic privacy laws’ and ‘genetic anti-discrimination laws’, and they advocate for the latter. Genetic anti-discrimination laws arise from the misuse of information obtained from individuals’ genetic information by the researcher or unintended and unknown third parties (Bathe & McGuire, 2009). Such third parties may include government, health insurers, and employers, who may discriminate against individuals based on disease susceptibility or behavioural predispositions, as indicated by medical research (Bathe & McGuire, 2009).

### *3.2.2 Scientific/social value*

According to Simitis (2004), biobanks should not only be primarily viewed from the perspective of dangers and risks, but should instead be viewed in terms of their social utility. Initially, when considering the values pertaining to individual privacy and those pertaining to medical research/research on human biological samples, they may appear to be conflicting (Gibbons & Kaye, 2007; Simitis, 2004). However, it is important rather to see how these work together in the pursuit of the public interest (Gibbons & Kaye, 2007). For example, the key function of medical practitioners (as outlined in their professional ethics) is protecting and promoting the welfare of their patients (Simitis, 2004). Since one of the core aims of biomedical research is to help improve future care of presently unknown beneficiaries/ patients, this means that doctors can be seen as fulfilling a legitimate professional obligation by asking patients to donate their samples (Simitis, 2004).

The ethics surrounding the issue of research on stored biological samples should ensure that public interest or social value (e.g. scientific, medical, and public health research) and autonomy are of paramount importance (Bauman et al., 2003; Gibbons & Kaye, 2007; Simitis, 2004). By autonomy, Bauman et al. (2003) refer specifically to ongoing respect for participants and informed consent. An individual's choice to donate samples can be seen as their expression of solidarity and moral duty to help future unknown beneficiaries (Simitis, 2004). According to Simitis (2004), this solidarity should entail a realisation by individuals that they too have benefitted from others' donations (of samples for medical research). Thus, it can be argued to be a moral obligation to donate one's own samples to potentially alleviate the suffering of others (Simitis, 2004). Simitis (2004) holds that voluntariness is important in maintaining public confidence and in emphasising the legitimacy of research, and he believes that this should work together with moral obligation.

A conflicting relationship can possibly be identified between the principles of autonomy and solidarity/social value (Bauman et al., 2003). This is because obtaining re-consent for use of stored biological samples for future unknown research can be financially impossible and it can also be seen as an intrusion on individuals' privacy; yet, at the same time, this research is beneficial to the larger public and holds social value (Bauman et al., 2003). Bathe and McGuire (2009) acknowledge that using stored samples may be counter to one's autonomy. They in turn argue that since these samples are such a valuable source of scientific knowledge and medical management of human disease, it would be difficult to justify discarding them (Bathe & McGuire, 2009). They do, however, emphasise that if consent is not obtainable, then researchers need to ensure that tissues are coded (Bathe & McGuire, 2009).

When research is intended on stored biological samples, it is often difficult to obtain consent due to the financial/economic constraints involved and there is also a potential difficulty or even impracticability in re-contacting participants, especially in cases where some may be deceased (Bathe & McGuire, 2009). There is also an issue of selection bias which could be a result of not being able to reach all participants, and this could affect the scientific validity of the research

(Bathe & McGuire, 2009). In light of the above, Bathe and McGuire (2009) conclude that, since the use of stored samples for research purposes contributes to the future care of future patients and that it is beneficial to society, then it can be considered acceptable to use them without participants' consent. Bauman et al. (2003) suggest that, in making laws governing the collection of human biological samples and governing research on stored biological samples, it is important to consider both individual autonomy and the common good as mutually beneficial. In saying this, Bauman et al. (2003) stress that donated and/or stored samples should be used to their fullest potential, provided that results are not misused by the researcher or any unintended third party.

### *3.2.3 Favourable risk/benefit ratio*

When pursuing their scientific aims, researchers need to ensure that the rights and dignity of their participants are protected throughout the duration of the study (National Bioethics Advisory Committee, 1999). Risks and benefits need to be reviewed continuously, and it is the responsibility of the researcher to inform participants of any potential new risks that may arise (National Bioethics Advisory Committee, 1999). It is important for researchers also to take into account non-physical risks that may arise in the process of research on stored human biological samples (National Bioethics Advisory Committee, 1999). By non-physical risks, the National Bioethics Advisory Committee (1999) refers to clinically relevant information about individuals that could lead to genetic discrimination.

Although biobanks and biomedical research are extremely useful in medical and pharmaceutical research, they may invoke feelings of anxiety and distrust for participants or donors (Simitis, 2004). These anxieties may be due to issues regarding donor protection and the prospects of unknown and uncontrolled research on samples; confidentiality and anonymity; and the risks associated with the proposed research (Simitis, 2004). According to Simitis (2004), when dealing with individuals' samples, it is important for researchers to realise that these samples contain personal information such as disease susceptibility, behavioural predispositions and certain aspects of personality. Ensuring protection from genetic discrimination becomes significantly

more difficult with research on stored samples because these are usually stored over long periods of time for unknown future research (National Bioethics Advisory Committee, 1999). For this reason, Simitis (2004) believes that necessary measures need to be taken by lawmakers to ensure protection from discrimination and stigmatisation of individuals and/or population groups by the researcher or any third parties (Bathe & McGuire, 2009).

In order to minimise risks associated with research on stored biological samples, it is suggested that databases containing information related to tissue and to clinical data should be coded, which means excluding any personally identifying phenotypic information (Bathe & McGuire, 2009). Limiting access to these databases solely to researchers for legitimate research purposes has also been suggested (Bathe & McGuire, 2009). Bathe and McGuire (2009) state that if such precautions are implemented properly, then research on stored biological samples should be considered as no more than a minimal risk.

When evaluating biomedical research in terms of social justice, one needs to consider the possible injustice of risks being imposed on certain individuals or population groups by using their samples for future unknown research from which they are not likely to benefit (Simitis, 2004). Simitis (2004) raises the question of whether or not benefits from the use of their samples should be shared with individuals and how this can be achieved. Those who stand to benefit the most from a research study should ideally bear the risks; however, this does not justify unnecessary risk being imposed on individuals. Furthermore, benefits need to be shared with those who contribute to the research and this process should not be delayed (Simitis, 2004). Anonymisation and confidentiality pose a challenge to benefit-sharing and informing participants of potential harms of new research on stored biological samples (Bauman et al., 2003). Anonymisation, coupled with distance and time, makes it almost impossible to find participants in order to share benefits or inform them of possible harms (Bauman et al., 2003).

#### *3.2.4 Informed consent*

One of the fundamental elements of an individual is self-determination, which is their right to make choices regarding themselves, their bodies, and their personal space (Simitis, 2004). This right is especially important in biomedical research which involves the use of individuals' biological samples (Simitis, 2004). In respect of their human dignity, individuals should be afforded the opportunity to make informed decisions regarding the use of their samples (Simitis, 2004). Researchers need to ensure that adequate information is provided to individuals, in a language that they can understand, before they may be willing to provide their consent to the use of their samples (Simitis, 2004).

When obtaining consent for a proposed research project using human bodily samples, researchers need to ensure that this consent is freely given, informed, and specific (Bauman et al., 2003). Important information to be included prior to individuals providing their consent is: (1) a detailed description of the study, including background information and the objectives of the research; (2) an explanation as to which other stakeholders have an interest in the research, along with the consequences of the research study and the consequences of participating in the research; (3) how the data from the samples will be used; and (4) how samples will be handled once the research project is over (Bauman et al., 2003). The information also needs to include the possible risks associated with participation in research with one's samples (Simitis, 2004). In addition to this, participation should always be voluntary, and participants should not be coerced into donating their samples for research (Simitis, 2004).

It is important for researchers to inform participants of any possibility of their samples being used in any research in the future, even if details of the research are still unknown to the researcher (Simitis, 2004). This is important as it respects participants' right to self-determination (Simitis, 2004). By informing participants, they then have the option to consent to the use of their samples, and impose limitations on the types of research that may be conducted on their samples (Simitis, 2004). While informed consent is an essential prerequisite for ethical research, Gibbons and Kaye (2007) state that obtaining it for research on stored biological

samples is not always possible, especially if the details of the future research are not yet known during the collection of the samples. According to Brownsword (n.d., in Gibbons & Kaye, 2007), since consent is an individual choice, it is morally unjustifiable to include individuals in genetic databases, or use their samples without their consent, even if it is of social value or it is for public health purposes. From this perspective, researchers and research teams need to ensure that explicit consent is provided for research, whether personal information is anonymised or not (Gibbons & Kaye, 2007).

According to Bathe and McGuire (2009), using individuals' samples without their consent is a violation of their basic human right of autonomy, especially if religious and cultural beliefs require that they be buried with all parts of their body. In some countries such as the United States of America, the law states that individuals do not own tissues that have been removed from their bodies (Bathe & McGuire, 2009). However, because of issues around invasion of privacy and respecting the dignity of individuals, consent is crucial in research as using individuals' samples in published or commercial research to which they have not consented, has posed challenges with regard to their samples being the source of intellectual property (Bathe & McGuire, 2009). Another reason why informed consent is important is because of culture and religious views which may include or imply various beliefs regarding science, research, and genetic discovery (Al-Jumah et al., 2011). These views are likely to influence individuals' decisions regarding certain research; thus, informed consent is critical in attempts to respect participants' autonomy (Al-Jumah et al., 2011).

While it may be important to re-contact individuals for consent to subsequent research on their samples, sometimes this may in itself be regarded as an invasion of privacy (Bathe & McGuire, 2009). This becomes especially awkward if the individual is deceased, or if the person requesting the consent is unknown to the participant (Bathe & McGuire, 2009). Not being able to reach participants for re-consent also poses a threat to the scientific validity of the research due to the high dropout rate of participants (Bathe & McGuire, 2009). According to the American Society of Human Genetics, researchers need not re-contact individuals for consent if the proposed

research on their stored samples is associated with minimal risk (Chen et al., 2005; Porter et al., 2000). However, since biomedical research is of value to society and serves the public good, Bathe and McGuire (2009) suggest that it may be justifiable to re-use individuals' samples without their consent.

It is suggested that, if possible, individuals be provided with full information regarding the possible future use of their samples (Bauman et al., 2003). This information should include how their samples will be used, the anticipated duration of the use of their samples, how the results will be used, and if there are any possible third parties who may be involved (Bauman et al., 2003). Bauman et al. (2003) further suggest that it can be acceptable for researchers to re-use individuals' samples for subsequent research provided that their samples are duly anonymised and that individuals have agreed to this when samples were collected. This raises the importance of providing an option for unknown future research when collecting samples, as this removes the intrusive need for re-contacting individuals (Bauman et al., 2003).

Upon collection of samples for biobanks, regulating authorities need to ensure that researchers explain the complicated nature of research with stored samples (Bauman et al., 2003). This is with regard to the protection of the interests of individuals whose samples are used and to the consent to future research, the specifics/details of which are not yet known (Bauman et al., 2003). According to Bauman et al. (2003), re-contacting of individuals should be avoided unless there is a justifiable reason. Individuals should, however, be given the opportunity to contact researchers or biobanks to query the use of their samples or should they want to express any limits to their consent (Bauman et al., 2003). Bauman et al. (2003) also suggest three further courses of action with regard to re-contacting individuals about clinically significant results. These include positive results being made available to individuals on a priority basis; enabling individuals to claim a share of royalties or copyright if their samples contribute to patents; and/or banning the collection of human biological samples intended for commercial use (Bauman et al., 2003).



The first course of action would only apply to specific groups and would not become the norm (Bauman et al., 2003). These groups would strictly include only those individuals who are personally affected and concerned by the specific therapeutic research (Bauman et al., 2003). Although the 'sharing of royalties' is a possible course of action, it is suggested that this trend towards individual appropriation of human biological material should be avoided (Bauman et al., 2003). Reasons for this include the fact that it contradicts the notion of community solidarity whereby individuals willingly donate their biological materials for research which could be beneficial to the community at large (Bauman et al., 2003).

A challenge can be apparent when collections are of concern to certain groups or communities at large, but where ethical issues need to be adapted for individual cases (Bauman et al., 2003). Ethically, researchers need to ensure that population studies of such magnitude that they provide access to genetic material do not fall into the hands of people who are indifferent to or unaware of the ethical principles for research (Bauman et al., 2003). Thus, researchers would need to ensure that the research design takes into account autonomy, respect for dignity, and freedom to participate - to name but a few (Bauman et al., 2003). The difficulty in trying to apply this in studies pertaining to certain groups or communities is that all these ethical issues pertaining to individuals could be seen as overly constraining and burdensome to researchers (Bauman et al., 2003). This poses a threat to scientific progress and the potential benefits of research for individuals and society at large (Bauman et al., 2003).

In order to prevent possible misuse of samples, it is suggested that consultative bodies are formed to enable individuals to enquire regarding the use of their samples (Bauman et al., 2003). This becomes particularly important should an individual wish to know if any medically significant results are obtained from their results and if their samples are used in generating a marketable product or technique (Bauman et al., 2003).

Campbell (n.d., in Gibbons & Kaye, 2007) supports the idea of 'broad consent' as he believes that re-contacting participants in order for them to provide consent for new research can be a

difficult, expensive, and time-consuming task, that can be viewed as ‘paternalistic’. Alternatively, the relationship between the individual and the research team and/or biobanks should be one based on trust and respect, whereby individuals may consent to a wide range of studies, and still have the appropriate control to refuse certain research (Campbell n.d., in Gibbons & Kaye, 2007). According to Caulfield (n.d., in Gibbons & Kaye, 2007) researchers cannot simply ignore the issue of obtaining consent for research on stored biological samples because they believe that it is time consuming, difficult, or expensive. He argues that ‘broad consent’ principles should be executed with caution and careful understanding of their implications as they alter the basic human right of autonomy (Caulfield n.d., in Gibbons & Kaye, 2007).

According to the National Bioethics Advisory Committee (1999), researchers also need to be ethical at all times, which means not compromising the rights and welfare of human participants when pursuing their scientific aims.

While many acknowledge the importance of informed consent when dealing with human biological samples, there appears to be little consensus over what type of consent is sufficient and when it should be obtained (Porter et al., 2000; Chen et al., 2005). Some have suggested that individuals provide consent each time a new study is proposed on their samples, while others feel that a future-consent model is sufficient (Porter et al., 2000; Chen et al., 2005). In this future-consent model, recommendations have been made to provide individuals with a list of options from which they can choose the research for they approve their samples to be used (Chen et al., 2005; Porter et al., 2000). While a checklist of options appears ideal, arguments over which options ought to be included still persist, with some suggesting that individuals be offered a certain number of choices of types of research that can be conducted on their samples (Chen et al., 2005).

Other analysts do not support the use of prospective consent at all and are of the opinion that individuals ought to be given the opportunity to consent for any new research intended on their

samples (Chen et al., 2005). The requirement for repeated consent when proposing further research on samples leads to the difficulty of obtaining the re-consent as it requires the identifying data of the donor (Bauman et al., 2003). This leads to the issue of how these identifying details should be archived, and the security obligation biobanks face in maintaining anonymity of donor samples (Bauman et al., 2003). In maintaining public trust, guarantees of security and anonymity are seen as essential and therefore the need for re-consent in biomedical research should be suppressed (Bauman et al., 2003). It is further suggested that archives of identifying data should be available for three reasons: firstly, if there is a justifiable need for re-contact; secondly, to allow donors to find out what has happened to their samples should they be interested; and thirdly, to enable and facilitate the process of possible withdrawal from research of a donors' sample should the need arise (Bauman et al., 2003).

When confronted with all these issues it is the responsibility of independent research ethics committees (RECs) to ensure that values of ethical medical research are respected and that the interests of researchers are not overlooked. (Emanuel et al., 2000; Emanuel et al., 2004). At the same time RECs need to ensure that human participants are protected at all times even after the initial research is completed (Emanuel et al., 2000; Emanuel et al., 2004). In South Africa, the National Health Act (NHAs 72(6(c) gave authority to the National Health Research Ethics Council (NHREC) under the National Health Act No 61 of 2003 (Department of Health RSA, 2015). This act stated that:

“Every organisation/institution, health agency and health establishment at which health and health-related research involving human participants is conducted, must establish or have access to a registered Human Research Ethics Committee (REC) (NHA s 73(1)).” (Department of Health RSA, 2015, p. 11).

### *3.2.5 Ongoing respect for participants*

One of the utmost values that researchers and research teams need to hold is that of respecting human dignity (Simitis, 2004). This value is central to the ethical and legal obligations of researchers, as it insists that individuals' freedom be respected, and that they not be treated as mere ends to researchers' needs (Simitis, 2004). Researchers need to ensure that individuals are

“respected in their uniqueness; their physical and psychological integrity must be protected” (Simitis, 2004, p. 42). This means that self-determination is one of the core components of an individual and must therefore be held in the highest regard by biobank managers and researchers using human biological samples (Simitis, 2004). Self-determination encompasses respecting individuals’ ability to make decisions personally that involve or affect them, or parts of them (Simitis, 2004).

With the importance placed on self-determination, Simitis (2004) emphasises that self-determination, or individual consent alone, are not the only necessary conditions for acceptable and justifiable research. Even with the necessary individual consent, it is still unethical for researchers to pursue research that may be risky to any unintended third parties (Simitis, 2004). When dealing with samples that have been anonymised, or that have never been personalised, Simitis (2004) argues that researchers should be able to pursue research without obtaining consent. According to Simitis (2004), in such cases public interest takes priority as there are no evident personal interests. Simitis (2004) does, however, note that if there are possibilities that individuals’ samples may be used for future research, then it is better to obtain consent for this so as to respect the self-determination of individuals. In addition to this, researchers have to respect any limits on the uses of their samples that donors have declared (Simitis, 2004).

According to Simitis (2004), biobanks can give rise to possible feelings of anxiety and distrust within donors regarding the protection of their samples. This is seen to arise from the fear of uncontrolled use of samples, the possibility of pressure to assume unreasonable risks, and the divulging of personal information (Simitis, 2004). As a result of these anxieties, legal aspects of data protection become vital, not only for individual donors but also for entire population groups, in efforts to reduce the possibilities of genetic discrimination and stigmatisation (Simitis, 2004).

The ethical principle of autonomy can also be applied when considering whether individuals should provide informed consent each time their biological samples are used, and when considering how many and which choices individuals should be given with regard to research on

their samples (Chen et al., 2005). Allowing individuals to control the use of their samples acknowledges and respects them as autonomous persons (Chen et al., 2005). Adequate information, voluntariness, consent, and freedom to withdraw ensure autonomy of donors (Chen et al., 2005; Simitis, 2004). Therefore, making provision for the above can be considered an ethical obligation (Chen et al., 2005).

An effort to archive identifiable details away from samples, unless there is a justified need for them to be stored together, addresses the ethical principle of ongoing respect for donors (Chen et al., 2005). Alongside this, offering donors the option to access results of research on their samples also shows ongoing respect, especially with regard to the dissemination of findings (Chen et al., 2005). This ongoing protection also extends to minimising the harms incurred by participants, by ensuring the confidentiality of their information, and maximising the benefits by sharing the benefits of the research (in the form of information) (Chen et al., 2005).

### **3.3 Biomedical research in the African context**

#### *3.3.1 Ethical considerations*

Most countries in Africa have been categorised as developing countries due to their vulnerable situation as a result of a lack of education, unfamiliarity with medical interventions, extreme poverty, and their dire need for adequate healthcare and nutrition (Barsdorf & Wassenaar, 2005). During apartheid in South Africa, the health sector drew a distinction between behaving ethically with patients and human rights (Baldwin-Ragaven, de Gruchy, & London, 1999). This was done by removing human rights as the fundamental aspect of ethics, thus rationalising violations of human rights (Baldwin-Ragaven et al., 1999). This differential was driven by preservation of self-interest and political convenience, at the expense of others (Baldwin-Ragaven et al., 1999).

Vulnerable populations globally, including the socially powerless and the disadvantaged, have historically been subjected to unethical research and exploitation. During the course of apartheid in South Africa, ruling institutions of the country violated the human rights of black people as they were targeted as research participants for unethical research due to their vulnerability

(Baldwin-Ragaven et al., 1999). This in turn may have led to black South Africans being apprehensive about their inclusion in medical research, and has led to a distorted view that participation in medical research is not voluntary (Barsdorf & Wassenaar, 2005).

Voluntary informed consent is of the utmost importance in low-income settings, and this consent should be obtained not only at the individual level, but also with permission from existing structures or authorities such as traditional leaders community leaders, religious leaders, and schools (Gikonyo, Bejon, Marsh, & Molyneux, 2008; Molyneux, Peshu, & Marsh, 2004). Researchers and research teams need to ensure that potential research participants know exactly what they are consenting to (Molyneux et al., 2004). This means consent should be negotiated in clear language that the participants are able to understand, and if individuals cannot read or write, alternative methods of communicating this information need to be adopted (Gikonyo et al., 2008; Molyneux et al., 2004). In addition, consent should not merely be a once-off process, but should rather be evaluated at different stages of the research process, giving individuals the freedom to withdraw (Gikonyo et al., 2008).

The legacy of unethical research on vulnerable populations in Africa and internationally has led to a more cautious approach to research involving human participants in developing countries (Barsdorf & Wassenaar, 2005). Vulnerability and need often make individuals in developing countries more susceptible to exploitation (Barsdorf & Wassenaar, 2005). Thus, ethical guidelines have been published by the Council for International Organisations of Medical Science (CIOMS) for health research in developing countries to ensure the protection of individuals (CIOMS, 2002, in Barsdorf & Wassenaar, 2005).

### *3.3.2 Laws, regulations and guidelines in South Africa pertaining to biomedical research*

Due to its high rate of infectious diseases such as HIV/AIDS and TB, and the growing number of medical researchers, South Africa is considered 'fertile ground' for research, and for medical research in particular (Moodley, Sibanda, February, & Rossouw, 2014). There has been an increase in HIV-related research and biobanking, along with an increase in registered clinical

trials from 946 trials in 2010 to 1,390 trials currently (Moodley et al., 2014). Research projects in South Africa have included those pertaining to biospecimen collection, analysis, and storage for future use (Moodley et al., 2014). Samples have also been exported to developed countries for research (Moodley et al., 2014). As is the case in other developing countries and BRICS countries, the guidelines and frameworks for the analysis of human biological materials have been shaped by institutions in Europe and the USA (Molyneux & Geissler, 2008; Sathar & Dhai, 2012).

In South Africa, the National Health Act (NHA) [Act No. 61 of 2003] governs the national ethics regulations, with Chapter 8 specifically focusing on the legal aspects of the use of human biological materials (Sathar & Dhai, 2012). Bodies such as the Health Professions Council of South Africa and the South African Medical Research Council have also independently published research guidelines specific to professionals in their fields (Sathar & Dhai, 2012). Furthermore, The South African Intellectual Property Rights from Publicly Financed Research and Development Act (IPR Act) [Act No. 51 of 2008] is responsible for regulating intellectual property rights, patents, and benefits that may be applicable to research on human biological materials (Sathar & Dhai, 2012). According to the Department of Health RSA (2015) *Ethics in Health Research*, biological material may be stored in repositories for future research once collected. Biological material is regarded as pertaining to personal information thus privacy issues should be addressed. It then becomes the role of the REC to ensure that thorough provisions are made in consent forms for future research purposes (Department of Health RSA, 2015). In doing so researchers also need to make clear distinction to participants regarding biological materials or data collected for clinical purposes and those collected for research purposes (Department of Health RSA, 2015).

In cases whereby no provision is made for broad consent there are 6 recommendations (Department of Health RSA, 2015):

- i. “Use of existing or archived material collected for clinical or diagnostic purposes, including waste and surplus samples, requires expedited review. The nature of the previously obtained consent should be determined to ascertain whether

- subsequent usage was envisaged and whether it falls within the scope of the current proposal. If so, new consent is not required.
- ii. If the scope of the current proposal is different, then new consent may be required.
  - iii. If samples are anonymous 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.
  - iv. 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.
  - v. The person who holds the code of link should sign an explicit written agreement not to release the identifiers to the research team. This agreement should accompany the submission to the REC.
  - vi. 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” (Department of Health RSA, 2015, p.44).

In South Africa, there has been very little published empirical research on public attitudes to the use of human biological samples in research, and the ethical implications of this (Moodley et al., 2014). It is important to take into consideration that South Africa is a very diverse country especially with regard to culture. Therefore, public attitudes to the use of human biological samples in research need to be explored widely (Moodley et al., 2014). These views of the public are of paramount importance, especially with regard to informing legislature on the use of individuals’ samples (Moodley et al., 2014). Therefore, a gap can be seen in the literature in relation to South Africa (Moodley et al., 2014).

### **3.4 Public attitudes to the use of their biological samples**

Medical biobanks are those that have been established for both healthcare and research purposes (Hoeyer, Olofsson, Mjomdal, & Lynoe, 2004). As research using tissue samples becomes increasingly popular, it has received more legal and ethical attention (Hoeyer et al., 2004). In developing policies about the donation and use of human samples, researchers and law-makers need to consider public attitudes towards this (Hoeyer et al., 2004). There has been a great deal



of research conducted to assess public attitudes to the use of their samples in medical/genetic research. This section will describe the findings of some of this research, in chronological order.

#### *3.4.1 Wendler and Emanuel (2002)*

Consent is one of the key aspects of ethical research, and with regard to research on stored biological samples, there is debate over when this consent should be obtained (Wendler & Emanuel, 2002). Wendler and Emanuel (2002) conducted a study with 504 participants by means of a telephonic survey which aimed at eliciting their views about research on their stored biological samples (Wendler & Emanuel, 2002). Nearly two thirds of respondents (65.8%) felt that consent was necessary for research on clinically derived and personally identifiable samples, while 27.3% of the respondents felt that they would require consent on clinically derived samples if the samples were anonymised (Wendler & Emanuel, 2002). With regard to samples derived from research, 29% of the respondents said that they would require consent if their samples were identifiable, while 12.1% of respondents said they would require consent if their samples were anonymised before research commenced (Wendler & Emanuel, 2002). A large majority of the respondents (88.8%) did wish to be informed of results of uncertain clinical significance (Wendler & Emanuel, 2002). Finally, 91.9% of the respondents felt that it was not necessary to impose stricter consent requirements on future research related to a different disease (Wendler & Emanuel, 2002).

#### *3.4.2 Hoeyer, Olofsson, Mjomdal, and Lynoe (2004)*

A quantitative study of 1,000 participants conducted by Hoeyer et al. (2004) aimed to understand public attitudes to the use of tissue for genetic research. The results showed that participants found the use of their medical records without prior consent to be a greater invasion of privacy compared to genetic research (Hoeyer et al., 2004). Individuals wanted to be informed about their results, especially if they suggested susceptibility to contracting a disease which could be preventable if detected early (Hoeyer et al., 2004). Even if the researcher did not initially inform participants that certain types of information could arise from research on their samples, individuals still wanted to be informed of this (Hoeyer et al., 2004). However, they did

not believe that it was advisable to be informed about diseases that could not be treated. A small minority had no desire to be re-contacted for any form of results (Hoeyer et al., 2004).

Although legal and ethical debates have highlighted informed consent as one of the most important factors in biobanks, respondents in this study did not rank it as the most important issue when assessing research on stored samples (Hoeyer et al., 2004). Important issues in ranked order were: that all population groups receive equal access to research results; that the research is readily applicable; that corporate interests do not determine the research outlook; that confidentiality is protected; that research results are not used for selective abortion; and followed last of all by informed consent (Hoeyer et al., 2004).

#### *3.4.3 Kettis-Linblad, Ring, Virbeth, and Hansson (2004)*

A Swedish cross-sectional study was conducted by Kettis-Linblad et al. (2004) which aimed at identifying the general public's perceptions about research involving human tissue, assessing the public's willingness to donate samples to biobanks, and identifying factors associated with the public's willingness to donate samples to biobanks. Most respondents showed a positive attitude towards research involving human tissue (Kettis-Linblad et al., 2004). The respondents' trust in different authorities' capability to evaluate the risks and benefits showed that respondents were more likely to trust researchers at university hospitals followed by research ethics committees, researchers and laymen, healthcare personnel, industry-based researchers, government authorities, county councils, and then lastly, the Swedish Parliament (Kettis-Linblad et al., 2004).

In general, participants showed a willingness to donate samples, with 86% of participants willing to donate a blood sample for research purposes and 78% willing to both donation of samples and storage for future use (Kettis-Linblad et al., 2004). Factors found to be related to the willingness to donate samples were attitudes to genetic research and trust in authorities (Kettis-Linblad et al., 2004). Age was also seen as a factor, with higher age being associated with willingness to donate (Kettis-Linblad et al., 2004). Education and gender were not found to be contributing factors (Kettis-Linblad et al., 2004).

#### *3.4.4 Chen, Rosenstein, Hilsenbeck, Miller, Emanuel, and Wendler (2005)*

Amongst researchers, a debate still exists with regard to what type of consent is required for research with stored biological samples, with some believing that consent is required every time a new study is proposed on stored samples, and others opting for broader consent models. A quantitative study consisting of 1,670 participants was conducted by Chen et al, (2005) to assess what research participants preferred regarding research on their stored biological samples. According to Chen et al. (2005), most research participants were willing to allow their samples to be used without restriction if given the opportunity to do so. The study found that this willingness was common in all participants in terms of sex, age, and proximity to research centres, health status, and prospects of direct benefits (Chen et al., 2005). Although it was found that African Americans were significantly less likely to allow the unlimited use of their samples compared to other race groups, the majority of African Americans (75%) nevertheless allowed the unlimited future use of their samples (Chen et al., 2005).

#### *3.4.5 Wendler, Pace, Ambrose, Talisuna, Maiso, Grady, and Emanuel (2005)*

The first empirical study to research the attitudes of individuals in developing countries regarding research on stored biological samples was conducted in Uganda with respondents associated with a randomised clinical trial (Wendler et al., 2005). This study found that most respondents were willing to contribute a coded sample of their children's blood for future research (Wendler et al., 2005). The study also showed that respondents were also willing to allow for the samples to be exported to other countries, and they were willing to allow the sample to be used for research on any condition (Wendler et al., 2005).

#### *3.4.6 Abou-Zeid, Silverman, Shehata, Shams, Elshabrawy, Hifnawy, Rahman, Galal, Sleem, Mikhail, and Mohharam (2010)*

In a qualitative study pertaining to the collection, storage, and use of blood samples for research conducted with 600 adult Egyptian patients receiving medical care at the time, over 80% of respondents were willing to donate their blood samples for the purposes of future research

(Abou-Zeid et al., 2010). Less than half of the respondents wanted to be provided with the opportunity to consent to their samples being stored for future research purposes (Abou-Zeid et al., 2010). Forty percent of respondents wanted potential future research on their samples to be restricted to the initial illness it was collected for (clinically/research), while 54% of the respondents were willing to consent to the unlimited and unrestricted use of their samples and did not see the need for consenting for restricted use (Abou-Zeid et al., 2010).

With regard to the storage of linked samples, 89% of individuals wanted to be informed of results of uncertain clinical significance (Abou-Zeid et al., 2010). More than half of the participants would allow samples which were still linked to be used in genetic research, regardless of whether or not confidentiality had been assured (Abou-Zeid et al., 2010). According to Abou-Zeid et al. (2010), participants were less willing to donate their samples for genetic research because of fears of stigmatisation (individually and population groups) and because of concerns about the extent to which their private information would be kept confidential (Abou-Zeid et al., 2010).

Egyptian participants did not believe that samples should be kept for a set amount of time, and they felt that participants did not need to be given the option to withdraw the use of their samples (Abou-Zeid et al., 2010). This study also showed that individuals did not want the right to share in commercial profits (Abou-Zeid et al., 2010).

#### *3.4.7 Bussey-Jones, Garrett, Henderson, Moloney, Blumenthal, and Corbie-Smith (2010)*

For genetic research to grow and succeed, members of the public need to show solidarity and be willing to donate their samples (Bussey-Jones et al., 2010). A qualitative and quantitative study assessing ‘the role of race and trust in tissue/blood donation for genetic research’ was conducted by Bussey-Jones et al. (2010). In this research, participants in the North Carolina Colorectal Cancer Study were surveyed and biological samples were collected from consenting participants (Bussey-Jones et al., 2010). Respondents who were unwilling to donate samples were more likely to be African American and less trusting of medical researchers (Bussey-Jones et al.,

2010). These respondents were also found less likely to agree to participating in future genetic research (Bussey-Jones et al., 2010).

To understand the relationship between race and trust in donation of samples, open-ended qualitative questions supplemented the survey (Bussey-Jones et al., 2010). It was found that generic concerns such as needle sticks, inconvenience, discomfort, and mistrust were factors that influenced individuals' decisions about donating their samples (Bussey-Jones et al., 2010). Other factors associated with less willingness to consent included African American race, female gender, older age, lower income, less education, higher occupation category, and worse health status (Bussey-Jones et al., 2010). Although research has shown that individuals associate medical research with the development of better healthcare, lower acceptance of research was seen in minority groups (Bussey-Jones et al., 2010). Minority groups have cited control of DNA, potential misuse of data, racial discrimination, stigmatisation, and unequal access to potential benefits as reasons for their unwillingness to participate in medical research (Bussey-Jones et al., 2010).

#### *3.5.8 Al-Jumah, Abolfotouh, Alabdulkareem, Balkhy, Al-Jeraisy, Al-Swaid, Musaaed, and Al-Knawy, 2011*

A quantitative study of 1,051 adult participants conducted at outpatient clinics in Saudi Arabia found that 68.8% of respondents had positive attitudes to the potential benefits and ethics of research, as well as in the willingness to participate (Al-Jumah et al., 2011). Positive attitudes and beliefs towards biomedical research were found to be significantly more prevalent in female participants (76.1%) compared to male participants (62.5%) (Al-Jumah et al., 2011). A little over half of the participants (57%) agreed that advancements in genetic research were beneficial in finding cures for new diseases (Al-Jumah et al., 2011). Little concern was shown with regard to research on human genetics tampering with religion (only 12.2% agreed it was tampering with religion) (Al-Jumah et al., 2011). A small percentage of participants (15.8%) believed that researchers were primarily motivated by selfish commercial/monetary reasons (Al-Jumah et al., 2011). Some participants felt that denying consent to the use of their samples for research would

jeopardise their relationship with their healthcare practitioner, and this in turn would impact negatively on their healthcare (Al-Jumah et al., 2011).

Most participants (70.1%) were willing to allow the use of their residual samples for future research, with willingness being significantly higher in females (77%) than in males (63.9%) (Al-Jumah et al., 2011). However, it was found that willingness to donate samples (86.6%) was slightly more common in males (88.8%) than in females (84.4%) (Al-Jumah et al., 2011). Only 27.3% showed willingness to donate organs of deceased family members, and there were no significant differences between the sexes in this regard (Al-Jumah et al., 2011).

Age, marital status, current employment status, having children, perceptions of health status, presence of chronic disease, previous tissue testing, previous blood donation, and the desire for feedback were all found to be non-significant predictors of positive attitudes towards biomedical research (Al-Jumah et al., 2011). Factors found to be significant predictors of positive attitudes to biomedical research were sex, education, having had a previous blood test, and previous participation in health-related research (Al-Jumah et al., 2011). Factors found to be significantly associated with willingness to allow the use of residual surgical tissue for research were sex, history of previous blood tests, and history of previous hospitalisation (Al-Jumah et al., 2011). Females and those who previously had blood tests, those who had a history of previous hospitalisation, and those who had previously participated in health-related research were found to be twice as likely to allow the use of their residual surgical tissue in research (Al-Jumah et al., 2011).

#### *3.4.9 Halverson and Friedman Ross (2012)*

Biobank-based research grows in importance alongside the debate of the return of results to individuals and population groups (Halverson & Friedman Ross, 2012). Halverson and Friedman Ross (2012) conducted a mixed-methods study to assess the attitudes of African American parents about biobank participation and the return of research results for themselves and their children (Halverson & Friedman Ross, 2012). It was found that most parents would enrol

themselves and their children in a biobank (Halverson & Friedman Ross, 2012). However, a small minority were reluctant to enrol their children (especially young children), as they felt it was necessary to involve them in the decision-making process (Halverson & Friedman Ross, 2012).

Most of the participants (97%) showed equal levels of interest in receiving their results and those of their children, and several participants rejected the idea of children having a right to keep healthcare information private from their parents (Halverson & Friedman Ross, 2012). Generally, most participants believed that children should be given the right of access to their health information, but parents wanted to be involved in deciding when and how the information was shared (Halverson & Friedman Ross, 2012).

#### *3.4.10 Opinion Leader (2012)*

A mixed-methods study was conducted by Opinion Leader in 2012 to assess public attitudes to health-related research. Qualitative findings were obtained by means eight focus groups with the general public and twenty in-depth interviews with research participants and people affected by medical conditions (Opinion Leader, 2012). The quantitative results were obtained by means of a survey of 1,105 members of the general public (Opinion Leader, 2012). There were five main areas of focus, namely: the public's attitude towards participation in medical research; the benefits and harms of receiving feedback; when health-related findings should not be fed back; how health-related findings should be addressed in the consent process; and the mechanisms of feedback of health-related findings (Opinion Leader, 2012).

The qualitative and quantitative findings showed different results and it was evident that participants had varying perceptions about medical research (Opinion Leader, 2012). In the qualitative aspect of the study, participants generally viewed medical research as negative, and associated medical research with drug trials and testing involving human and animal subjects (Opinion Leader, 2012). In the quantitative results, however, more positive views were expressed about medical research and participants felt that the advantages of medical research outweighed

the disadvantages (Opinion Leader, 2012). Participants were found to be more trusting of medical doctors and scientists working in universities in conducting medical research, as opposed to pharmaceutical companies (Opinion Leader, 2012). These results are similar to those obtained by Kettis-Linblad et al. (2005).

Participants saw more benefits than harms in receiving feedback, and cited reasons such as: early detection of conditions, psychological preparation for illnesses, and benefits for relatives in being prompted to screen for risk of developing similar conditions (Opinion Leader, 2012). The severity and treatability of the condition were found to have the strongest influence on participants wishing to receive feedback (Opinion Leader, 2012). Clinically trained researchers had more of an obligation to provide feedback on health-related findings as opposed to researchers, who were not clinically trained (Opinion Leader, 2012).

This study also focused on establishing how participants felt health-related findings should be addressed in the consent process (Opinion Leader, 2012). It was found that individuals would be more likely to take part in a study if it was made clear how the health-related findings would be used, as this would help them in making an informed decision (Opinion Leader, 2012). This was seen as critical in the consent process (Opinion Leader, 2012). Some participants felt that it was important for researchers to give individuals a choice as to whether or not they wish to receive feedback (Opinion Leader, 2012). However, most people felt that, regardless of a person's preference, researchers were obligated to provide feedback if they had a condition that could harm others or themselves (e.g., an infectious disease) (Opinion Leader, 2012). Participants felt that the best way to receive feedback was via face-to-face discussions, especially if an individual was found to have a life-threatening or unmanageable condition (Opinion Leader, 2012). Participants also showed a preference for receiving results from someone with medical knowledge, such as a healthcare professional (Opinion Leader, 2012).



#### *3.4.11 Moodley, Sibanda, February, and Rossouw (2014)*

To date, there has been very little research conducted in South Africa that assesses the public's attitudes to health-related research (Moodley et al., 2014). This has ethical considerations as it is the perspectives of individuals that should inform guideline development (Moodley et al., 2014). Moodley et al. (2014) sought to explore South African research participants' attitudes to the use, storage, and exportation of their biological samples. Data was obtained by means of a semi-structured survey which elicited both quantitative and qualitative results; 200 participants responded (Moodley et al., 2014).

While individuals supported the collection and storage of samples, they also showed strong views about storage and future use, export, and benefit-sharing (Moodley et al., 2014). Underlying many of the participants' views was the concept of ownership (Moodley et al., 2014). Only half of the participants favoured the one-time broad consent model, while the other half felt that consent should be sought for new studies proposed, and that RECs could not decide on their behalf (Moodley et al., 2014). A small percentage of individuals (19.5%) did not wish to share the profit if the research was conducted for a good cause, while 39.5% said that they would mind if a profit was made (Moodley et al., 2014). Of the 39.5%, 43% wanted a share of the profit, while 56% said that they would be very unhappy about profits being made from their samples (Moodley et al., 2014).

Most participants were comfortable with their samples being exported from South Africa; however, 10% of the participants expressed strong views of discomfort with regard to exporting their samples to other African Countries and to developed countries (Moodley et al., 2014). This study also explored the concept of ownership and what emerged was that, while some participants refer to samples in the context of donation, many still showed a sense of ownership by using phrases such as "my blood" (Moodley et al., 2014). This sense of ownership was consistent with views of needing to be re-contacted every time samples were being used and benefit-sharing (Moodley et al., 2014).

### 3.5 Summary

While the importance of biomedical research on human biological samples cannot be denied, it is important for researchers and research teams to be equally aware of the ethical guidelines from the conceptualization of a research study throughout till after the study is complete (Emanuel et al., 2000; Emanuel et al., 2004).

Throughout history, many atrocities have been committed on human participants by researchers in pursuit of scientific aims. Individuals were treated as a ‘means to specific ends’ (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006; Wassenaar & Mamotte, 2012). As a result of this unjust treatment of human research participants, guidelines for ethical conduct were developed to avoid recurrence of past abuses. Central to all of these ethical guidelines is the obligation of researchers and RECs/IRBs to ensure that the welfare of research participants is protected throughout the research process (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006; Wassenaar & Mamotte, 2012).

Human biological samples are invaluable for medical and pharmaceutical research, but they contain confidential and clinically relevant information on individuals that has the potential to be misused (Elger & Caplan, 2006). This makes it even more important for there to be suitable and efficient frameworks that safeguard the rights of individuals and that also promote beneficial research for the public good (Gibbons & Kaye, 2007; Porter et al., 2000). Ethical issues in biomedical research should be thought of within the framework of the eight ethical guidelines. When samples or residual samples are obtained and stored (for current and/or prospective research), RECs and IRBs need to ensure that regulations are applied sensitively for participants whose human biological samples are used (National Bioethics Advisory Committee, 1999; Simitis, 2004). Arising from this is:

- knowing whether participants require consent for the future use of their samples
- the degree of anonymity and confidentiality with regard to information obtained on samples

- whether participants consent to the unlimited use of their samples
- whether results of research could lead to any forms of genetic discrimination against the individual or their population group
- whether clinically significant results need to be reported to research participants
- whether individuals wish to share possible economic benefits from their samples.

In establishing policies and regulations about the donation and use of biological samples, law-makers need to take public attitudes into consideration. Many studies have been conducted internationally to assess public attitudes to the use of samples in medical/genetic research. Studies have shown that individuals are willing to donate their samples and would not mind their samples being used without consent as long as samples are not personally identifiable (Abou-Zeid et al., 2010; Al-Jumah et al., 2011; Chen et al., 2005; Halverson & Friedman Ross, 2012; Hoeyer et al., 2004; Kettis-Linblad et al., 2004; Moodley et al., 2014; Opinion Leader, 2012; Wendler & Emanuel, 2002; Wendler et al., 2005).

One study also showed that participants were willing to allow for samples to be exported to others countries (Wendler et al., 2005). Willingness to donate was found to be related to attitudes to genetic research and trust in researchers, which was found to be lower among African Americans (Bussey-Jones et al., 2010; Chen et al., 2005; Kettis-Linblad et al., 2004). Factors such as education, race, sex health status, income were unrelated to willingness to donate samples. (Al- Jumah et al., 2011; Bussey-Jones et al., 2010; Chen et al., 2005; Kettis-Linblad et al., 2004).

With regard to consent, studies showed that participants were happy to provide broad consent for the use of their materials (Chen et al., 2005; Wendler & Emanuel, 2002). However, in Moodley et al. (2014), participants showed a greater sense of ownership of their samples and only half would agree to broad consent.

Most participants wanted to be informed of results of clinical significance, especially if there is a susceptibility to contracting a disease that is preventable through early detection (Abou-Zeid et al., 2010; Hoeyer et al., 2004; Opinion Leader, 2012; Wendler & Emanuel, 2002). One study showed that individuals did not wish to receive their results if they contained information about an incurable disease (Hoeyer et al., 2004; Opinion Leader, 2012). One study showed that individuals did not want the right to share in commercial profit (Abou-Zeid et al., 2010), whilst another study showed that individuals held strong views on benefit-sharing (Moodley et al., 2014).

Although there is substantial research published on public attitudes towards biomedical research, a gap exists in South Africa as very little literature has been published (Moodley et al., 2014). Given the high rate of infectious diseases in Africa, and the growing rate of highly skilled medical researchers, African countries should be flourishing scientifically. The views of the public are important in informing legislation which is in line with people's views, beliefs and needs (Moodley et al., 2014). As seen in the Moodley et al. (2014) study, it is evident that South Africans hold strong views about the storage and future use, export, and benefit-sharing of human biological samples. It is also evident that South Africans show a strong sense of ownership of their materials (Moodley et al., 2014). Thus, it is important that studies such as these are conducted both quantitatively and qualitatively in order to assess and gain an in-depth understanding of whether these views are common among most individuals in this country. This study hopes to contribute to addressing this gap in the South African data.

#### **Chapter 4: Aim and rationale**

The aim of this study was to quantitatively explore public attitudes towards the collection and storage of human biological samples for future research purposes. For the sake of this research, the public was defined as those individuals from whom human biological samples could be obtained. In South Africa to date, there has been very little published empirical research that focuses on public attitudes to the use of their biological samples in research (Moodley et al.,

2014). Knowledge of public attitudes towards research with human biological samples is important as it provides key ethical aspects of participant perspectives towards this type of research (Moodley et al., 2004). Therefore, in developing guidelines and regulations about the use of human biological samples, law-makers need to take relevant public attitudes into consideration.

The rationale for this research was to develop a better understanding of people's attitudes towards the use of their biological samples. Given the great cultural, social, geographical, and economic diversity in South Africa, these attitudes are important in informing guideline development, research ethics deliberation, and legislation which is in line with people's views, beliefs, and needs.

#### **4.1 Questions to be answered by research**

The main question this research sought to explore was regarding public attitudes towards the collection and storage of human biological samples for future research purposes. In order to answer the above question, the following three sub-questions were used:

- ✓ Do individuals from whom stored biological samples were obtained think their consent should be required for future research?
- ✓ Do they want to receive results of clinical significance?
- ✓ What are people's perceptions of confidentiality?

The researcher was also interested in finding out the following:

- ✓ Is there a significant association between any of the socio-demographic variables and the above questions?
- ✓ Is there a significant association between previous clinical experience and any of the above questions?

## **Chapter 5: Methodology**

### **5.1 Research design**

A research design is a strategic framework which researchers use to fulfil the purpose of the research (Durrheim, 1999; Peil, 1982; Robson, 1993). This framework enables researchers to conceptualise research questions in order to obtain the information that is sought (Durrheim, 1999; Peil, 1982; Robson, 1993). Furthermore, it also provides a plan for which data is collected, analysed, and interpreted within research (Durrheim, 1999; Peil, 1982; Robson, 1993). For the purpose of this research, a quantitative research design was adopted. According to Punch (2013), the main aims of quantitative research are to conceptualise reality in terms of variables; to measure these variables; and to study relationships between these variables. This framework was most suitable as the researcher was interested in a larger scale study. Quantitative methods are most useful in large-scale studies as they are efficient for communicating numbers and this made this approach most suitable for this research.

The style of quantitative research that was used in this study is descriptive research by means of a cross-sectional survey. Descriptive research aims at describing social phenomena of interest and the distribution of attributes in a population (Durrheim, 1999; Robson, 1993; Schutt, 1996; Tredoux, 1999). The social phenomenon that the researcher was interested in was public opinions about the collection, storage, and use of human biological samples for future research purposes. Cross-sectional surveys focus on the make-up of the sample and on the state of affairs in the population at one point in time (Robson, 1993). The specific make-up of the sample in this study was out-patients who were currently accessing medical care at the major government hospitals in Pietermaritzburg. According to Robson (1993), surveys are useful in answering questions of what, who, where, how many, and how much. Surveys can also be useful in exploring aspects of a situation, or in seeking explanation and providing data for testing hypotheses (Robson, 1993).

## 5.2 Sample

### *5.2.1 Sampling method*

For the purpose of this study, probability sampling was used. Probability sampling is where the probability of the individual being chosen is known (Peil, 1982; Robson, 1993; Schutt, 1996). The advantages of using probability sampling are that, firstly, the chances of selection bias by the researcher are removed, and secondly, the accuracy of samples may be estimated through the application of the principles of probability theory (Mouton, 1996). This type of sampling is considered to be representative sampling and allows researchers to make probabilistic generalisations from the sample to the population (Peil, 1982; Robson, 1993; Schutt, 1996).

The specific probability sampling technique that will be used to select participants will be simple random sampling which involves the selection of participants at random from the population of interest (Peil, 1982; Robson, 1993; Schutt, 1996; Seale, 2012). This technique ensures that all participants have an equal chance of being chosen to participate (Peil, 1982; Robson, 1993; Schutt, 1996; Seale, 2012). This sampling approach was most useful given that the population was quite large. A handful of participants were selected from waiting areas from the various departments of hospitals on different days.

### *5.2.2 Recruitment of participants*

For the purpose of this research, 200 participants were recruited. These participants were all out-patients at Pietermaritzburg government hospitals. Approximately one hundred participants were randomly selected from each of two government hospitals in Pietermaritzburg, namely Grey's Hospital and Edendale Hospital. In the initial proposal, the researcher had aimed to recruit fifty participants from each of the three major government hospitals in Pietermaritzburg; this included the two abovementioned and Northdale Hospital. Due to the non-response from Northdale Hospital, the researcher was forced to exclude this site from the study. The researcher then chose to recruit one hundred participants from each of the two remaining hospitals.

The inclusion criteria were adult males and females in the hospital waiting area who were willing and competent to consent. Persons accompanying patients were also approached if they were willing and competent to consent. The exclusion criteria were minors, adults unwilling and unable to consent, and obviously distressed or uncomfortable patients. The reason for this particular sample was that the researcher was interested in people who were currently seeking some sort of medical attention in one of the Pietermaritzburg government hospitals, as they were likely at some point to be required to provide their human biological samples for clinical purposes. This makes their current attitudes to the possible collection and storage of their samples relevant to this cross-sectional survey.

Participants were recruited in the various waiting rooms of the different medical departments of the two hospitals. In each of the waiting rooms, the first thing that the researcher did was approach the nursing sister in charge to explain the study and show the relevant documentation (consent from the relevant bodies and from the hospital management). This was done to ensure that the hospital staff were aware of the researcher so that the researcher would not impinge on the normal day-to-day functioning of the hospital. Once staff were addressed, the researcher explained the study to those in the waiting area and those who were willing to participate showed their interest by raising their hand.

Recruitment of participants and data collection happened over the course of two weeks. Each weekday, the researcher attempted to collect at least five surveys from each waiting area of a hospital. The reason for the collection being stretched out across the five days in each of the hospitals was because sometimes in government hospitals, certain illnesses are dealt with only on certain days; therefore, the researcher wanted to ensure that the sample was diverse, that individuals had a fair chance of being selected, and that certain people were not excluded due to the fact that their illness was not catered for on the day that data was collected.



### **5.3 Ethical considerations**

#### *5.3.1 Independent ethical review*

In order to ensure the protection of human participants and enhance the quality of this research, it was necessary for the researcher to obtain ethical clearance prior to the commencement of this research (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). This was done firstly through the submission of a research proposal internally to the University of KwaZulu-Natal College of Humanities Research and Higher Degrees review panel. Provisional approval was obtained from this review panel (Appendix A subsequently, the proposal had to be submitted to the University of KwaZulu-Natal Biomedical Research Ethics Committee. Once the proposal was approved by this committee (Appendix B,), the researcher was able to approach the KwaZulu-Natal Department of Health and the hospitals for gate-keeper permissions (Singh & Wassenaar, 2016).

#### *5.3.2 Gate-keeper permission*

Prior to the researcher being able to enter the hospitals to recruit participants for participation in the study, it was necessary to obtain permission from the gate-keepers, namely the KwaZulu-Natal Department of Health and the CEOs of both of the hospitals. Permissions were sought in writing and in personal meetings with the CEOs and medical managers. Once they were both obtained (Appendix C and D), the researcher was then able to apply for permission from the KwaZulu-Natal Department of Health. This application was submitted online and permission was obtained (Appendix E).

#### *5.3.3 Informed consent*

When individuals were invited to participate, the study was first explained to them verbally, then further by an information sheet. This verbal explanation and the information sheet were provided in both English and isiZulu, as not all participants were able to understand and read English. This information sheet made clear all the information regarding the study, its methodology, and the potential risks and benefits that are directly or indirectly associated with participation. It also highlighted the fact that participation was entirely voluntary, and that they had the freedom to

decline to participate, or to withdraw once the study had started, without any negative consequences to themselves. According to Emanuel et al. (2000), Emanuel et al. (2004), and (Wassenaar (2006), informed consent requires the provision of appropriate information, the competence and understanding of participants, and that participation is voluntary and uncoerced. Attached to this information sheet was the consent form which was also provided in both English and isiZulu for the same reasons as above ((Appendix F and G).

#### *5.3.4 Potential risks or harms and benefits*

Through participation in this study, no risks or harms - whether biological, psychological, social, legal or financial - were incurred by the participants. Participants, however, did raise questions about research on human biological samples and these questions were answered as soon as they were brought to the researcher. No costs were incurred by participants in participation for this research except for the time it took for them to complete the survey (approximately 10 minutes). Participants did not lose their places in clinic queues if they participated in the study.

There were also no direct benefits to participants who participated in this study, nor were there any incentives offered (due to budget constraints); however, through participation in this study, participants may have directly benefitted their overall body of knowledge on related issues.

#### *5.3.5 Confidentiality*

The researcher took the necessary measures to ensure that confidentiality was maintained throughout the course of the research. Firstly, participants' surveys had no names or personal identifying details written on them, so as to keep responses anonymous. Instead, all answered surveys were coded and each participant was given a unique code. Secondly, the individual survey responses were stored separately from the information sheet and consent forms, for the same reason. Some participants preferred to have the researcher read out the survey to them so as they could answer it verbally and have it filled out on their behalf. In instances such as these, privacy was maintained by the researcher and the participant doing this away from other people.

#### *5.3.6 Dissemination of results*

Results from this research have been written up in the form of a dissertation in partial completion of a Master's Degree by the researcher. A copy of this dissertation will be available at the University of KwaZulu-Natal Pietermaritzburg Campus Cecil Renaud Library and may hopefully published in a peer-reviewed journal. Results will also be forwarded in the form of a report to the KwaZulu-Natal Department of Health Research Committee.

#### *5.3.7 Data storage*

Hard copies of surveys and consent forms were scanned and are stored electronically in a password-protected folder by the researcher. Statistical data and analyses are also stored in the same password-protected folders to ensure that they are not accessed by any unintentional third parties. All this data will be backed up in password-protected cloud storage space in case the hard drive is lost or damaged in any way. Hard copies of all the surveys and consent forms will be incinerated so as to avoid any risks of breach of confidentiality.

### **5.4 Data collection**

Data was collected by means of a survey at two local government hospitals in Pietermaritzburg, namely Grey's Hospital and Edendale Hospital. In each of these hospitals, one hundred outpatients were recruited from the various waiting areas. At each of the waiting areas, the nursing sister in charge was approached to inform the patients in queues about the researcher. Thereafter, the researcher explained the study to the patients and those who were interested in participating in the study were given an information sheet and consent form, then the actual survey. As stated previously, some of the participants preferred to have the survey read out to them with them providing their responses verbally. In the case of these participants, they were taken to the back of the waiting area and the survey was completed with the researcher there.

#### *5.4.1 Data collection tool*

Data was collected by means of a survey. This was a pre-existing survey that was obtained from literature and was adapted to suit the needs of this study. Permission to use the survey was sought from Dr. D. Wendler via email (Wendler & Emanuel, 2002)

The original survey (Appendix H) was intended for two cohorts - namely older individuals at four geographically dispersed US research centres who have a first-degree relative with probable Alzheimer's disease, and randomly selected Medicare beneficiaries (Wendler & Emanuel, 2002). The inclusion criteria were that participants were required to be 50 years or older, able to speak and understand English, able to understand the survey questions, and be able to hear well enough to respond to questions over the phone (Wendler & Emanuel, 2002).

In order for this survey to be relevant for the current research, the researcher had to make a few changes to adapt it to suit the current needs. The original survey was broken up into five sections namely: (1) research and clinical experience; (2) consent/research on stored samples; (3) perceptions of confidentiality; (4) socio-demographic; and (5) conclusion. For the purpose of this study, this general format was kept; however, content was changed in some places.

The first part of the original survey focused on getting an understanding of participants' past experiences of having an Alzheimer's disease test using their blood or saliva. For this study, the researcher made a choice to shift the focus away from Alzheimer's disease and asked participants of their experiences of having any test run using their biological samples (not limited to blood and saliva). Clear examples of human biological samples were listed so participants had an understanding of what was meant. A total of 9 questions that were specific to Alzheimer's disease and that could not be adapted were left out. Nine other questions were adapted slightly to move away from Alzheimer's disease.

The second part of the original survey focused on consent and research on stored samples. Various hypothetical scenarios were given to participants about future research on research-derived residual samples. For this study, the researcher chose to include six additional questions

that addressed clinically derived residual samples. Other questions that addressed one-time general consent and providing limits to the use of one's samples were included.

No changes were made in the third section of the original survey regarding perceptions of confidentiality. Minor changes were made in the fourth socio-demographic section. These changes were made according to the Stats SA format of categories and groupings in South Africa (e.g., race groups, religious groups, income brackets, levels of education, etc.).

The fifth section of the original survey was the conclusion which asked participants how they felt about the survey and whether they had experienced any stress resulting from participation in this study. This remained unchanged as well; however, it was not included in the overall analysis as it was more not directly related to the current research.

The final English survey (Appendix I) was simplified as much as possible and it was also translated into isiZulu since it is the main language in KwaZulu-Natal. The isiZulu version was given to three first-language speakers to read independently, and corrections were made and a discussion was held to ensure that everyone understood the questions in the same way (Final IsiZulu survey- Appendix J).

## **5.5 Data analysis**

Data obtained from the surveys was analysed in various stages. Firstly, it was necessary for the researcher to check all the surveys individually to ensure that participants had filled them out correctly. Secondly, the researcher had to create a codebook and give each variable (question) a unique SPSS variable name and a coding instruction (Appendix K). This was followed by the researcher entering the data onto a Microsoft Excel spreadsheet for analysis using SPSS at a later stage. Using Microsoft Excel meant that the researcher was able to enter the data as it would appear on SPSS; however, defining the variables and providing coding instructions were only available on SPSS and this was the next step. Once that had been done, it was necessary for the researcher to screen the data and check for errors; after this, the data was ready for analysis.

For the purpose of this research, univariate and bivariate analysis were used. Univariate analysis was necessary for obtaining frequency counts of single variables. This was followed by bivariate analysis which was necessary for obtaining cross-tabulations between the dependent (main research questions) and independent variables (socio-demographic variables and previous clinical experience) in order to analyse for patterns and relationships. The chi-square test of association was used to analyse whether there was a significant association between the dependent and independent variables. The assumptions of this test are that (1) the two variables should be measured at an ordinal or nominal level, and (2) the two variables should consist of two or more categorised independent groups. The null hypothesis states that there is no significant association between the sets of the categories.

Pearson chi-square was used as a test for association, and confidence levels were set at 95% ( $p=0.05$ ). When interpreting the output, it was necessary for the researcher to check whether assumptions had been violated. If the minimum expected cell count is less than 5 or 20% of cells have an expected count of 5, then assumptions have been violated. In this case, the better measure of association would be the Likelihood Ratio figure. The measure of association was also calculated and reported (Cramer's V; 95% confidence intervals).

## **5.6 Reliability, validity and rigour**

The questionnaire that will be used from this study was obtained from literature. A pre-existing questionnaire was obtained from Wendler and Emanuel (2002) and was adapted to suit the South African population and the needs of this study. With regard to reliability and validity of this instrument; the questionnaire development in the original study occurred over a series of seven steps namely: (1) comprehensive literature review (2) draft survey development (3) review by experts in survey methodology genetics research (4) survey revision (5) cognitive pre-test using in-person interviews with 3 elderly individuals who were participating in clinical research in the Boston area (6) behavioural pre-test with 3 additional elderly individuals who were participating in clinical research in the Boston area (7) final revision (Wendler & Emanuel, 2002).

Furthermore, it was approved by the institutional review boards at UCLA, Stanford University, Duke University, the National Institute of Mental Health, and the University of Massachusetts, Boston (Wendler & Emanuel, 2002). Validity and reliability of this questionnaire in the South African context have not been tested.

### **5.7 Limitations of the design**

The original study noted four limitations of the design. The first limitation in the original study was regarding the low response rate for the Medicare cohort and how this affected generalizability of the research results (Wendler & Emanuel, 2002). The second limitation in the original study was about the phrasing of identifiable samples as samples ‘with names still attached’ in the research questions regarding consent for research on stored samples (Wendler & Emanuel, 2002). The authors felt it was necessary for future researchers to include questions about research on coded samples (where identifying details are known but not given to investigators) as this could have an impact as to whether participants are likely to require consent. The third limitation in the original study was due to the fact that one of the cohorts was individuals with a family history of Alzheimer's disease and how this affected their cognitive capacities (Wendler & Emanuel, 2002). However individuals were assessed before the study and they were Alzheimer's free and competent (Wendler & Emanuel, 2002).

The last limitation in the original study was due to the fact that participants possibly may have little to no understanding of the potential risks and benefits of research on stored biological samples thus their (un)willingness may be due to a misunderstanding. This was a limitation of this study as well and perhaps future research could focus more on engaging qualitatively with participants on an individual and group level to assess their understanding of research on stored samples.

## Chapter 6: Results

### 6.1 Introduction

The first of two sections of this analysis will present the simple descriptive statistics/ frequency counts of the participants' socio-demographic factors and their previous clinical experience (independent variables). The analysis will then be presented thematically in sections according to the three main research questions (dependent variables) namely:

- Do individuals from whom stored biological samples were obtained think their consent should be required for future research?
- Do individuals want to receive results of clinical significance?
- What are people's perceptions of confidentiality?

In each section, the frequency counts of each of the variables will be reported. The researcher will then report of the analysis of significant associations existing between the any of these variables (dependent variables) and the above-mentioned independent variables.

### 6.2 Participants' socio-demographics

Table 1 below summarises respondents' socio-demographic details

*Table 1. Frequency table of respondent socio-demographics*

Characteristic	Overall frequency (N=200)	Percentage (%)
<b>Hospital</b>		
Edendale	94	47.0
Grey's	106	53.0
<b>Sex</b>		
Male	74	37.0
Female	126	63.0



<b>Race</b>		
African/Black	174	87.0
Coloured	16	8.0
Indian/Asian	7	3.5
White	2	1.0
Other	1	0.5
<b>Religion</b>		
Muslim	12	6.0
Christian	80	40.0
Catholic	46	23.0
Jewish	6	3.0
Hindu	2	1.0
African Traditional	37	18.5
Apostolic	4	2.0
None	13	6.5
<b>How religious</b>		
very religious	50	25.0
moderately religious	67	33.5
not very religious	53	26.5
not religious at all	30	15.0
<b>Level of Education</b>		
No schooling	15	7.5
Primary School ( grade 1 to 7)	18	9.0
High school (grade 8 to 12)	92	46.0
Higher certificate	31	15.5
Diploma	28	14.0
Bachelor's Degree	11	5.5
Post-grad qualification	5	2.5
<b>Current Employment</b>		
employed full time	49	24.5
employed part time	56	28.0
not employed	71	35.5
retired	13	6.5
student	9	4.5
self employed	2	1.0

<b>Income before taxes</b>		
none	60	30.0
R1 - R400	11	5.5
R401 - R800	17	8.5
R801- R1600	35	17.5
R1601- R3200	20	10.0
R3201- R6400	10	5.0
R6401- R12800	12	6.0
R12801- R25600	4	2.0
over R25601	1	0.5
refused	25	12.5
don't know	5	2.5
<b>Rate personal health</b>		
excellent	24	12.0
very good	54	27.0
good	54	27.0
fair	49	24.5
poor	19	9.5
<b>Hospitalisation in past year</b>		
Yes	51	25.5.
No	149	74.5
<b>Hospitalisation in past 5 years</b>		
Yes	65	32.5
No	135	67.5

### 6.3 Clinical experience

With regard to having tests using their biological samples, 86.5% of participants had previously had such tests done (Table 2). Of these tests, 28.5% were done less than six months ago; followed by 23% that were done between six months and a year ago; 21.5% that were done between one year and two years ago; and 13% that were done more than two years ago. About three-quarters (75.5%) of the participants received an explanation or discussion about the respective test using their biological samples, whilst 7% of participants received no explanation or discussion, and 3.5% were unsure as to whether or not they received one.

Less than half (42.5%) of participants decided to have the test using their biological samples done because the explanation prior to the test convinced them, while 31.5% decided to have the test done prior to the explanation, and 8% were unsure as to why they decided to have the test done. Most participants (70%) felt that everything was discussed sufficiently prior to the test, while others (12%) felt that some things were not discussed adequately. Things that were not discussed included the reason for the test (6%); living with the disease that they were going to be tested for (4%); what they were going to do with the results (0.5%); and some people had difficulty understanding because of a language barrier (0.5%). For less than half of the participants (40.5%), it was stated very clearly that the test using their biological samples was an option. For 26%, it was stated clearly; not very clearly for 8%; not clearly at all for 3%, and for 3%, it was not reportedly discussed at all.

After the tests were performed, 65.5% of participants had a post-test discussion whilst 20.5% of participants did not receive one. Results of the tests were explained very well to 43% of participants; well to 30% of participants; not very well to 6% of participants; and not well at all to 1.5% of participants. Discussions of how results of the test using their samples might affect the families of the participants were done very well for 38.0% of the participants, while 32% of participants found them to be done well; 6% found them to be done not very well; 2.5% found them to be done not well at all, and for 2% of the participants, these discussions were not held.

Discussions of the possibility of future research using the already collected samples of the participants were mostly not done at all (47.5%) or the participants did not recall having these discussions (21%). Only a small percentage of participants (12.5%) actually had these discussions.

## 6.4 Consent

According to Simitis (2004), it is an individual's inherent right to make decisions regarding their bodies and their personal space, and this right is especially important in biological research which uses individuals' biological samples. It is therefore important in respect of their human dignity for researchers to inform individuals/participants of any possibility of their samples being used in any research in the future, to afford individuals the opportunity to make informed decisions regarding the use of their samples (Simitis, 2004). While the issue of consent when dealing with human biological samples is undeniably important, there are differing opinions over what type of consent is sufficient in different situations, and when it should be obtained (Porter et al., 2000; Chen et al., 2005). For the purpose of this research, different hypothetical scenarios were given to participants regarding research on stored biological samples. The findings were as follows (Table 3).

### *6.4.1 Consent and residual clinical samples - identifiable and unidentifiable*

Most participants felt that consent was necessary for research on residual clinical samples which were identifiable (70.5%), while others felt that it was not necessary (20.5%) and some were not sure (9.0%). A significant association was observed between consent for residual identifiable clinical samples and current employment (Likelihood Ratio=24.886;  $df=10$ ;  $p=0.006$ ). Students and self-employed individuals were most likely to require consent for research on residual identifiable clinical samples. The effect size of this association was considered to be moderate and significant (Cramer's  $V=0.232$ ;  $p=0.018$ ). It should be noted, however, that 'students and 'self-employed' were small groups; therefore, the significance of the association is questionable (Figures 1a and 1b).

A significant association was also discovered between consent for residual identifiable clinical samples and income before taxes (Pearson chi-square=33.957;  $df=20$ ;  $P=0.026$ ). The effect size of this association was considered to be strong and significant (Cramer's  $V=0.302$ ;  $p=0.014$ ). All participants who had an income over R25601 were unsure as to whether consent was necessary for research on residual identifiable samples. With that being said, it is also noteworthy that the

factor of 'income before taxes' had a large number of categories and certain categories had too few respondents; therefore, the significance of the association may be due to chance (Figures 2a and 2b).

A significant association was also discovered between consent for residual identifiable clinical samples and the hospital at which the participants were currently being seen (Pearson chi-square=10.433;  $df=2$ ;  $p=0.005$ ). Grey's Hospital had significantly more participants who were unsure if they would require 'consent for research on residual identifiable clinical samples', compared to Edendale Hospital participants. The effect size of this association was considered to be moderate and significant (Cramer's  $V=0.228$ ;  $p=0.005$ ) (Figures 3a and 3b).

When clinically derived samples were unidentifiable, 53.5% of participants felt that consent was not necessary; 37.5% felt that it was still necessary; and 9% were unsure. A significant association was observed between consent for clinically derived unidentifiable samples and current employment (Likelihood Ratio=20.058;  $df=10$ ;  $p=0.029$ ). Self-employed participants were less likely to require consent for residual unidentifiable clinical samples. The effect size of this association was moderate but not significant (Cramer's  $V=0.207$ ;  $p=0.070$ ) (Figures 4a and 4b). A significant association was also observed between clinically derived unidentifiable samples and income before taxes (Likelihood Ratio= 34.102;  $df=20$ ;  $p=0.025$ ). Participants who earned between R12801 to R 25600 and those that earned over R 25601 were less likely to require consent for use of their residual unidentifiable clinical samples. The effect size of this association was moderately strong but not significant (Cramer's  $V=0.274$ ;  $p=0.071$ ) (Figures 5a and 5b).

A significant association was also observed between clinically derived unidentifiable samples and the last time participants had tests done using their biological samples (Likelihood Ratio=13.970;  $df=6$ ;  $p=0.030$ ). Participants who had tests involving their samples less than six months ago were more likely to require consent for the use of their residual unidentifiable

clinical samples. The effect size of this association was weak but significant (Cramer's  $V=0.199$ ;  $p=0.034$ ) (Figures 6a and 6b).

A significant association was also observed between consent for residual unidentifiable clinical samples and whether participants had discussions after the test using their samples (Likelihood Ratio=6.245;  $df=2$ ;  $p=0.044$ ). Participants who did not partake in a discussion after the test were less likely to require consent for their residual unidentifiable clinical samples. The effect size of this association was weak but significant (Cramer's  $V=0.188$ ;  $p=0.048$ ) (Figures 7a and 7b).

#### *6.4.2 Consent and residual research samples - identifiable and unidentifiable*

Most participants felt that it was necessary to obtain consent for research on residual research samples which were identifiable (63.0%), while 27.5% of participants felt that it was not necessary, and 9.5% of participants were unsure. A significant association was observed between consent for residual identifiable research sample and the hospital at which the participants were currently being seen (Pearson chi-square=7.943;  $df=2$ ;  $p=0.019$ ). Grey's Hospital had significantly more participants who were unsure as to whether consent was required on residual identifiable research samples. The effect size of this association was weak but significant (Cramer's  $V= 0.199$ ;  $p= 0.019$ ) (Figures 8a and 8b). Income before taxes also showed a significant association showing that participants with an income over R 25601 were more likely to be unsure as to whether consent was required on residual identifiable research samples. However, as noted before, some categories had too few respondents; therefore, the significance of the association is questionable.

When research-derived samples were unidentifiable, 51.5% of participants felt consent was not necessary, while 37.5% felt that it was necessary, and 11.0% were unsure. A significant association was also observed between consent for residual unidentifiable research sample and the hospital at which the participants were currently being seen (Pearson chi-square=6.425;  $df=2$ ;  $p=0.040$ ). Grey's Hospital had significantly more participants who were unsure as to whether

consent was required for research on residual unidentifiable research samples. The effect size of this association was weak but significant (Cramer's  $V=0.179$ ;  $p=0.040$ ) (Figures 9a and 9b).

A significant association was also observed between consent for residual unidentifiable research sample and whether participants had discussions after the test using their biological samples (Likelihood Ratio=7.868;  $df=2$ ;  $p=0.020$ ). Participants who did not partake in a discussion after the test using their samples were less likely to require consent for their residual unidentifiable research samples. The effect size of this association was weak but significant (Cramer's  $V=0.209$ ;  $p=0.023$ ) (Figures 10a and 10b). Current employment and income were also observed to have significant associations. With regard to current employment, 100% of self-employed participants felt that consent was not necessary for research on residual unidentifiable research samples. While this was a moderately strong association it must be noted that this 100% of self-employed participants only represented 1% of the total sample. In terms of income before taxes, individuals who earned between R 12801 to R 25600 were more likely to not require consent while individuals who earned over R 25601 were more likely to be unsure. This was a strong and significant association even though percentage of the sample was 2% for individuals who earned between R 12801 to R 25 600 and 0.5% for those who earned over R 25601.

#### *6.4.3 Consent for research studying a disease other than what the sample was initially collected for - identifiable and unidentifiable*

With regard to consent for research studying a disease other than what the sample was collected for using identifiable human biological samples, 70% of participants felt that consent was necessary, while 22% felt that it was unnecessary, and 8% were unsure. No significant associations were found between this variable and any of the socio-demographic variables or any of the clinical experience variables

Given the same scenario but with unidentifiable samples, 54.5% of participants felt that consent was not required, while 34.5% felt that it was necessary, and 11% were unsure. A significant association was observed between consent for research studying a disease other than what the sample was initially collected for using unidentifiable human biological samples and personal health (Likelihood Ratio=15.693;  $df=8$ ;  $p=0.047$ ). Participants with excellent health were less likely to require consent and those with poor health were more likely to require consent. The effect size of this association was moderate and significant (Cramer's  $V=0.2$ ;  $p=0.043$ ) (Figures 11a and 11b).

A significant association was also observed between consent for research studying a disease other than what the sample was collected for using unidentifiable human biological samples and the hospital at which the participants were currently being seen (Pearson chi-square=11.751;  $df=2$ ;  $p=0.003$ ). Grey's Hospital had significantly more participants who were unsure as to whether consent was required for research studying a disease other than what the sample was initially collected for using unidentifiable samples. The effect size of this association was moderate and significant (Cramer's  $V=0.242$ ;  $p=0.003$ ) (Figures 12a and 12b).

A significant association was also seen between consent for research studying a disease other than what the sample was collected for using unidentifiable human biological samples and the last time participants had tests using their biological samples (Likelihood Ratio=13.712;  $df=6$ ;  $p=0.033$ ). Participants who had tests done less than six months ago were more likely to require consent for research studying a disease other than what the sample was collected for using unidentifiable human biological samples. The effect size of this association was moderate and significant (Cramer's  $V=0.201$ ;  $p=0.031$ ) (Figures 13a and 13b). Income before taxes was also observed as having a strong and significant association and participants earning between R 12801 and R 25601 and those earning R 25601 and over were least likely to require consent for research studying a different disease other than what the samples were initially collected for were those with no income,



*6.4.4 When should consent be obtained and by whom? Is one-time general consent sufficient or should individuals be able to provide limits to the use of their samples?*

When asked about when they felt it was appropriate to obtain consent for future research on residual clinical samples, a small majority of participants (55.5%) suggested that consent be obtained when samples are initially collected. This was followed by 25.0% who believed that it was necessary each time a new study was proposed, and 15% who were unsure. A significant association was observed between when to obtain consent for future research and personal health (Likelihood Ratio=34.418;  $df=12$ ;  $p=0.001$ ). Participants with poor (4.5%) and excellent health (9.0%) were the least likely to agree that consent be obtained when samples were initially collected. The effect size of this association was moderately strong and significant (Cramer's  $V=0.24$ ;  $p=0.001$ ) (Figures 14a and 14b).

A significant association was also observed between when to obtain consent for future research and the hospital at which the participants were currently being seen (Likelihood Ratio=15.113;  $df=3$ ;  $p=0.002$ ). Participants at Grey's Hospital were more likely to be unsure as to when samples should be obtained. The effect size of this association was moderately strong and significant (Cramer's  $V=0.270$ ;  $p=0.002$ ) (Figures 15a and 15b). Income before tax also showed a moderately strong and significant association as 100% of participants who earned a salary over R 25601 were unsure as to when it was necessary to obtain consent. It should be noted however that this 100% only represents 0, 5% of the sample.

When asked who was responsible for obtaining consent, 45% felt that it was the duty of the researcher or clinician for whom the samples were initially collected, while 24.5% of participants were unsure, 21.5% felt that it was the duty of the researcher who intended to use the samples; 8.5% felt that it was the duty of the doctor or nurse to obtain consent, and 0.5% felt that it was the duty of the laboratories to obtain consent. No significant associations were found between this variable and any of the socio-demographic variables or any of the clinical experience variables

With regard to one-time general consent, 53.0% of participants felt that it was sufficient, while 28.0% felt that it was not sufficient, and 17.5% were unsure. No significant associations were found between this variable and any of the socio-demographic variables or any of the clinical experience variables.

Half (50%) of participants felt that it is necessary to provide limits to the use of their biological samples, while 28.5% felt that it was not necessary, and 18.5% of participants were unsure. A small group (3%) of participants chose the ‘other’ option; however, no further explanations were provided in the comments line after this question. A significant association was observed between providing limits to the use of one’s samples and religion (Likelihood Ratio=35.254;  $df=21$ ;  $p=0.026$ ). Hindu participants were found to be the most likely to require limits on the use of their samples while non-religious individuals were the least likely to require limits on the use of their samples. The effect size of this association was moderate but not significant (Cramer’s  $V=0.227$ ;  $p=0.073$ ) (Figures 16a and 16b).

A significant association was also observed between providing limits to the use of one’s samples and how religious an individual was (Likelihood Ratio=28.978;  $df=9$ ;  $p=0.001$ ). Participants who were not religious at all (5%) were least likely to require that limits be imposed to the use of their samples. The effect size of this association was moderate and significant (Cramer’s  $V=0.223$ ;  $p=0.000$ ) (Figures 17a and 17b).

## **6.5 Desirability of receiving clinically significant results**

According to the Department of Health (2015) it is the ethical obligation of researchers to maximize benefits and seek to improve the human condition in research involving human participants. Research with human participants is not only beneficial to the researchers and the public, but also to individual donors who may too benefit from the results (Simitis, 2004). It is thus the responsibility of researchers to inform participants and the study community of the results of the research in a language which they are able to understand, and in a format that is

relevant and appropriate (Emanuel et al., 2000; Emanuel et al., 2004; Wassenaar, 2006). Frequency of responses on *Table 4*.

When questioned as to whether they would like to be informed about clinically significant results, 88.0% of participants said yes, 8.0% said no, and 4.0% were unsure. A significant association was observed between desirability of being informed about clinically significant results and whether participants received a discussion after the test using their biological samples (Likelihood Ratio=7.502;  $df=2$ ;  $p=0.023$ ). The effect size of this association was weak and not significant (Cramer's  $V=0.162$ ;  $p=0.106$ ) (Figures 18a and 18b).

When they were asked if they would want the researcher to inform the doctor about these clinically significant results, 76.0% of participants said yes, 17.5% said no, and 6.5% were unsure. A significant association was observed between the desirability of informing the doctor of results of clinical significance and sex (Likelihood Ratio=7.167;  $df=2$ ;  $p=0.028$ ). Female participants were more likely than males to want their doctors to be informed of results of clinical significance. The effect size of this association was weak but significant (Cramer's  $V=0.192$ ;  $p=0.025$ ) (Figures 19a and 19b).

A significant association was also observed between the desirability of informing the doctor of results of clinical significance and level of education (Likelihood Ratio=21.371;  $df=12$ ;  $p=0.045$ ). Participants with higher certificates, diplomas and bachelor's degrees were more likely to want their doctors to be informed of their results. The effect size of this association was moderate and significant (Cramer's  $V=0.248$ ;  $p=0.017$ ) (Figures 20a and 20b).

A significant association was also observed between the desirability of informing the doctor of results of clinical significance and one's personal health (Likelihood Ratio=21.090;  $df=8$ ;  $p=0.007$ ). Participants with poor health were more likely to want their doctors to be informed of results of clinical significance. The effect size of this association was moderate and significant (Cramer's  $V=0.213$ ;  $p=0.020$ ) (Figures 21a and 21b).

A significant association was also observed between the desirability of informing the doctor of results of clinical significance and whether participants had ever had tests done using their biological samples (Likelihood Ratio=6.421;  $df=2$ ;  $p=0.040$ ). Participants who had previous tests done using their biological samples were more likely to want their doctors to be informed of results of clinical significance. The effect size of this association was weak but significant (Cramer's  $V=0.190$ ;  $p=0.027$ ) (Figures 22a and 22b).

## **6.6 Confidentiality**

When pursuing their scientific aims, researchers need to ensure that the rights and dignity of their participants are protected throughout the duration of study (National Bioethics Advisory Committee, 1999). Part of this protection includes protection from non-physical risks such as divulging of personal information (National Bioethics Advisory Committee, 1999). When dealing with human biological samples it is important for researchers to realise that these samples contain personal information about individuals and they need take all necessary measures to ensure that participants' rights to confidentiality are respected (National Bioethics Advisory Committee, 1999). Ensuring protection becomes increasingly difficult with research on stored samples because these are usually stored over long periods of time for unknown future research (National Bioethics Advisory Committee, 1999). It is thus the duty of researchers, RECs, policies and legislation to guide the process of research on stored biological samples. These need to be informed by systematic assessments of public opinion.

To gain perspective on perceptions of confidentiality, participants were given an example of three types of sensitive personal information, namely medical information, credit history information, and employment history information. They were then asked which of the three types of the aforementioned sensitive personal information was most likely to be misused (Table 5). Over half (55.0%) said medical information, 26.5% were unsure, 11.0% said employment history information, and 7.5% said credit history information. A significant association was observed between the confidential information that was most likely to be misused and religion

group (Likelihood Ratio=33.912;  $df=21$ ;  $p=0.037$ ). All Hindu respondents (100%) and 83.3% of Muslim respondents felt that medical information was the most likely to be misused. It is worth noting that these categories had very few participants so this association could possibly be due to chance. The effect size of this association was moderate but not significant (Cramer's  $V=0.226$ ;  $p=0.079$ ) (Figures 23a and 23b).

Although not one of the research aims or questions, a significant association was observed between the confidential information that was most likely to be misused and the hospital at which the participants was currently being seen (Pearson chi-square=22.996;  $df=3$ ;  $p=0.000$ ). Participants at Edendale Hospital felt that medical information was the most likely to be misused, while participants at Grey's Hospital felt that employment information was the most likely to be misused. The effect size of this association was very strong and significant (Cramer's  $V=0.339$ ;  $p=0.000$ ) (Figures 24a and 24b). When asked about which type of information was *least* likely to be misused, 37.0% said employment history information, 34.5% were unsure, 14.5% said medical information, and 14.0% said credit history information. A significant association was observed between the confidential information that was least likely to be misused and the hospital at which the participant was currently being seen (Pearson chi-square=9.386;  $df=3$ ;  $p=0.025$ ). Participants at Grey's Hospital felt that medical information was least likely to be misused. The effect size of this association was moderate and significant (Cramer's  $V=0.217$ ;  $p=0.025$ ) (Figures 25a and 25b).

Participants were then asked about the risk of moving from records written on paper to computerised records, with regard to the possibility of violation of confidentiality. Just under half (44.0%) of participants felt that moving to computerised records decreases the risk of violation of confidentiality, while 26.5% felt that it does not change the risk, 15.5% felt that it increases the risk, and 14.5% were unsure. No significant associations were found between this factor and any of the socio-demographic variables

When questioned as to whether the confidentiality of their medical records had ever been violated, 80% of participants said they had not, 11.5% said they were unsure, and 8.5% said they had. A further probing qualitative question revealed that confidentiality had been violated when nurses disclosed to family members without consent and when contents of the participant's records were discussed in spaces where other people could hear.

Participants were then asked if they had ever avoided seeking physical or mental help out of concerns about confidentiality; a large majority (78.5%) said no, while 21.5% said yes.

Avoiding seeking physical or mental health out of concerns about confidentiality had moderately significant associations with how religious a person is; level of education; and current employment. With reference to how religious a person was, participants who were not religious at all were least likely to avoid seeking help because of concerns about confidentiality. With regard to level of education, participants with a higher certificate and those with a bachelor's degree were also the least likely to avoid seeking help because of confidentiality concerns. None of the self-employed participants had avoided help out of concerns about confidentiality, but it must be noted that there were only two respondents in this category thus the generalizability of this is questionable.

Personal health also showed a very strong association. Participants with poor health were more likely to avoid seeking medical help because of concerns about confidentiality.

Participants were then given an example of four types of medical information, namely genetic information, laboratory test information, doctor's notes from visits, and mental health information. Of these four types of medical information, participants were asked which type was most sensitive. A third (31.5%) said they were all equally important, 22.0% said doctor's notes from visits, 21.5% said laboratory test information, 10.5% said genetic information, and 10.5% said that they were unsure. Significant associations were observed with religion, level of education, current employment status, and personal health, the hospital where participants were

currently being seen, and whether they had previously had tests done using their biological samples. The effect sizes of religion and personal health were not significant. Level of education and current employment were both moderately significant factors and participants who are self-employed and those who had bachelor's degrees felt that notes from doctor visits were most likely to be misused. Hospital had a very significant association and Grey's had significantly more participants who were unsure as to which type of medical information was most sensitive.

## **6.7 Summary of results**

The main aim of the study was to quantitatively explore public attitudes to the collection and storage of human biological samples through cross-sectional surveys conducted at Greys and Edendale Hospitals. The main questions that the researcher was interested in were 1) whether individuals from whom stored biological samples were obtained think that their consent should be required? 2) would they like to receive results of clinical significance? 3) what are people's perceptions of confidentiality? The researcher was also interested in whether any significant associations existed between any of these factors and the socio-demographic factors and the previous clinical experience factors. For the purpose of this summary only associations that have a significant effect size will be reported. As stated in most parts of this research, some of the independent variable questions have several so the generalizability of the results must be viewed with caution. These factors variables include current employment, income before taxes, level of education and religion. This will be addressed again in section 8.1. *Limitations*.

The findings show that more than half of participants believed that their consent was necessary for future research on stored biological samples. When samples were identifiable 54%  $\geq$  of participants thought consent was necessary and for unidentifiable samples the percentages range from 63%  $\leq$  70.5% Participants were more likely to require consent for clinically derived samples and for research studying diseases other than what their samples were taken for. Factors that were observed as having a significant association with participants who believed that consent was necessary included current employment, income before taxes, personal health and whether an

individual had previously had tests run using their samples. The effect size of these associations ranged from moderately strong to strong.

The study suggested that participants most likely to require consent for future research included students, self-employed participants, those earning salaries between R 12801- R 25600, those with excellent personal health and those who had had tests (using biological samples) run in the last 6 months. Participants that were least likely to require consent for future research included those with poor health; those who had tests using their biological samples run in the last 6 months, and those who earned R 12 801- R 25600 and over; and those who had no post-test discussion after they previously had a test run using their biological samples. Participants that were more likely to be unsure were those who earned a salary over R 25601 and those who were currently being seen at Grey's Hospital.

There were some contradictions with some of the factors, such as participants who earned between R 12 801- R 25600 and participants who had tests run in the past 6 months. These differences were due to participants responding differently in the different consent scenarios of clinically derived samples, research derived samples and consent for studying a different disease other than what the samples were collected for. It is also worth considering that the difference regarding income applied to very few respondents.

With regard to when participants felt that it was necessary to obtain consent for future research, over half of the participants believed that it ought to be obtained when samples were initially collected. Participants who rated their personal health as poor or excellent were less likely to agree to this. Participants who earned a salary over R 25601 and those from Grey's Hospital were most likely to be unsure.

The results show that a little under half of the participants felt that obtaining consent for future research was the responsibility of the initial clinician or researcher while 53% believed that one-time general consent was sufficient. No significant associations were observed with these and any of the socio-demographic factors or clinical experience factors. With regard to providing limits to



the use of one's samples- 53% of participants felt that it was necessary to set limits. Participants that were not religious were more likely to think that it is not necessary.

Most participants expressed a wish to know about their results on samples taken for research purposes, especially for results of clinical significance (88%) and they would like their doctors to be informed of these results. Participants that were more likely to want their doctors to be informed of clinically significant results were females, those with poor health, those who had had previous tests using biological samples, those with a higher certificate, diploma and a bachelor's degree.

With regard to different types of confidential information - medical information was regarded as the most sensitive and the most likely to be misused. Participants from Edendale Hospital were more likely to agree to this while participants at Grey's Hospital saw it as the least likely to be misused. Participants at Grey were more likely to believe that employment information was the most likely to be misused.

Finally with regard to medical information, a little less than half of participants felt that moving from paper records to computerized records would decrease the chances of violation of medical records. Most participants (80%) reported to have never had the confidentiality of their medical records violated and the majority (70%) had never avoided seeking medical help in fear of their confidentiality being violated. A third of participants felt that all types of medical information were equally important. However, those with bachelor's degrees and those who were self-employed were most likely to think that notes from doctors' visits were the most important.

## **Chapter 7: Discussion**

This chapter will discuss the findings/results of this research in light of the literature presented in previous chapters regarding ethics in biomedical research. The South African context will also be taken into consideration when discussing the results. This section will start by discussing

participant socio-demographics and previous clinical experience, which are the independent variables. It will be followed by a discussion of the research questions (dependent variables).

### **7.1 Participant socio-demographics and previous clinical experience**

Participant socio-demographics showed that most participants were Black and that there were significantly more females than males. The researcher attributes this to two factors: firstly, in South Africa the majority of the population is Black; therefore, the fact that they are the most represented in this sample is justifiable. The discrepancy between the genders can be explained by the fact that, when it comes to help-seeking behaviour, women are more likely than men to seek help for problems from health professionals (Oliver, Pearson, Coe & Gunnel, 2005). This means that a higher representation by women in this sample is also justifiable in relation to the population of help-seekers.

With regard to previous clinical experience, most participants had previously had tests done using their biological samples and most of these tests had been done within the past two years. Most participants had been engaged in discussions by healthcare professionals both before and after the tests were done, and these discussions were mostly satisfactory. Most participants were aware that tests using their biological samples were optional. Discussions about the possibility of future research on residual human biological samples were mostly not done within the hospitals. The possible reason behind the lack of these discussions is that in South Africa clinically obtained samples are not routinely retained for future research purposes yet.

### **7.2 Do individuals from whom stored biological samples were obtained think their consent should be required for future research?**

When discussing the topic of research on stored biological samples one of the main issues that arise is that of consent. Debates over consent for research on stored biological samples revolve

around questions of: (1) whether it is necessary for research on stored biological samples (2) when it should be obtained (3) who should be responsible for obtaining it (4) whether one-time general consent is sufficient (5) whether individuals should be allowed to provide limits to the use of their samples. While ethical guidelines that govern the use of human biological samples are available in South Africa as published by the Department of Health (and entities such as the Health Professions Council of South Africa and the South African Medical Research Council), relatively little has been published with regard to public attitudes to the use of their samples. In addition to legal and ethical principles, public attitudes should inform guideline development to ensure that they are in line with individual beliefs and values.

Findings in this study show that more than half of participants required consent for all research on stored biological samples. Participants were stricter about consent requirements when samples were identifiable, when they were clinically derived and when the samples will be used to study a different disease other than what they were initially collected for. Notable differences and minor similarities were evident between this study and the original study which it is based on. Wendler and Emanuel (2002) also found that respondents were more likely to require consent when samples were clinically derived and identifiable. The difference that was noted between this study and the original study was that in the original study participants were far less likely to require consent for research derived samples and for research studying diseases other than what the sample was collected for. Even when samples were identifiable, less than a third of the respondents felt that consent was necessary. While the original study found that no significant associations existed between consent and any of the socio-demographic and clinical experience variables; the current study observed that students, self-employed participants, those earning between R12 801 to R25 600, those with excellent health and those who had had tests using biological samples run less than 6 months ago were more likely to require consent. Previous studies support that previous clinical experience and health status have significant associations with willingness to donate (Al-Jumah et al., 2011; Bussey-Jones et al., 2010). Participants with excellent health are possibly more likely to require consent as compared with those with poor health because they are in less need of sophisticated medical interventions whereas

poor people would be more open to these for the sake of their health. Current employment (students and self-employed) and income were not found to be significant by any of the literature presented. The researcher attributes the associations of these variables in this study as possibly due to chance judging from the very few respondents in these categories.

An observation that was made comparing these two studies was that participants in the current study were more likely to require consent as opposed to those in the original study. The original study claimed that participants were less likely to require future consent for research derived samples as it had previously been obtained (Wendler & Emanuel, 2002). It also claimed that respondents view future consent for further research on research derived samples as ‘unnecessary’; and it suggests that if participants could be given the opportunity to consent for their clinically derived samples to be used for research purposes then they can be treated as research samples (Wendler & Emanuel, 2002).

The original study made the assumption that because respondents were less likely to require consent for research derived samples and for research studying diseases other than they were collected for, it suggested that individuals did not feel the need to provide limits to the use of their samples and that broad consent applied. The current study chose to investigate this assumption by adding questions that addressed when participants thought it was necessary to obtain consent, and which consent model they preferred. The present findings showed that while almost one third of participants supported the idea of future consent being obtained when samples were initially collected, an almost equal split was seen between participants who felt that one-time general consent was enough and those who felt that it was necessary to set limits on the future use of their samples. Non-religious participants were less likely to require that limits be imposed on their samples. The reason for this could be because they are less likely to have religious views which may include beliefs about science and genetic discovery (Al- Jumah et al., 2011).

This data suggests that individuals need to be provided with the opportunity to consent for any future research using their stored biological samples. Should the task of re-contacting individuals for further consent be costly and difficult, then it is the responsibility of the initial researcher or clinician to obtain this consent (Bauman et al., 2003). The findings also suggest that individuals need to be given the option to either provide broad consent or provide consent with limits to certain diseases/illnesses. Department of Health guidance (2015) states that in the absence of broad consent where samples are anonymous, unidentifiable, and where the results would not cause any harm to participants, the need for re-consent can be waived by a registered REC. Re-consent for research on stored samples may only be necessary if future research is studying a disease other than what it was initially collected for or if there is a way of linking identifying details to samples (Department of Health, 2015). While some of these guidelines allow for a waiver of re-consent, the fact that over half of the participants felt that future consent was necessary in all scenarios of research on biological samples should be considered. Researchers and RECs need to consider what participants regard as ‘causing harm’ and assess whether the use of samples without consent could be classified as such – or as a possible harm to dignity, if not to body. While it is important for researchers to respect individuals as autonomous persons by allowing them control over the use of their samples; re-contacting individuals (in the absence of future consent) can be regarded as an invasion of privacy (Chen et al., 2005; Simitis, 2004). Previous literature further suggests that initial clinicians and researchers should provide individuals a checklist of options from which they can choose the research they approve or disapprove of regarding their samples (Porter et al., 2000; Chen et al., 2005). This again highlights the need for South African guidelines to consider requiring a process of obtaining consent for future use.

Another noteworthy finding that was made was that for most questions pertaining to consent, participants from Grey’s Hospital were more likely to respond ‘unsure’ as compared to participants from Edendale Hospital. This could be because Grey’s is a referral hospital (patients referred from other hospitals or clinics) while Edendale is more of a self-referral hospital. This

might mean that patients from Grey's are more ill or have conditions that cannot be treated elsewhere.

### **7.3 Do participants want to receive results of clinical significance?**

Findings showed that most participants wanted to be informed of results of clinical significance. No significant associations were found between this variable and any other variables. Participants also wanted their doctor to be informed of results of clinical significance, especially females, and those with a higher certificate, diploma and bachelor's degree. These results echo those found in previous literature (Abou-Zeid et al., 2010; Halverson & Friedman Ross, 2012; Hoeyer et al., 2004; Opinion Leader, 2012; Wendler & Emanuel, 2002). According to Hoeyer et al. (2004) and Opinion Leader (2012), participants wanted to be informed of results of clinical significance, especially if these suggested susceptibility to contracting a disease that could be preventable by early detection. The reason that participants would want their doctors to be informed of clinically significant results is likely because they would need their doctors' support in treating or managing the condition detected. The fact that females were more likely to want their doctors informed of their results again highlights the point of how they are more likely to seek help more than men (Oliver et al., 2005).

Informing participants of results of clinical significance can be regarded as an important part in benefit sharing. However it poses a challenge to researchers especially if samples are unidentifiable. Even with identifiable details it could be difficult /impossible tracking down participants because of distance, time and possibly death (Bauman et al., 2003). In light of the findings of the current research and of applicable ethics guidance, it would seem like in order to facilitate this process of disseminating clinically significant results the researcher/clinician who collected the initial sample and the researcher who uses the stored sample should work collaboratively. The initial researcher/clinician would have to include in their consent form

provisions for future research and give participants the option of obtaining significant results. The initial researcher would also have to code these samples and provide the researcher with coded samples. Databases would have to be created and a decision could be made for either the researcher to relay significant results to the initial clinician/researcher to inform participants; or participants could be given the option to contact the initial/clinician or researcher to find out.

#### **7.4. What are participants' perceptions of confidentiality?**

Findings show that medical information was regarded as the most important type of confidential information especially for participants who were currently being seen at Edendale Hospital. Most participants reported that the confidentiality of their medical records had never been violated and they had never avoided seeking medical assistance out of fear of their confidentiality being violated. Approximately half of the participants felt that moving from paper records to computerized records decreased the likelihood of their confidentiality being violated. These findings suggest that participants have trust in their clinician's ability to protect confidential information. Public trust is important as individuals are more likely to provide future consent for the use of their clinical samples if they have faith that clinicians will protect their samples (Baumen et al., 2003; Kettis-Linblad et al., 2004; Simitis, 2004).

In order to start the process of requesting future consent for clinical samples, it is important for clinicians to maintain this trust by engaging in open and honest dialogues about confidentiality with participants. Clinicians need to make clear if samples are intended for future use and they need to obtain consent and find a way to disseminate results of clinical significance to individuals. Hospitals provide a convenient source of biological samples but it is not enough to assume that they can freely be used at researchers' discretion. This should be considered when relevant ethics guidelines are being revised.

## **Chapter 8: Limitations, conclusions and recommendations**

### **8.1 Limitations**

Several possible limitations of this study can be noted. Firstly, the initial proposal intended for fifty participants to be recruited from each of the three major government hospitals in Pietermaritzburg (Edendale Hospital, Grey's Hospital, Northdale Hospital). However permission was not obtained from Northdale Hospital. As a result of this the researcher took the decision to use only two hospitals and increase the sample size to one hundred participants from each hospital.

Secondly, certain variables such as current employment, income, religion and level of education had too many categories and some of these categories had too few respondents. This limits generalizability as some significant association may have been purely due to chance as opposed to statistical significance. Thirdly, since the subject of research on stored samples was a fairly new concept to participants it possibly meant that they had little to no understanding about the potential benefits or harms associated with it. Responses thus could have been due to a misunderstanding. Fourthly, since participants were currently seeking help at hospitals one cannot be sure how the nature of their illness affected their cognitive abilities and emotional state whilst completing the survey, although the researcher (a psychology intern) took care to avoid those in obvious distress or incompetent. The last limitation was due to the fact that the researcher only asked questions about identifiable and unidentifiable samples and failed to ask about coded samples. The interest in coded samples is that they could affect participants' (un)willingness to participate. Finally, the survey focused too much on issues surrounding consent only and did not do justice on desirability of clinically significant results and perceptions of confidentiality. Part of this was because the original survey was structured this way; however the researcher only realised this during the analysis stages of the research.



## 8.2 Conclusions

The main aim of this research was to quantitatively explore public attitudes the collection and storage of their human biological samples. To gain perspective of the public, the researcher used three questions. The first question sought to find whether individuals thought consent was necessary for research on their stored biological samples. Stored biological samples for the purpose of this question were classified as identifiable or unidentifiable; and they were further classified as clinically derived, research derived, and those used to study a different disease other than what they were collected for. In general, the findings of this research show that consent was regarded as always necessary for more than half of the participants when a study research is proposed on their stored samples, regardless of whether they were identifiable/unidentifiable clinically/research derived or were being used to study a different disease. Participants were however more likely to require consent for clinically derived samples and for research studying a different disease other than what they were collected for. Individuals who had excellent health and those who had previous tests using their biological samples were also more likely to require consent.

The second question asked whether individuals wanted to be informed of results of clinical significance after research had been conducted on their stored samples. Most participants wanted to be informed of clinically significant results and they also wanted researchers to inform their doctor. Females were more likely than males to want their doctors to be informed.

Lastly, the research sought to explore individuals' perceptions of confidentiality. From the findings it was deduced that individuals had a positive perception of the protection of their confidentiality at medical facilities. Most participants reported that there had never been any breach of confidentiality of their medical records and they had never avoided seeking help out of concerns of confidentiality. Participants saw the move from paper to computerized records as a way of minimising the risks of breach of confidentiality.

### 8.3 Recommendations

- Research on stored biological samples was a fairly new concept to participants, suggesting that there is a need for public knowledge on this subject. Researchers need to find a way of making this knowledge available to the general public in a way that is simple to understand for most. A possible way of doing this would be via posters in hospital waiting areas and pamphlets throughout hospitals. These would have to be in various languages to accommodate everyone. Creating this awareness is the first step in encouraging participants to make informed decisions about research on their stored samples
- It is also suggested that clinicians/researchers need to start engaging with issues around research on stored biological samples with their patients/participants. Biomedical research is not only beneficial to researchers but it is beneficial to the general public as well. Information needs to trickle down to ground level in order to achieve public support
- Future researchers on this topic need to consider a qualitative approach in order to gain a deeper insight into the views expressed in this study. This qualitative research could be done with individual participants or with focus groups. Further researchers on this topic also need to consider focusing on only one concept at a time (e.g., confidentiality only) so that they are able to explore related issues in depth.

## References

- Abou-Zeid, A., Silverman, H., Shehata, M., Shams, M., Elshabrawy, M., Hifnawy, T. ... Moharram, N. (2010). Collection, storage and use of blood samples for future research: Views of Egyptian patients expressed in a cross-sectional survey. *Journal of Medical Ethics*, 36, 539-547.
- Al-Jumah, M., Abolfotouh, M. A., Alabdulkaree, I. B., Balkhy, H. H., Al-Jeraisy, M. I., Al-Swaid, A. F., Al-Musaaes, E. M., & Al-Knawy, B. (2011). Public attitudes towards biomedical research at outpatient clinics of King Abdulaziz medical city, Riyadh, Saudi Arabia. *Eastern Mediterranean Health Journal*, 17(6), 536-545.
- Baldwin-Ragaven, L., de Gruchy, J., & London, L. (1999). *An ambulance of the wrong colour: Health professionals, human rights and ethics in South Africa*. Cape Town: University of Cape Town Press.
- Barsdorf, N. W., & Wassenaar, D. R. (2005). Racial differences in public perceptions of voluntariness of medical research participants in South Africa. *Social Science and Medicine*, 60, 1087-1098.
- Bathe, O. F., & McGuire, A. L. (2009). The ethical use of existing samples for genome research. *Genetics in Medicine*, 11(10), 712-715.
- Bauman, N., Cambon-Thomsen, A., Canto-Sperber, M., Gaumont-Prat, H., Kriegel, B., Loizeau, M. ... Orth, G. (2003). *Ethical issues raised by collections of biological material and associated information data: "biobanks", "biolibraries"*. National Consultative Ethics Committee for Health and Life Sciences: Opinion 77. Retrieved from [https://ec.europa.eu/research/biosociety/pdf/opinion\\_77.pdf](https://ec.europa.eu/research/biosociety/pdf/opinion_77.pdf)
- Berger, R. L. (1990). Nazi science: The Dachau hypothermia experiments. *New England Journal of Medicine*, 322(20), 1435-1440.
- Biobank Ethics Committee of the University of the Witwatersrand's Human Research Ethics Committee (Medical). (2013). *Principles and policy on biobanks*. Johannesburg: University of the Witwatersrand.
- Bussey-Jones, J., Garrett, J., Henderson, G., Moloney, M., Blumenthal, C., & Corbie-Smith, G. (2010). The role of race and trust in tissue/blood donation for genetic research. *Genetics in Medicine*, 12(2), 116-121.
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada (2010). *Tri-council policy statement: Ethical conduct for research involving human subjects*. Retrieved November 17, 2013 from [http://www.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)
- Chen, D. T., Rosenstein, D. L., Muthappan, P., Hilsenbeck, S. G., Miller, F. G., Emmanuel, E.J., & Wendler, D. (2005). Research with stored biological samples: What do research participants want? *Archives of Internal Medicine*, 165, 652-655.
- Corbie-Smith, G. (1999). The continuing legacy of the Tuskegee Syphilis Study: Considerations for clinical investigation. *American Journal of the Medical Sciences*, 317(1), 5-8.

- Department of Health Republic of South Africa (2005). *Ethics in health research: Principles, processes and structures*.
- Durrheim, K. (1999). Research design. In M. Terre Blanche, K. Durrheim, & D. Painter (Eds.), *Research in Practice* (pp. 33 ). Cape Town: University of Cape Town Press.
- Elger, B. S., & Caplan, A. L. (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.
- Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? *Journal of the American Medical Association*, 283(20), 2701-2711.
- Emanuel, E. J., Wendler, D., Killen, J., & Grady, C. (2004). What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases*, 189, 930-937.
- Gefenas, E., Dranseika, V., Serepkaite, J., Cekanauskaite, A., Caenazzo, L., Gordjin, B., Pegoraro, R., & Yuko, E. (2012). Turning residual human biological materials into research collections: Playing with consent. *Journal of Medical Ethics*, 28, 351-355.
- Gibbons, S. M. C., & Kaye, J. (2007). Governing genetic databases: Collection, storage and use. *King's Law Journal*, 18, 201-295.
- Gikonyo, C., Bejon, P., Marsh, V., & Molyneux, S. (2008). Taking social relationships seriously: Lessons learned from the informed consent practices of a vaccine trial on the Kenyan Coast. *Social Science and Medicine*, 67, 708-720.
- Godard, B., Schmidtke, J., Cassiman, J., & Ayme, S. (2003). Data storage and DNA banking for biomedical research: Informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *European Journal of Human Genetics*, 11(2), 88-122.
- Halverson, C. M. E., & Friedman Ross, L. (2012). Attitudes of African American parents about biobank participation and return of results for themselves and their children. *Journal of Medical Ethics*, 33, 561-566.
- Hoeyer, K., Olofsson, B., Mjomdal, T., & Lynoe, N. (2004). Informed consent and biobanks: A population-based study of attitudes towards tissue donation for genetic research. *Scandinavian Journal of Public Health*, 32, 224-229.
- Isler, M. R., Odulana, A. A., & Corbie-Smith, G. (2011). The legacy of Tuskegee. In R. V. Katz, R. C. Warren, & M. J. Elders (Eds.), *The search for the legacy of the USPHS Syphilis Study at Tuskegee* (pp. 89-97). Plymouth, PA: Lexington Books.
- Kapp, M. B. (2006). Ethical and legal issues in research involving human subjects: Do you want a piece of me? *Journal of Clinical Pathology*, 59, 335-339.
- Kettis-Linblad, A. K., Ring, L., Viberth, E., & Hansson, M. G. (2005). Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think? *European Journal of Public Health*, 4(16), 433-440.
- Koen, J., Slack, C., Barsdof, N., & Essack, Z. (2008). Payment of trial participants can be ethically sound: Moving past a flat-rate. *South African Medical Journal*, 98(12), 926-929.
- Molyneux, C. S., Peshu, N., & Marsh, K. (2004). Understanding of informed consent in a low-income setting: Three case studies from the Kenyan coast. *Social Science and Medicine*, 59, 2547-2559.

- Molyneux, S., & Geissler, P. (2008). Ethics and the ethnography of medical research in Africa. *Social Science and Medicine*, 67, 685-695.
- 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). Doi: 10.1186/1472-6939-15-4
- Mouton, J. (1996). *Understanding social research*. Pretoria: Van Schaik Publishers.
- National Bioethics Advisory Committee (1999). *Research involving human biological materials: Ethical issues and policy guidance*. Rockville: National Bioethics Commission.
- Oliver, M.I., Pearson, N., Coe, N., & Gunnell, D. (2005). Help-seeking behaviour in men and women with common mental health problems: cross-sectional study. *The British Journal of Psychiatry*, 186(4) 297-301
- Opinion Leader. (2012). *Assessing public attitudes to health related findings in research*. London: Wellcome Trust and Medical Research Council.
- Orb, A., Eisenhauer, L., & Wynaden, D. (2000). Ethics in qualitative research. *Journal of Nursing Scholarship*, 33(1), 93-96.
- Organisation for Economic Co-operation and Development (OECD). (2007). *Glossary of statistical terms*. Paris: Organisation for Economic Co-operation and Development.
- Peil, M. (1982). *Social research methods: An African handbook*. London: Hodder and Stoughton
- Porter, T., Hughes, K., Finer, S., & Woolcott, C. (2000). *Public perception of the collection of human biological samples*. London: Wellcome Trust.
- Punch, K. (2013) *Introduction to social research: Quantitative and qualitative approaches*. London: Sage Publications.
- Robson, C. (1993). *Real world research: A resource for social scientists and practitioner-researchers*. Oxford: Blackwell Publishers.
- Sathar, M. A., & Dhali, 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. *South African Journal of Bioethics and Law*, 5(1), 51-54.
- Schutt, R. K. (1996). *Investigating the social world: The process and practice of research*. London: Sage.
- Seale, C. (2012). *Researching society and culture*. London: Sage.
- Simitis, S. (2004). *Biobanks for research*. Berlin: German National Ethics Council.
- Singh, S., & Wassenaar, D.R. (2016). Contextualising the role of gatekeeper in social science research. *South African Journal of Bioethics & Law*, 9(1), 42-46.
- Tredoux, C. (1999). Sound conclusions: Judging research design. In M. Terre Blanche, & K. Durrheim (Eds.), *Research in practice* (pp. ). Cape Town: UCT Press.
- Wassenaar, D. R. (2006). Ethical issues in social science research. In M. Terre Blanche, K. Durrheim, & D. Painter (Eds.), *Research in practice: Applied methods for the social sciences* (2nd ed.) (pp. 60-80). Cape Town: University of Cape Town Press.
- Wassenaar, D.R., & Mamotte, N. (2012). Ethical issues and ethics reviews in social science research. In M. Leach, M. Stevens, G. Lindsay, A. Ferrero, & Y. Korkut (Eds.) *The*

- Oxford handbook of international psychological ethics* (pp. 268- 282). New York: Oxford. Doi: 10.1093/oxfordhb/9780199739165.013.0019
- Wendler, D., & Emanuel, E. (2002). The debate over research on stored biological samples: What do sources think? *Archives of Internal Medicine*, 162, 1457-1462.
- Wendler, D., Pace, C., Talisuna, A. O., Maiso, F., Grady, C., & Emanuel, E. (2005). Research on stored biological samples: The view of Ugandans. *Ethics and Human Research*, 27(2), 1-5.

## 10. Appendices

### Appendix A: The University of KwaZulu-Natal College of Humanities Research and Higher Degrees approval



20 May 2015

#### To Whom it may concern

This Letter serves to confirm that Miss Nonhlanhla Keswa (student No. 208506027) has had her Research Proposal titled “Public attitudes to the collection of human biological samples for future research purposes: A quantitative study based on out-patients at Grey’s Hospital” reviewed and accepted, The proposal was approved at the Research Higher Degrees Committee meeting on 28 April 2015.

Please do not hesitate to contact me on these details should you require further information; 033 260 5549; [Duma@ukzn.ac.za](mailto:Duma@ukzn.ac.za).

Sincerely

A handwritten signature in black ink, consisting of several loops and a horizontal line at the bottom.

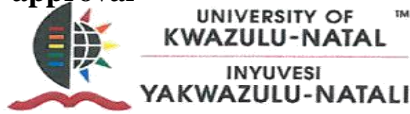
Mr. Sbonelo Duma Postgraduate Officer

School of Applied Human Sciences

Postal Address: Private Bag X01, Scottsville, Pietermaritzburg3209, South Africa

Telephone: +27 (0)33 260 5549      Facsimile: +27 (0)33 260 5809      Email:  
[Khanyilet@ukzn.ac.za](mailto:Khanyilet@ukzn.ac.za)      Website: [psychology.ukzn.ac.za](http://psychology.ukzn.ac.za)

## Appendix B: University of KwaZulu-Natal Biomedical Research Ethics Committee approval



03 November 2015

Ms N Keswa  
Discipline of Psychology  
Applied Human Sciences  
[missk3003@gmail.com](mailto:missk3003@gmail.com)

**Protocol:** Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients.

**Degree:** MSocSci

**BREC reference number:** BE232/15

### EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 15 May 2015.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 21 October 2015 to queries raised on 09 September 2015 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval to be undertaken at Greys and Edendale Hospital.

This approval is valid for one year from 03 November 2015. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on 10 November 2015.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor J Tsoka-Gwegweni  
Chair: Biomedical Research Ethics Committee

cc Supervisor: [wassenaar@ukzn.ac.za](mailto:wassenaar@ukzn.ac.za)

Biomedical Research Ethics Committee  
Professor J Tsoka-Gwegweni (Chair)

Westville Campus, Govan Mbeki Building

Postal Address: Private Bag X54001, Durban 4000

Telephone: +27 (0) 31 260 2486 Facsimile: +27 (0) 31 260 4609 Email: [brec@ukzn.ac.za](mailto:brec@ukzn.ac.za)

Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>



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## Appendix C: Greys Hospital approval



health

Department:  
Health  
PROVINCE OF KWAZULU-NATAL

GREYS HOSPITAL  
OFFICE OF THE CEO

Private Bag X 9001, Pietermaritzburg, 3200  
Town Bush Road, Chase Valley, Pietermaritzburg, 3201  
Tel.: 033 – 897 3321 Fax.: 033 – 8973398  
www.kznhealth.gov.za

<b>To:</b>	<b>Ms. Nonhlanhla Keswa</b> <b>Discipline of Psychology</b> <b>Applied Human Sciences - UKZN</b>
<b>From:</b>	<b>Dr. K. B. Bilege</b> <b>CEO - Greys Hospital</b>
<b>Date:</b>	<b>27 August 2015</b>
<b>Re:</b>	<b>Request for permission to conduct research at Grey's Hospital: <i>Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients</i></b>

Dear Ms. Keswa

Your request to conduct research at Grey's Hospital refers.

Permission to conduct the above study is hereby granted under the following conditions:

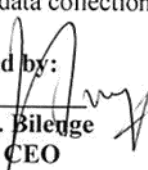
- Your provisional ethics approval and research protocol is assumed to be valid and final ethics approval is a prerequisite for conducting your study at our hospital. Once obtained from BREC, please submit a copy of the full ethics approval;
- You are also required to obtain approval for your study from the Provincial Department of Health KZN Health Research Unit prior to commencing your study at Grey's Hospital. You will find more information on their website: <http://www.kznhealth.gov.za/hrkm.htm>
- Confidentiality of hospital information, including staff and patient medical and/or contact information, must be kept at all times; Patient records are not to be removed from the hospital premises nor are you allowed to photocopy/ photograph them.
- You are to ensure that your data collection process will not interfere with the routine services at the hospital, and must not delay or inconvenience outpatients and clinic appointments;
- You are to ensure that hospital resources are not used to manage your data collection, e.g. hospital staff collecting/collating data; photocopying; telephone; facsimile, etc.;
- Informed consent is to be obtained from all participants in your study, if applicable;
- Policies, guidelines and protocols of the Department of Health and Grey's Hospital must be adhered to at all times;
- Professional attitude and behaviour whilst dealing with research participants must be exhibited;
- The Department of Health, hospital and its staff will not be held responsible for any negative incidents and/or consequences, including injuries and illnesses that may be contracted on site, litigation matters, etc. that may arise as a result of your study or your presence on site;
- You are required to submit to this office a summary of study findings upon completion of your research.
- You are requested to make contact with the Assistant Nursing Manager - OPD, **Mr. D. Naidoo**, at Grey's Hospital once you are ready to commence data collection.

Recommended by:

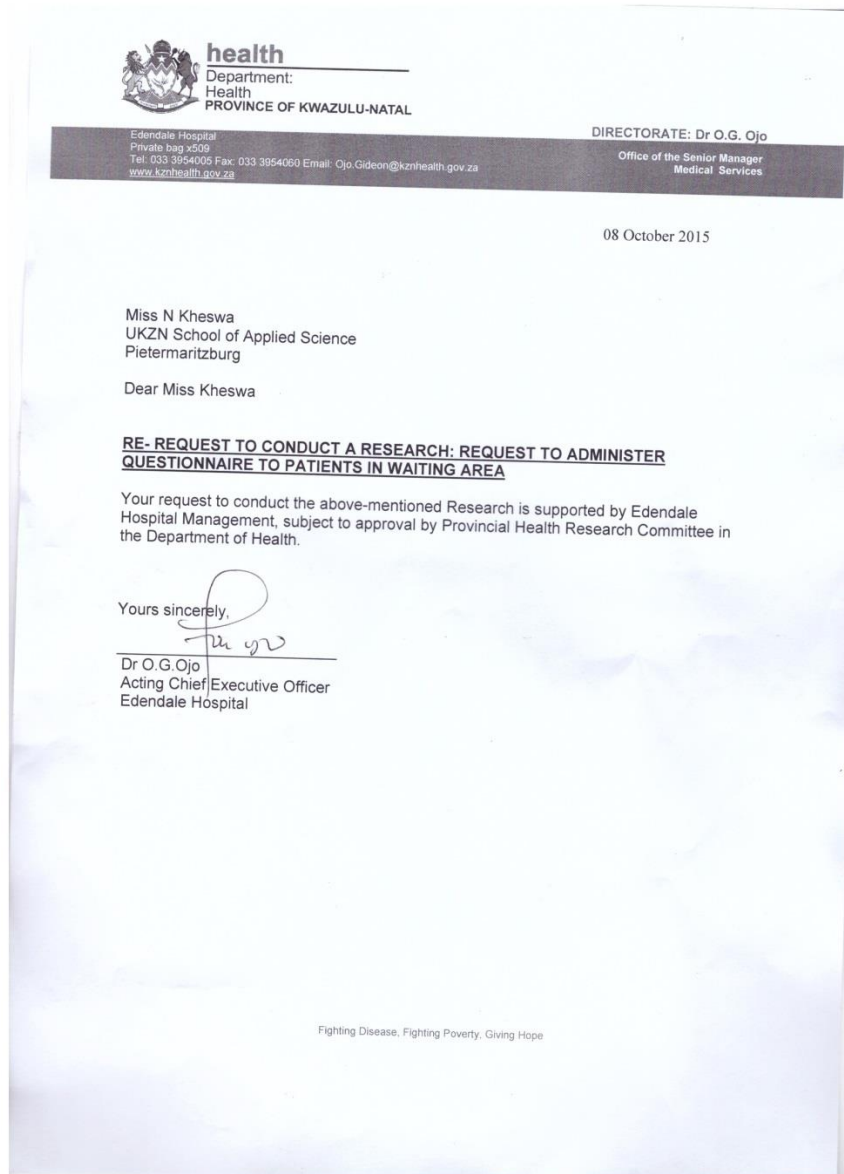
  
**Dr L. Naidoo**  
Senior Manager: Medical Services

88

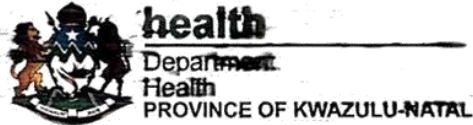
Approved by:

  
**Dr. K. B. Bilege**  
Hospital CEO

## Appendix D: Edendale Hospital approval



## Appendix E: Department of Health approval



330 Langalibalele street,  
Private Bag X9051 PMB, 3200  
Tel: 033 395 2805/3189/3123 Fax: 033 394 3782  
Email: [hrkm@kznhealth.gov.za](mailto:hrkm@kznhealth.gov.za)  
[www.kznhealth.gov.za](http://www.kznhealth.gov.za)

### DIRECTORATE:

Health Research & Knowledge  
Management (HKRM)

Reference: HRKM282/15  
KZ\_2015RP43\_437

Date: 14 October 2015

Dear Ms N Keswa

### Subject: Approval of a Research Proposal

1. The research proposal titled 'Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Greys and Edendale Hospitals.

2. You are requested to take note of the following:
  - a. Make the necessary arrangement with the identified facility before commencing with your research project.
  - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to [hrkm@kznhealth.gov.za](mailto:hrkm@kznhealth.gov.za)

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

**Dr E Lutge**

Chairperson, Health Research Committee

Date: 14/10/15

## **Appendix F: English information sheet and consent form**

### **Information Sheet and Consent Form**

Information Sheet and Consent to Participate in Research Entitled: *Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients.*

12 November 2015

Dear Sir/ Madam

My name is Nonhlanhla Keswa from the University of KwaZulu-Natal. I am currently pursuing my Master's Degree in Educational Psychology, and in partial fulfilment of this, I am required to conduct a research study. Should you wish to contact me, you may do so on 082 666 8118 or alternatively you may email me on [missk3003@gmail.com](mailto:missk3003@gmail.com).

You are being invited to participate in a research study that seeks to determine the attitudes of Pietermaritzburg government hospital out-patients to the collection and storage of human biological samples for future research purposes. The aim of this study is to determine how people feel about the collection, use and storage of their human biological samples (e.g.: blood, urine, tissue) for future research purposes. The study is expected to enrol a minimum of 50 participants from each of the local government hospitals, namely; Edendale Hospital, Northdale Hospital and Grey's Hospital. Participation in this study involves completing a questionnaire which will take approximately 10 minutes of your time. Should you wish to find out more about the collection and storage of biological samples for future research purposes before or after you complete questionnaire, all questions will be kindly answered. Information obtained from this questionnaire will remain entirely anonymous as you will not be required to provide your name or any identifiable details on your answer sheet. Instead your form will be coded into a number.

Your participation in this study does not involve any physical risk or emotional risk to you. There will be no direct benefit to you by your participation in this research study. Scientifically, this study hopes to lead to a better understanding of people's attitudes to the use of their human biological samples as this

could lead to more measures being taken when requesting consent from patients/participants for the use of their samples for research purposes.

This study has been ethically reviewed and approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee (**approval number: BE 232/15**).

In the event of any problems or concerns/questions you may contact the researcher at (082 6668118 or [missk3003@gmail.com](mailto:missk3003@gmail.com)) or my supervisor Prof D Wassenaar ([Wassenaar@ukzn.ac.za](mailto:Wassenaar@ukzn.ac.za) Ph 033-2605853), or the UKZN Biomedical Research Ethics Committee, contact details as follows:

#### **BIOMEDICAL RESEARCH ETHICS ADMINISTRATION**

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)

Participation in this study is completely voluntary, and you are free to withdraw at any stage. In the event of refusal or withdrawal of participation, you will not incur penalty or loss of treatment or any other benefit to which you are normally entitled to. Should you wish to withdraw, you will be required to inform the researcher. Upon withdrawal, you may choose whether previously obtained information may be used or whether it should be discarded.

No costs will be incurred by participants as a result of participation in the study, and there are no incentives or reimbursements for participation in the study.

Information obtained from this questionnaire will remain entirely anonymous as you will not be required to provide your name or any identifiable details on your questionnaire, and your informed consent form will be stored independent from your questionnaire. Your questionnaire will be coded with a number which cannot be linked back to you. The results of this research could be presented at a post-graduate conference which is hosted at the University of KwaZulu-Natal; or they could be published, but as mentioned above your identity will remain fully anonymous. A final copy of this study can be accessed at the University of KwaZulu-Natal main campus library if you so wish to read it.

-----

## CONSENT

I (Name \_\_\_\_\_) have been informed about the study entitled *“Collection, storage and use of blood samples for future research: views of Pietermaritzburg government hospital out-patients as expressed in a cross-sectional survey ”* by Nonhlanhla Keswa

- I understand the purpose and procedures of the study.
- I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.
- I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any treatment or care that I would usually be entitled to.
- I have been informed about any available compensation or medical treatment if injury occurs to me as a result of study-related procedures.
- If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at (provide details).
- If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

### BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

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Private Bag X 54001

Durban

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KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)

---

**Signature of Participant**

---

**Date**

\_\_\_\_\_  
Signature of Witness  
(Where applicable)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Translator

\_\_\_\_\_  
Date

## Appendix G: IsiZulu information sheet and consent form

### Ifomu lokuchazeleka kanye nefomu lesivumelwano

Ifomu lokuchazeleka kanye nefomu lesivumelwano yokuba ingxenye yocwaningo, isihloko:

***Ukuqoqwa kanye nokugcinwa kwama-sampula omzimba ukuze asentshenziswe  
kucwaningoolusesikhathini esizayo: Ucwaningo lobuningi oluhlola imibono yeziguli  
ezingalalisiwe ezibhedlela zikaHhulumeni ePietermaritzburg.***

12 November 2015

**Ngiyakubingelela,**

Igama lami ngingu-Nonhlanhla Keswa owenza izifundo zakhe ze-Masters kwi-Psychology eNyuvesi yaKwaZulu-Natali. Ngenza ucwaningo olunesihloko: “***Ukuqoqwa kanye nokugcinwa kwama-sampula omzimba ukuze asentshenziswe kucwaningoolusesikhathini esizayo: Ucwaningo lobuningi oluhlola imibono yeziguli ezingalalisiwe ezibhedlela zikaHhulumeni ePietermaritzburg***”. Uma ufisa ukuthintana nami ungangithinta kwinombolo ethi 0826668118 noma ungangithumela i-email ku [missk3003@gmail.com](mailto:missk3003@gmail.com) .

Uyamenywa ukuba ube yingxenywe yalolucwaningo. Injongo yalolucwaningo ukuthola ulwazi ngokuthi abantu bacabangani ngokuqoqwa kanye nokugcinwa kwamasampula omzimba (igazi, umchamo, amathe njalo njalo) ukuze asetshenziswa kucwaningo olusesikhathini esizayo. Lolucwaningo kuzoba ucwaningo lobuningi oluzodinga iziguli ezingalalisiwe eziwe-50 kuzo zonke izibhedlela zikaHhulumeni ePietermaritzburg (Grey's Hospital, Edendale Hospital and Northdale Hospital). Ngokuba ingxenywe kulolucwaningo ulindeleke ukuba ufake imibono yakho ngokuphendula imibuzo, okungathatha imizuzu elishumi. Imibono yakho kulolucwaningo iyogcinwa iyimfihlo; igama nesibongo sakho ngeke kwadingeka kwifomu lohlelo lwemibuzo yocwaningo.

Ukuba yingxenywe yalolucwaningo angeke kube yingozi kuwena emzimbeni noma emoyeni. Akukho okuphathekayo ozokuthola ngokuba ingxenywe yalolucwaningo. Ngokolwazi, lolucwaningo lufisa ukuthola ulwazi olubanzi ngemibono yabantu mayelana nokusetshenziswa kwama-sampula abo ngoba lemibono ibalulekile ukuze kubekwe imithetho nemigomo uma kusetshenziswa amasampula abantu.

Lolucwaningo lunikwe imvume yiBiomedical Research Ethics Committee yase University yaKwaZulu-Natal (**inombolo yemvume: BE 232/15**).

Uma uba nenkinga noma unemibuzo ungathinta mina umcwaningi (Nonhlanhla Keswa-0826668118) noma ungathinta umhloli wami (Professor Douglas Wassenaar- ph 033-2605853/ email [wassenaar@ukzn.ac.za](mailto:wassenaar@ukzn.ac.za)). Imininingwane yeBiomedical Research Ethics Committee yase University yaKwaZulu-Natal:

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Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)



Ukuba yingxenye yalolucwaningo yinketho yakho, akuphoqelekile. Ukubamba kwakho iqhaza kulolucwaningo kumahhala futhi ukungalibambi iqhaza ngeke kukubeke encupheni yokuthola usizo lapha esibhedlela. Unelungelo lokukhetha ukuqhubeka noma ukungaqhubeki uma usuqalile. Uma ukhetha ukungaqhubeki usuqalile, unelungelo futhi lokukhetha ukuthi imibono yakho osuyibhalile ingasetshenziswa noma cha.

Ukuba yinxenya yalolucwaningo ngeke kwakukhubaza ngokumuphefumulo noma ngayiphi enye indlela. Imininingwane ebanzi ngalolucwaningo iyatholakala, unelungelo lokubuza.

Imiphumela yalolucwaningo ingadingidwa kwinkomfa ezobe ibanjelwe eNyuvesi yaKwaZulu-Natali ekupheleni konyaka. Eminye yayo ingashicilelwa emabhukwini ahlukene, futhi ingatholakala emtapweni wolwazi waseNyuvesi yaKwaZulu-Natali. Isiqiniseko sizothathwa ukuthi igama lakho kanye neminingwane yakho igcineke iyimfihlo.

## IFOMU LESIVUMELWANO

Mina \_\_\_\_\_ (igama lakho eliphelele), sengifundile futhi nginolwazi lwemigomo yokuba inxenye yalolucwaningo, isihloko: ***“Ukuqoqwa kanye nokugcinwa kwama-sampula omzimba ukuze asentshenziswe kucwaningoolusesikhathini esizayo: Ucwaningo lobuningi oluhlola imibono yeziguli ezingalalisiwe ezibhedlela zikaHhulumeni ePietermaritzburg”*** olwenziwa uNonhlanhla Keswa.

- Ngichazelekile ngesizathu kanye nohlelo lwalolucwaningo.
- Nginikeziwe ithuba lokuthi ngibuze imibuzo enginayo ngaze ngagculiseka.
- Ngiaqiniseka ukuthi angiphoqiwe ukuthi ngibe yingxenye yalolucwaningo. Ngiyazi ukuthi nginelungelo lokukhetha ukuqhubeka noma ukungaqhubeki.

- Uma nginemibuzo ngiyazi ukuthi ngingathintana nobani.
- Uma nginemibuzo noma kukhona engikathazeka ngoko ngalolucwaningo ngingathintana ne:

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**I-signature yami**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**I-signature yafakazi**  
**(Where applicable)**

\_\_\_\_\_  
**Date**

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**I-Signature yomuntu ongitolikelayo**  
**(Where applicable)**

\_\_\_\_\_  
**Date**

## **Appendix H: Original Survey**

1. Researchers now have genetic tests that allow them to assess if Alzheimer's Disease runs in families.

Has anyone ever tested your blood or saliva for Alzheimer's Disease?

Γ<sub>1</sub> YES (SKIP TO 2)

Γ<sub>2</sub> NO

1a. Has anyone offered you a blood or saliva test for Alzheimer's Disease that you decided not to have done?

Γ<sub>1</sub> YES

Γ<sub>2</sub> NO (SKIP TO 18)

1b. Why did you decide not to have the test done at that time?

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(SKIP TO 18)

2. About how long ago were you tested, would you say it was less than 6 months ago, between 6 months and a year ago, between 1 and 2 years ago, or more than 2 years ago?

Γ<sub>1</sub> LESS THAN 6 MONTHS AGO

Γ<sub>2</sub> BETWEEN 6 MONTHS AND A YEAR AGO

Γ<sub>3</sub> BETWEEN 1 AND 2 YEARS AGO

Γ<sub>4</sub> MORE THAN 2 YEARS AGO

3. Was it the genetic test for Apolipoprotein-E, or APOE for short?

Γ<sub>1</sub> YES (SKIP TO 4)

Γ<sub>2</sub> NO

Γ<sub>9</sub> DON'T KNOW (SKIP TO 4)

3a. Which genetic test was it? \_\_\_\_\_

4. As I ask you about the details of your genetic testing for Alzheimers, I want to reassure you that your answers will be kept confidential so that no one outside our research team will know what you say.

Did you receive an explanation or participate in a discussion about the Alzheimer's test either before or at the time you went to receive it?

Γ<sub>1</sub> YES

Γ<sub>2</sub> NO (SKIP TO 7)

Γ<sub>9</sub> DON'T KNOW (SKIP TO 7)

5. Did you decide to be tested because you were convinced by the explanation or had you already decided to be tested before hearing the explanation?

Γ<sub>1</sub> EXPLANATION CONVINCED

Γ<sub>2</sub> ALREADY DECIDED

Γ<sub>9</sub> DON'T KNOW

6. Before you were tested for Alzheimer's Disease, was there anything that was not discussed as much as you would have liked?

Γ<sub>1</sub> YES

Γ<sub>2</sub> NO (SKIP TO 7)

6a. What was that?

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7. Was there a discussion about the Alzheimer's test at any time after it was performed?

Γ<sub>1</sub> YES

Γ<sub>2</sub> NO (IF NO TO 4 AND 7, SKIP TO 14)

8. Added together, how much time in minutes would you estimate was spent providing you with information about the test before, during, and after you had it done?

\_\_\_\_\_ MINUTES

9. Who explained or discussed the test with you, was it a doctor, a nurse, a social worker, a genetic counselor, or someone else?

Γ<sub>1</sub> A DOCTOR

Γ<sub>2</sub> A NURSE

Γ<sub>3</sub> SOCIAL WORKER

Γ<sub>4</sub> A GENETIC COUNSELOR

Γ<sub>5</sub> SOMEONE ELSE (SPECIFY \_\_\_\_\_)  
Γ<sub>6</sub> COMBINATION (SPECIFY \_\_\_\_\_)  
Γ<sub>9</sub> DON'T KNOW

10. As part of the information you received, how clearly was it explained that being tested for Alzheimer's Disease was your option, and not a requirement? Would you say very clearly, clearly, not very clearly, or not clearly at all?

Γ<sub>1</sub> VERY CLEARLY  
Γ<sub>2</sub> CLEARLY  
Γ<sub>3</sub> NOT VERY CLEARLY  
Γ<sub>4</sub> NOT CLEARLY AT ALL  
Γ<sub>5</sub> WAS NOT DISCUSSED AT ALL

11. How well was it explained that Alzheimer's tests do not tell us for certain whether a person will or will not develop the disease? Would you say very well, well, not very well, or not well at all?

Γ<sub>1</sub> VERY WELL  
Γ<sub>2</sub> WELL  
Γ<sub>3</sub> NOT VERY WELL  
Γ<sub>4</sub> NOT WELL AT ALL  
Γ<sub>5</sub> WAS NOT DISCUSSED AT ALL (SKIP TO 12)

11a. As best as you can remember, based on the explanation you received, what does a positive test result for Alzheimer's Disease mean?

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Γ<sub>1</sub> WAS NOT DISCUSSED  
Γ<sub>9</sub> DON'T KNOW

12. How well was it explained that the results from a test for Alzheimer's Disease might affect your ability to get health insurance in the future?

Γ<sub>1</sub> VERY WELL  
Γ<sub>2</sub> WELL  
Γ<sub>3</sub> NOT VERY WELL

Γ<sub>4</sub> NOT WELL AT ALL  
Γ<sub>5</sub> WAS NOT DISCUSSED AT ALL

13. How helpful was the discussion you had for understanding how taking the test might affect your family? Would you say very helpful, moderately helpful, not very helpful, or not helpful at all?

Γ<sub>1</sub> VERY HELPFUL  
Γ<sub>2</sub> MODERATELY HELPFUL  
Γ<sub>3</sub> NOT VERY HELPFUL  
Γ<sub>4</sub> NOT HELPFUL AT ALL  
Γ<sub>5</sub> NOT COVERED BY THE GENETIC COUNSELING

13a. Did the person explaining the test tell you whether or not your blood sample could be used for future research?

Γ<sub>1</sub> YES  
Γ<sub>2</sub> NO  
Γ<sub>3</sub> DON'T RECALL

14. Were you allowed to have the results of your test for Alzheimer's?

Γ<sub>1</sub> YES (SKIP TO 16)  
Γ<sub>2</sub> NO

15. How strong was your desire to know the results of your genetic test for Alzheimer's Disease, would you say it was very strong, moderately strong, not very strong, or not strong at all?

Γ<sub>1</sub> VERY STRONG (SKIP TO 17)  
Γ<sub>2</sub> MODERATELY STRONG (SKIP TO 17)  
Γ<sub>3</sub> NOT VERY STRONG  
Γ<sub>4</sub> NOT STRONG AT ALL  
Γ<sub>5</sub> DON'T KNOW (SKIP TO 17)

15a. Why weren't you interested in the results?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ (SKIP TO 17)

16. Can you recall the specific results of your genetic test for Alzheimer's Disease?

Γ<sub>1</sub> YES  
Γ<sub>2</sub> NO (SKIP TO 17)  
Γ<sub>2</sub> NEVER GOT RESULTS (SKIP TO 17)

16a. What were the results of your test?

$\Gamma_1$  HOMOZYGOUS E2/E2  
 $\Gamma_2$  HETEROZYGOUS E2/E3  
 $\Gamma_3$  HETEROZYGOUS E2/E4  
 $\Gamma_4$  HOMOZYGOUS E3/E3  
 $\Gamma_5$  HETEROZYGOUS E3/E4  
 $\Gamma_6$  HOMOZYGOUS E4/E4  
 $\Gamma_7$  SOMETHING ELSE (SPECIFY \_\_\_\_\_)  
 $\Gamma_9$  DON'T KNOW (SKIP TO 17)

16b. Does this result indicate you have an increased chance of getting Alzheimer's Disease?

$\Gamma_1$  YES  
 $\Gamma_2$  NO  
 $\Gamma_9$  DON'T KNOW

17. On a 0 to 10 scale where 0 is no certainty at all and 10 is complete certainty, how certain are you that your test results will be kept confidential?

NO CERTAINTY AT ALL						COMPLETE CERTAINTY				
$\Gamma_0$	$\Gamma_1$	$\Gamma_2$	$\Gamma_3$	$\Gamma_4$	$\Gamma_5$	$\Gamma_6$	$\Gamma_7$	$\Gamma_8$	$\Gamma_9$	$\Gamma_{10}$

#### ABSTRACT CHOICES - PHYSICAL SAMPLES

1. Now I want you to help with another research problem. Suppose you had participated in a research study on Alzheimer's Disease two years ago and as part of that study the researcher took a sample of your blood. Now the researcher would like to do more research with your blood sample.

Should the researcher have to get permission from you to use the left over blood for further research on Alzheimer's Disease if your name is still attached to the sample?

$\Gamma_1$  YES  
 $\Gamma_2$  NO (SKIP TO 3)  
 $\Gamma_9$  DON'T KNOW (SKIP TO 3)

2. What if your name and identifying information have been removed from the sample, should the researcher still have to get your permission a second time?

$\Gamma_1$  YES (SKIP TO 5)  
 $\Gamma_2$  NO (SKIP TO 4)  
 $\Gamma_9$  DON'T KNOW (SKIP TO 4)

3. Suppose the researcher wanted to use your blood to study a different disease, like diabetes, should the researcher have to get your permission to use the left over blood for that research if your name is still attached to the sample?

$\Gamma_1$  YES

$\Gamma_2$  NO (SKIP TO 5)

$\Gamma_9$  DON'T KNOW (SKIP TO 5)

4. Suppose the researcher wanted to use your blood to study a disease other than Alzheimer's, and your name and identifying information had been removed from the sample, should the researcher have to get your permission a second time?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_9$  DON'T KNOW

5. Imagine that while doing the new research, the researcher learned something about you, but wasn't sure if it might affect your health.

Would you want the researcher to contact you and tell you?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_9$  DON'T KNOW

5b. Would you want the researcher to tell your doctor?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_9$  DON'T KNOW

## H. CONFIDENTIALITY

1. Some people have concerns about the confidentiality of information about them. The confidentiality of medical records is one area of concern, while there is also concern about the confidentiality of credit histories and the confidentiality of employment histories, to name two others.

Which of the 3 types of information I have mentioned, medical information, credit history information, or employment history information, do you think is the most likely to be misused?

$\Gamma_1$  MEDICAL INFORMATION

$\Gamma_2$  CREDIT HISTORY INFORMATION

$\Gamma_3$  EMPLOYMENT HISTORY INFORMATION

$\Gamma_4$  DON'T KNOW



2. Which do you think is the least likely to be misused?

$\Gamma_1$  MEDICAL INFORMATION

$\Gamma_2$  CREDIT HISTORY INFORMATION

$\Gamma_3$  EMPLOYMENT HISTORY INFORMATION

$\Gamma_4$  DON'T KNOW

Now I want to narrow the discussion to medical records only.

3. On a 0 to 10 scale where 0 is no certainty at all and 10 is complete certainty, how certain are you that your medical records are kept confidential?

NO CERTAINTY AT ALL

COMPLETE CERTAINTY

$\Gamma_0$     $\Gamma_1$     $\Gamma_2$     $\Gamma_3$     $\Gamma_4$     $\Gamma_5$     $\Gamma_6$     $\Gamma_7$     $\Gamma_8$     $\Gamma_9$     $\Gamma_{10}$

4. Do you think going from paper medical records to computerized medical records increases the risk for misuse of the information on you, decreases the risk for misuse of the information on you, or do you think computerization does not change the risk for misuse of the information on you?

$\Gamma_1$  INCREASES THE RISK

$\Gamma_2$  DECREASES THE RISK

$\Gamma_3$  DOES NOT CHANGE THE RISK

$\Gamma_4$  DON'T KNOW

5. Has there ever been an instance when someone disclosed information about your medical history in a way you considered a violation of your confidentiality?

$\Gamma_1$  YES

$\Gamma_2$  NO (SKIP TO H7)

$\Gamma_3$  DON'T KNOW

6. What were the circumstances?

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7. Have you ever wanted to seek help for a physical or mental health problem but did not because you were concerned that information about you would not be kept confidential?

$\Gamma_1$  YES

$\Gamma_2$  NO

8. Several different kinds of medical information can exist on a person. Medical information can include genetic information, lab test information, doctor's notes from visits, and mental health information to name a few.

For which of the 4 I mentioned genetic information, lab test information, doctor's notes from visits, and mental health information, would a loss of confidentiality upset you the most?

$\Gamma_1$  GENETIC INFORMATION

$\Gamma_2$  LAB TEST INFORMATION

$\Gamma_3$  DOCTOR'S NOTES FROM VISITS

$\Gamma_4$  MENTAL HEALTH INFORMATION

$\Gamma_5$  ALL ARE EQUALLY IMPORTANT (SKIP TO H10)

$\Gamma_6$  DON'T KNOW (SKIP TO H10)

9. Which would be second?

$\Gamma_1$  GENETIC INFORMATION

$\Gamma_2$  LAB TEST INFORMATION

$\Gamma_3$  DOCTOR'S NOTES FROM VISITS

$\Gamma_4$  MENTAL HEALTH INFORMATION

$\Gamma_5$  DON'T KNOW

## J. SOCIAL BACKGROUND

1. What is your date of birth?

2. Male Female (CIRCLE ONE, ENQUIRE IF UNSURE)

3. Do you consider yourself

$\Gamma_1$  African American

$\Gamma_2$  Hispanic

$\Gamma_3$  White/non-Hispanic

$\Gamma_4$  Native American

$\Gamma_5$  Asian

$\Gamma_6$  Other (PLEASE SPECIFY: \_\_\_\_\_)

4. What is your religious background?

$\Gamma_1$  Muslim

$\Gamma_2$  Protestant

$\Gamma_3$  Catholic

$\Gamma_4$  Jewish

$\Gamma_5$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_6$  None

5. Do you consider yourself very religious, moderately religious, not very religious, or not religious at all?

$\Gamma_1$  VERY RELIGIOUS

$\Gamma_2$  MODERATELY RELIGIOUS

$\Gamma_3$  NOT VERY RELIGIOUS

$\Gamma_4$  NOT RELIGIOUS AT ALL

6. How much schooling have you had? Would you say less than high school, high school, some college, completed college, some graduate school, or completed graduate school?

$\Gamma_1$  less than high school

$\Gamma_2$  high school

$\Gamma_3$  some college

$\Gamma_4$  completed college

$\Gamma_5$  some graduate school

$\Gamma_6$  completed graduate school

7. Are you currently:

$\Gamma_1$  Employed full-time

$\Gamma_2$  Employed part-time

$\Gamma_3$  Not employed

$\Gamma_4$  Retired

$\Gamma_5$  SOMETHING ELSE (PLEASE SPECIFY) \_\_\_\_\_

8. Approximately how much did you and your immediate family earn last year before taxes?

$\Gamma_1$  Under \$15,000

$\Gamma_2$  \$15,000-\$24,999

$\Gamma_3$  \$25,000-\$49,999

$\Gamma_4$  \$50,000-\$74,999

$\Gamma_5$  \$75,000-\$99,999

$\Gamma_6$  Over \$100,000

$\Gamma_7$  REFUSED

$\Gamma_9$  DON'T KNOW

9. How would you rate your personal health, would you say it is excellent, very good, good, fair, or poor?

$\Gamma_1$  EXCELLENT

$\Gamma_2$  VERY GOOD

$\Gamma_3$  VERY GOOD

$\Gamma_4$  FAIR

$\Gamma_5$  POOR

10. Have you been hospitalized:

10a. In the past year?

$\Gamma_1$  YES

$\Gamma_2$  NO

10b. In the past 5 years?

$\Gamma_1$  YES

$\Gamma_2$  NO

## K. CONCLUSION

Coming to the end, I would like to know what it was like for you to answer my questions

1. First, how much stress would you say that this interview caused you? Would you say a great deal of stress, some stress, a little stress, or no stress at all?

$\Gamma_1$  A GREAT DEAL OF STRESS

$\Gamma_2$  SOME STRESS

$\Gamma_3$  A LITTLE STRESS

$\Gamma_4$  NO STRESS AT ALL

2. How helpful would you say this interview was for you? Would you say it was it was very helpful, moderately helpful, a little helpful, or not helpful at all?

$\Gamma_1$  VERY HELPFUL

$\Gamma_2$  MODERATELY HELPFUL

$\Gamma_3$  A LITTLE HELPFUL,

$\Gamma_4$  NOT HELPFUL AT ALL

3. Was there anything that bothered you about the questions I asked?

$\Gamma_1$  YES

$\Gamma_2$  NO (SKIP TO 4)

3a. What?

Those are all the questions I have. Thank you very much for taking the time to answer my questions. Your answers will help us improve research on Alzheimer=s Disease.

## Appendix I: Final English Survey

Number: .....

### Research Survey

**Title of study:** *Collection, storage and use of biological samples for future research: A cross-sectional study of opinions of Pietermaritzburg government hospital out-patients.*

(Acknowledgements: Survey adapted from- “*The debate over research on stored biological samples: What do sources think?*” Dave Wendler, PhD; Ezekiel Emanuel, MD, PhD)

#### Part 1- Research/Clinical Experience

1. Researchers have tests that allow them to detect certain diseases and assess whether they run in families. Have you ever had tests done using your biological material? (e.g.: blood, saliva, urine, stools etc...)

☐<sub>1</sub> YES (SKIP TO 2)  
☐<sub>2</sub> NO

- 1.1. Has anyone offered you a test involving your biological material that you decided not to have done?

☐<sub>1</sub> YES  
☐<sub>2</sub> NO (SKIP TO 12)

- 1.2. Why did you decide not to have the test done?

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(SKIP TO 12)

2. About how long ago were these tests run?

☐<sub>1</sub> LESS THAN 6 MONTHS AGO  
☐<sub>2</sub> BETWEEN 6 MONTHS AND A YEAR AGO  
☐<sub>3</sub> BETWEEN 1 AND 2 YEARS AGO  
☐<sub>4</sub> MORE THAN 2 YEARS AGO

3. Which tests were these?

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4. Did you receive an explanation or participate in a discussion about the particular test either before or at the time you went to receive it?

- ☐1 YES  
☐2 NO (SKIP TO 7)  
☐3 DON'T KNOW (SKIP TO 7)

5. Did you decide to be tested because you were convinced by the explanation or had you already decided to be tested before hearing the explanation?

- ☐1 EXPLANATION CONVINCED  
☐2 ALREADY DECIDED  
☐3 DON'T KNOW

6. Before you were tested, was there anything that was not discussed as much as you would have liked?

- ☐1 YES  
☐2 NO (SKIP TO 7)

6.1. What was that?

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7. Was there a discussion about the test at any time after it was performed?

- ☐1 YES  
☐2 NO (IF NO TO 4 AND 7, SKIP TO 12)

8. Added together, how much time in minutes would you estimate was spent providing you with information about the test before, during, and after you had it done?

\_\_\_\_\_ MINUTES

9. As part of the information you received, how clearly was it explained that the test was your option and not a requirement?

- ☐<sub>1</sub> VERY CLEARLY
- ☐<sub>2</sub> CLEARLY
- ☐<sub>3</sub> NOT VERY CLEARLY
- ☐<sub>4</sub> NOT CLEARLY AT ALL
- ☐<sub>5</sub> WAS NOT DISCUSSED AT ALL

10. How well were the results of the test explained?

- ☐<sub>1</sub> VERY WELL
- ☐<sub>2</sub> WELL
- ☐<sub>3</sub> NOT VERY WELL
- ☐<sub>4</sub> NOT WELL AT ALL
- ☐<sub>5</sub> WAS NOT DISCUSSED AT ALL

11. How helpful was the discussion you had for understanding how taking the test might affect your family?

- ☐<sub>1</sub> VERY HELPFUL
- ☐<sub>2</sub> MODERATELY HELPFUL
- ☐<sub>3</sub> NOT VERY HELPFUL
- ☐<sub>4</sub> NOT HELPFUL AT ALL
- ☐<sub>5</sub> NOT COVERED

11.1. Did the person explaining the test tell you whether or not your biological sample could be used for future research?

- ☐<sub>1</sub> YES
- ☐<sub>2</sub> NO
- ☐<sub>3</sub> DON'T RECALL

12. On a scale of 0 to 10 (where 0 is no certainty at all and 10 is complete certainty) how certain are you that your test results will be kept confidential?

NO CERTAINTY AT ALL

COMPLETE CERTAINTY

- ☐<sub>0</sub>   ☐<sub>1</sub>   ☐<sub>2</sub>   ☐<sub>3</sub>   ☐<sub>4</sub>   ☐<sub>5</sub>   ☐<sub>6</sub>   ☐<sub>7</sub>   ☐<sub>8</sub>   ☐<sub>9</sub>   ☐<sub>10</sub>



## **Part 2- Consent**

1. I want you to help me with a research problem. Suppose you had surgery two years ago and during the operation your doctor took a sample of your tissue. Now a researcher would like to use that tissue in a research study

Should the researcher have to get permission from you to use your leftover tissue for further research if your name is still attached to the sample?

- ☐<sub>1</sub> YES  
☐<sub>2</sub> NO  
☐<sub>3</sub> DON'T KNOW

- 1.1. What if your name and identifying information have been removed from the sample, should the researcher still have to get your permission a second time?

- ☐1 YES  
☐2 NO  
☐3 DON'T KNOW

2. Now I want you to help with another research problem. Suppose you had participated in a research study on Diabetes two years ago and as part of that study the researcher took a sample of your blood. Now the researcher would like to do more research with your blood sample.

Should the researcher have to get permission from you to use the left over blood for further research on Diabetes if your name is still attached to the sample?

- $\Gamma_1$  YES  
 $\Gamma_2$  NO  
 $\Gamma_3$  DON'T KNOW

- 2.1. What if your name and identifying information have been removed from the sample, should the researcher still have to get your permission a second time?

- $\Gamma_1$  YES  
 $\Gamma_2$  NO  
 $\Gamma_3$  DON'T KNOW

3. Suppose the researcher wanted to use your blood to study a disease other than diabetes, like cancer; should the researcher have to get your permission to use the left over blood for that research if your name is still attached to the sample?

$\Gamma_1$  YES

$\Gamma_2$  NO (SKIP TO 5)

$\Gamma_3$  DON'T KNOW (SKIP TO 5)

- 3.1. Suppose the researcher wanted to use your blood to study a disease other than Diabetes, like cancer, and your name and identifying information had been removed from the sample, should the researcher have to get your permission a second time?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_3$  DON'T KNOW

**\*Questions 4 to 8 are based on the above scenarios is general\***

4. When should consent for future research be obtained?

$\Gamma_1$  When samples are initially collected

$\Gamma_2$  Each time a new study is proposed

$\Gamma_3$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_4$  Don't know

5. Who should be responsible for obtaining consent?

$\Gamma_1$  The researcher/clinician for whom the samples were initially collected for

$\Gamma_2$  The researcher(s) who intends to use your sample for the proposed research

$\Gamma_3$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_4$  Don't know

6. Some researchers have proposed that individuals provide once-off general consent when their samples are collected so as to remove the need to re-contact sources for further research. Is once-off general consent enough?

$\Gamma_1$  Yes

$\Gamma_2$  No

$\Gamma_3$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_4$  Don't know

7. Should individuals be able to provide limits to the use of their samples?

$\Gamma_1$  Yes

$\Gamma_2$  No

$\Gamma_3$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_4$  Don't know

8. Imagine that while doing the new research, the researcher learned something about you, but wasn't sure if it might affect your health.

Would you want the researcher to contact you and tell you?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_3$  DON'T KNOW

8.1. Would you want the researcher to tell your doctor?

$\Gamma_1$  YES

$\Gamma_2$  NO

$\Gamma_3$  DON'T KNOW

### **Part 3- Confidentiality**

1. Some people have concerns about the confidentiality of information about them. The confidentiality of medical records is one area of concern, while there is also concern about the confidentiality of credit histories and the confidentiality of employment histories, to name two others.

Which of the 3 types of information I have mentioned, medical information, credit history information, or employment history information, do you think is the most likely to be misused?

$\Gamma_1$  MEDICAL INFORMATION

$\Gamma_2$  CREDIT HISTORY INFORMATION

$\Gamma_3$  EMPLOYMENT HISTORY INFORMATION

$\Gamma_4$  DON'T KNOW

2. Which do you think is the least likely to be misused?

$\Gamma_1$  MEDICAL INFORMATION

$\Gamma_2$  CREDIT HISTORY INFORMATION

$\Gamma_3$  EMPLOYMENT HISTORY INFORMATION

$\Gamma_4$  DON'T KNOW

Now I want to narrow the discussion to medical records only.

3. On a 0 to 10 scale where 0 is no certainty at all and 10 is complete certainty, how certain are you that your medical records are kept confidential?

NO CERTAINTY AT ALL      COMPLETE CERTAINTY

$\Gamma_0$   $\Gamma_1$   $\Gamma_2$   $\Gamma_3$   $\Gamma_4$   $\Gamma_5$   $\Gamma_6$   $\Gamma_7$   $\Gamma_8$   $\Gamma_9$   $\Gamma_{10}$

4. Do you think going from paper medical records to computerized medical records increases the risk for misuse of the information on you, decreases the risk for misuse of the information on you, or do you think computerization does not change the risk for misuse of the information on you?

$\Gamma_1$  INCREASES THE RISK

$\Gamma_2$  DECREASES THE RISK

$\Gamma_3$  DOES NOT CHANGE THE RISK

$\Gamma_4$  DON'T KNOW

5. Has there ever been an instance when someone disclosed information about your medical history in a way you considered a violation of your confidentiality?

$\Gamma_1$  YES

$\Gamma_2$  NO (SKIP TO 7)

$\Gamma_3$  DONT KNOW (Skip to 7)

6. What were the circumstances?

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7. Have you ever wanted to seek help for a physical or mental health problem but did not because you were concerned that information about you would not be kept confidential?

$\Gamma_1$  YES

$\Gamma_2$  NO

8. Several different kinds of medical information can exist on a person. Medical information can include genetic information, lab test information, doctor's notes from visits, and mental health information to name a few.

For which of the 4 I mentioned genetic information, lab test information, doctor's notes from visits, and mental health information, would a loss of confidentiality upset you the most?

- $\Gamma_1$  GENETIC INFORMATION
- $\Gamma_2$  LAB TEST INFORMATION
- $\Gamma_3$  DOCTOR'S NOTES FROM VISITS
- $\Gamma_4$  MENTAL HEALTH INFORMATION
- $\Gamma_5$  ALL ARE EQUALLY IMPORTANT
- $\Gamma_6$  DON'T KNOW

9. Which would be second?

- $\Gamma_1$  GENETIC INFORMATION
- $\Gamma_2$  AB TEST INFORMATION
- $\Gamma_3$  DOCTOR'S NOTES FROM VISITS
- $\Gamma_4$  MENTAL HEALTH INFORMATION
- $\Gamma_5$  DON'T KNOW

#### **Part 4- Socio-Demographic**

1. What is your year of birth?

2. Male Female (CIRCLE ONE, ENQUIRE IF UNSURE)

3. Do you consider yourself?

- $\Gamma_1$  African/Black
- $\Gamma_2$  Coloured
- $\Gamma_3$  Indian/Asian
- $\Gamma_4$  White
- $\Gamma_5$  Other (PLEASE SPECIFY: \_\_\_\_\_)

4. What is your religious background?

$\Gamma_1$  Muslim

$\Gamma_2$  Christian

$\Gamma_3$  Catholic

$\Gamma_4$  Jewish

$\Gamma_5$  Hindu

$\Gamma_6$  African Traditional Belief

$\Gamma_7$  Other (PLEASE SPECIFY) \_\_\_\_\_

$\Gamma_8$  None

5. Do you consider yourself very religious, moderately religious, not very religious, or not religious at all?

$\Gamma_1$  VERY RELIGIOUS

$\Gamma_2$  MODERATELY RELIGIOUS

$\Gamma_3$  NOT VERY RELIGIOUS

$\Gamma_4$  NOT RELIGIOUS AT ALL

6. How much schooling have you had?

$\Gamma_1$  No schooling

$\Gamma_2$  Primary School (grade 1 to grade 7)

$\Gamma_3$  High School (Grade 8 to grade 12)

$\Gamma_4$  Higher Certificate

$\Gamma_5$  Diploma

$\Gamma_6$  Bachelor's Degree

$\Gamma_7$  Post-Graduate qualification

$\Gamma_8$  Other (PLEASE SPECIFY) \_\_\_\_\_

7. Are you currently?:

$\Gamma_1$  Employed full-time

$\Gamma_2$  Employed part-time

$\Gamma_3$  Not employed

$\Gamma_4$  Retired

$\Gamma_5$  SOMETHING ELSE (PLEASE SPECIFY) \_\_\_\_\_

8. Approximately how much do you earn before taxes (gross income, grant, pension)?

$\Gamma_1$  None

$\Gamma_2$  R1 to R400

$\Gamma_3$  R401 to R800

$\Gamma_4$  R801 to R1600

$\Gamma_5$  R1601 to R3200

$\Gamma_6$  R3201 to R6400

$\Gamma_7$  R6401 to R12800

$\Gamma_8$  R12801 to R25600

$\Gamma_9$  Over 25601

$\Gamma_{10}$  REFUSED

$\Gamma_{11}$  DON'T KNOW

9. How would you rate your personal health?

$\Gamma_1$  EXCELLENT

$\Gamma_2$  VERY GOOD

$\Gamma_3$  VERY GOOD

$\Gamma_4$  FAIR

$\Gamma_5$  POOR

10. Have you been hospitalized:

10a. In the past year?

$\Gamma_1$  YES

$\Gamma_2$  NO

10b. In the past 5 years?

$\Gamma_1$  YES

$\Gamma_2$  NO

## Part 5- Conclusion

Coming to the end, I would like to know what it was like for you to answer my questions

1. First, how much stress would you say that this interview caused you? Would you say a great deal of stress, some stress, a little stress, or no stress at all?

$\Gamma_1$  A GREAT DEAL OF STRESS

$\Gamma_2$  SOME STRESS

$\Gamma_3$  A LITTLE STRESS

$\Gamma_4$  NO STRESS AT ALL

2. How helpful would you say this interview was for you? Would you say it was very helpful, moderately helpful, a little helpful, or not helpful at all?

$\Gamma_1$  VERY HELPFUL

$\Gamma_2$  MODERATELY HELPFUL

$\Gamma_3$  A LITTLE HELPFUL,

$\Gamma_4$  NOT HELPFUL AT ALL

3. Was there anything that bothered you about the questions I asked?

$\Gamma_1$  YES

$\Gamma_2$  NO (End for you)

3a. What?

Those are all the questions I have. Thank you very much for taking the time to answer my questions. Your answers will help us improve research on stored human biological materials.

TIME TAKEN TO COMPLETE SURVEY: \_\_\_\_\_(MINUTES



## Appendix J: Final IsiZulu survey

Number: .....

### **Uhlelo lwemibuzo yocwaningo**

**Isihloko socwaningo:** *Ukuqoqwa kanye nokugcinwa kwama-sampula omzimba ukuze asentshenziswe kucwaningoolusesikhathini esizayo: Ucwaningo lobuningi oluhlola imibono yeziguli ezingalalisiwe ezibhedlela zikaHhulumeni ePietermaritzburg.*

(Acknowledgements: Survey adapted from- “*The debate over research on stored biological samples: What do sources think?*” Dave Wendler, PhD; Ezekiel Emanuel, MD, PhD)

### **Ingxenye 1- Isipiliyoni socwaningo**

1. Abacwaningi banama-test abavumela ukuthi basheshe bekwazi ukubona izifo ezithile kumuntu futhi bebone ukuthi lezozifo ziyahamba yini emndenini. Wake wayenza i-test esebenzisa ama-sampula akho omzimba (isb.: igazi, amathe, umchamo, njll)?

☐<sub>1</sub> YEBO (Dlulela ku No. 2)

☐<sub>2</sub> CHA

- 1.1. Ukhona owake wakucela ukuthi wenze i-test esebenzisa ama-sampula akho omzimba kodwa wakhetha ukungayenzi?

☐<sub>1</sub> YEBO

☐<sub>2</sub> CHA (Dlulela ku No. 12)

- 1.2. Sithini isizathu sakho sokukhetha ukungayenzi i-test?

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(Dlulela ku No. 12)

2. Sekudlule isikhathi esingakanani uwenzile lama-test?

- ☐<sub>1</sub> Azikakadluli izinyanga eziyisithupha
- ☐<sub>2</sub> Ngaphakathi kwezinyanga eziyisithupha kuya onyakeni owodwa
- ☐<sub>3</sub> Ngaphakathi konyaka owodwa kuya kwemibili
- ☐<sub>4</sub> Ngaphezu kweminyaka emibili

3. Imaphi lama-test?

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4. Wakuthola ukuchazeleka mayelana naleyo-test noma naxoxisana ngayo ngaphambi kokuthi uyenze noma ngenkathi uyenza?

- ☐<sub>1</sub> YEBO
- ☐<sub>2</sub> CHA (Dlulela ku No. 7)
- ☐<sub>3</sub> Angazi (Dlulela ku No. 7)

5. Wathatha isinqumo sokuyenza i-test ngoba wawuchazeliwe ngayo, noma wawusuvele ususithathile isinqumo sokuyenza ngaphambi kokuthi uchazelwe?

- ☐<sub>1</sub> Ukuchwazelwa nge-test kwangenza ngithathe isinqumo sokuyenza
- ☐<sub>2</sub> Ngathatha isinqumo sokwenza i-test ngingachazelwanga
- ☐<sub>3</sub> Angazi

6. Ngaphambi kokuthi uyenze i-test, kukhona okungakhulunyanga nawe owawuthanda ukuthi kukhulunywe?

- ☐<sub>1</sub> YEBO
- ☐<sub>2</sub> CHA (Dlulela ku No. 7)

6.1. Yikuphi lokho?

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7. Yayikhona inkulumo noma ingxoxiswano nge-test emuva kokuthi yenziwe?

- ☐<sub>1</sub> YEBO
- ☐<sub>2</sub> CHA ((Uma uphendule wathi CHA ku no. 4 **kanye** no no.7, dlulela ku no. 12)

8. Uma usubala, ungathi kwathatha isikhathi/ imizuzu emingaki ukuze uchazelwe nge-test ngaphambi kokuthi uyenze, ngesikhathi uyenza kanye nangesikhathi usuyenzile?

\_\_\_\_\_ Imizuzu (amaminithi)

9. Kulolulwazi abakunika lona mayelana ne-test, bakuchazela kahle kangakanani ukuthi ukwenza i-test ukuzikhethela kwakho awuphoqiwe?

- ☐<sub>1</sub> Bangichazela ngokucacile kakhulu
- ☐<sub>2</sub> Bangichazela ngokucacile
- ☐<sub>3</sub> Bangichazela kancane
- ☐<sub>4</sub> Abangichazelanga kahle
- ☐<sub>5</sub> Abangichazelanga nhlobo

10. Wachazelwa kahle kangakanani ngemiphumela ye-test?

- ☐<sub>1</sub> Kahle kakhulu
- ☐<sub>2</sub> Kahle
- ☐ Bangichazela kancane
- ☐<sub>4</sub> Abangichazelanga kahle
- ☐<sub>5</sub> Abangichazelanga nhlobo

11. Ingxoxo yaba usizo kangakanani ekukuchazeleni ukuthi i-test ingawuthinta kanjani umndeni wakho?

- ☐<sub>1</sub> Yaba usizo kakhulu
- ☐<sub>2</sub> Yabo usizo olanele
- ☐<sub>3</sub> Ayingisizanga kakhulu
- ☐<sub>4</sub> Ayingisizanga nhlobo
- ☐<sub>5</sub> Ayibanga khona ingxoxo

- 11.1. Umuntu owayekuchazela nge-test wakutshela ukuthi i-sampula lakho lomzimba lingase lisetshenziselwe olunye ucwaningo noma cha?

- ☐<sub>1</sub> YEBO
- ☐<sub>2</sub> CHA
- ☐<sub>3</sub> Angisakhumbuli

12. Esikalini esisuka ku 0 siye ku 10 (la u 0 uchaze ukuthi awunaso nhlobo isiqiniseko, u 10 uchaze ukuthi unaso isiqiniseko esiphelele) unesiqiniseko esingakanani ukuthi imiphumelo yakho ye-test izogcinwa iyimfihlo?

Anginaso nhlobo isiqiniseko	Nginesiqiniseko esiphelele
<input type="checkbox"/> <sub>0</sub> <input type="checkbox"/> <sub>1</sub> <input type="checkbox"/> <sub>2</sub> <input type="checkbox"/> <sub>3</sub> <input type="checkbox"/> <sub>4</sub> <input type="checkbox"/> <sub>5</sub> <input type="checkbox"/> <sub>6</sub> <input type="checkbox"/> <sub>7</sub>	<input type="checkbox"/> <sub>8</sub> <input type="checkbox"/> <sub>9</sub> <input type="checkbox"/> <sub>10</sub>

## **Ingxenye 2- Imvume/ Isivumelwano**

1. Ngicela ungisize ngalesi simo esilandelayo. Akesithi ubukade uhlinziwe eminyakeni emibili edlule, udokotela wathatha isampula lezicubu zomuzimba wakho. Manje khona umcwaningi ofuna ukusebenzisa isampula lakho lezicubu zomziba kucwaningo oluthize.

Kumele umcwaningi athole imvume kuwena ukuze asebenzise izicubu zakho zomzimba ezisalile uma igama lakho lisahlangene nesampula?

- ☐<sub>1</sub> YEBO  
☐<sub>2</sub> CHA  
☐<sub>3</sub> Angazi

- 1.1.Uma igama lakho kanye neminingwane ebonakalisa wena isusiwe kwisampula lakho, kungamele umcwaningi athole imvume yakho ukuze asebenzise izicubu zakho zomuzimba?

- ☐<sub>1</sub> YEBO  
☐<sub>2</sub> CHA  
☐<sub>3</sub> Angazi

2. Manje ngicela ungisize ngesinye isimo. Ake sithi wawukade uyingxenye yolunye ucwaningo Lwesifo saShukela eminyakeni emibili idlule, kulelocwaningo umcwaningi wathatha isampula segazi lakho. Manje lowomcwaningi usefuna ukwenza olunye ucwaningo ngegazi lakho.

Kumele umcwaningi athole imvume kuwena ukuze asebenzise igazi lakho elisalile kolunye ucwaningo Lesifo saShukela uma igama lakho lisahlangene nesampula?

- $\Gamma_1$  YEBO  
 $\Gamma_2$  CHA  
 $\Gamma_3$  Angazi

- 2.1. Uma igama lakho kanye nemininingwane ebonakalisa wena isusiwe kwisampula lakho, kungamele umcwaningi athole imvume yakho ukuze asebenzise igazi lakho?

$\Gamma_1$  YEBO  
 $\Gamma_2$  CHA  
 $\Gamma_3$  Angazi

3. Ake sithi umcwaningi ufuna ukusebenzisa igazi lakho kucwaningo lwesinye isifo ekungasona esikaShukewla, njengoMdlavuza. Kungamele athole imvume yakho ukuze asebenzise igazi lakho uma igama lakho kanye nemininingwane ebonakalisa wena isahlangene nesampula?

$\Gamma_1$  YEBO  
 $\Gamma_2$  CHA (Dlulela ku No. 5)  
 $\Gamma_3$  Angazi (Dlulela ku No. 5)

- 3.1. Ake sithi umcwaninigi ufuna ukusebenzisa igazi lakho kucwaningo lwesinye isifo ekungasona esikashukela, njengoMdlavuza. Kungamele athola imvume yakho ukuze asebenzise igazi lakho uma igama lakho kanye nemininingwane ekubonakalisayo isusiwe kwisampula lakho?

$\Gamma_1$  YEBO  
 $\Gamma_2$  CHA  
 $\Gamma_3$  Angazi

***\*Imibuzo 4 kuya ku 9 iphathelele nalezi zimo ezingaphezulu zonke\****

4. Imvume yokusebenzisa amasampula akho kucwaningo lwangomuso kumele itholwe nini?

$\Gamma_1$  Uma amasampula eqoqwa/etholwa okokuqala  
 $\Gamma_2$  Njalo uma kuhlongozwa ucwaningo olusha  
 $\Gamma_3$  Okunye (SICELA UCACISE) \_\_\_\_\_  
 $\Gamma_4$  Angazi

5. Kumele kube umsebenzi wabani ukuthole imvume?

$\Gamma_1$  Umcwaningi noma abomutholampilo-okuyibona abaqoqe amasampula kuqala  
 $\Gamma_2$  Umcwaningi/abacwaningi abafuna ukusebenzisa isampula lakho kucwaningo olusha  
 $\Gamma_3$  Okunye (SICELA UCACISE) \_\_\_\_\_  
 $\Gamma_4$  Angazi

6. Abanye abacwaningi babona engathi kuncono ukuthi abantu banike imvume yabo (imvume lanoma yiluphi ucwaningo lwangomuso) kanye uma kuqoqwa amasampula ukuze kususe isidingo sokuthi abantu bathintwe uma kukhona ucwaningo olusha. Ngokubona kwakho, lemvume enikwa kanye yanoma yiluphi ucwaningo yanele na?

$\Gamma_1$  YEBO

$\Gamma_2$  CHA

$\Gamma_3$  Okunye (SICELA UCACISE)

$\Gamma_4$  Angazi

\_\_\_\_\_

7. Kumele abantu bekwazi ukubeka imigomo mayelana nokusetshenziswa kwamasampula abo?

$\Gamma_1$  YEBO

$\Gamma_2$  CHA

$\Gamma_3$  Okunye (SICELA UCACISE)

$\Gamma_4$  Angazi

\_\_\_\_\_

8. Ake sithi ngesikhathi umcwaningi enza ocwaningo olusha uthola okuthile ngawe okungase kuthinte isimo sakho sempilo

Ungathanda ukuthi umcwaningi ekuthinte ekutshele?

$\Gamma_1$  YEBO

$\Gamma_2$  CHA

$\Gamma_3$  Angazi

- 8.1. Ungathanda ukuthi atshele udokotela wakho?

$\Gamma_1$  YEBO

$\Gamma_2$  CHA

$\Gamma_3$  ANGAZI

### **Ingxenye 3- Okuyimfihlo**

1. Abanye abantu banokukhathazeka ngokugcineka kwemfihlo mayelana neminingwane ephathelene nabo. Ukugcineka kwemfihlo kwama-rekhodi okulapha kuyindawo enkulu ekhathaza abantu, kanye nokugcineka kuyimfihlo okomlando wezimali/wokukweleta nomlando wokuqashwa.

Kulezi zinhlobo ezintathu zemininingwane esengizichazile (ama-rekhodi okulapha, umlando wezimali/wokukweleta, umlando wokuqashwa), yikuphi ocabanga ukuthi kungasebenziseka

ngokungeyikho kalula?

- $\Gamma_1$  Ama-rekhodi okulapha
- $\Gamma_2$  Umlando wezimali/wokukweleta
- $\Gamma_3$  Umlando wokuqashwa
- $\Gamma_4$  Angazi

2. Yikuphi ocabanga ukuthi ngeke kwabalula ukusebenziseka ngokungeyikho?

- $\Gamma_1$  Ama-rekhodi okulapha
- $\Gamma_2$  Umlando wezimali/wokukweleta
- $\Gamma_3$  Umlando wokuqashwa
- $\Gamma_4$  Angazi

Manje ngisacela sigxile kwama-rekhodi okulapha kuphela

3. Esikalini esisuka ku 0 siye ku 10 (la u 0 uchaze ukuthi awunaso nhlobo isiqiniseko, u 10 uchaze ukuthi unaso isiqiniseko esiphelele) unesiqiniseko esingakanani sokuthi amarekhodi akho okulapha agcinwa eyimfihlo?

Anginaso nhlobo isiqiniseko

Nginesiqiniseko esiphelele

$\Gamma_0 \quad \Gamma_1 \quad \Gamma_2 \quad \Gamma_3 \quad \Gamma_4 \quad \Gamma_5 \quad \Gamma_6 \quad \Gamma_7 \quad \Gamma_8 \quad \Gamma_9 \quad \Gamma_{10}$

4. Ngokubona kwakho, ucabanga ukuthi ukusuka kwamarekhodi abhalwe ngesandla ephepheni kuyiwe kwamarekhodi agcinwe ekhompuyutheni kwandisa noma kunciphisa noma akuyishintshi ingozi yokuthi asebenziseke ngokungeyikho?

- $\Gamma_1$  Andisa ingozi
- $\Gamma_2$  Kunciphisa ingozi
- $\Gamma_3$  Akuyishintshi ingozi
- $\Gamma_4$  Angazi

5. Wake wabhekana nesimo lana umuntu wakhipha imininingwane yamarekhodi akho okulapha ngendlela obona engathi iphula okuyimfihlo kwakho?

- $\Gamma_1$  YEBO
- $\Gamma_2$  CHA (Dlulela ku No. 7)
- $\Gamma_3$  ANGAZI (Dlulela ku No. 7)

6. Sicela usichazele kabanzi ngaleso simo

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7. Wake wafuna ukuthola usizo lwenkinga ephathelene ngokomzimba noma inkinga ephathelene ngokwengqondo kodwa wasaba ukuthi imininingwane yalezo zinkinga angeke igcinwe iyimfihlo?

$\Gamma_1$  YEBO

$\Gamma_2$  CHA

8. Kukhona izinhlobo ezihlukene zemininingwane yokwelapha zomuntu. Imininingwane yokwelapha kungaba ulwazi lofuzo, imiphumela yokuhlola yase-laboratory, imibhalo emuva kokuvakashela udokotela, kanye nemininingwane ephathelene ngokwengqondo.

Kulokhu okune engikubalile (ulwazi lofuzo, imiphumela yokuhlola yase-laboratory, imibhalo emuva kokuvakashela udokotela, nemininingwane ephathelene ngokwengqondo) yikuphi okungakuphatha kabi kakhulu engase kungagcinwa ngokwemfihlo?

$\Gamma_1$  Ulwazi lofuzo

$\Gamma_2$  Imiphumela yokuhlola yase-laboratory

$\Gamma_3$  Imibhalo emuva kokuvakashela udokotela

$\Gamma_4$  Imininingwane ephathelene ngokwengqondo

$\Gamma_5$  Konke kubalulekile ngokulingana

$\Gamma_6$  Angazi

9. Yikuphi okungalandela?

$\Gamma_1$  Ulwazi lofuzo

$\Gamma_2$  Imiphumela yokuhlola yase-laboratory

$\Gamma_3$  Imibhalo emuva kokuvakashela udokotela

$\Gamma_4$  Imininingwane ephathelene ngokwengqondo

$\Gamma_5$  Angazi

#### **Ingxenye 4-Imininingwane yakho**

1. Unyaka wakho wokuzalwa?

2. Owesilisa      Owesifazane      (Dweba indingiliza kokukodwa, buza uma ungenaso isiqiniseko)

3. Uma ngabe uzibheka uzibona u...?



$\Gamma_1$  Umuntu Omunyama  
 $\Gamma_2$  i-Khalathi  
 $\Gamma_3$  i-Ndiya  
 $\Gamma_4$  Umuntu Omuhlophe  
 $\Gamma_5$  Okunye (SICELA UCACISE): \_\_\_\_\_

4. Ukhulwa kephi?

$\Gamma_1$  Inkolo yamaSulumane  
 $\Gamma_2$  Inkolo yobuKristu  
 $\Gamma_3$  Inkolo yamaKatolika  
 $\Gamma_4$  Inkolo yamaJuda  
 $\Gamma_5$  Inkolo yamaHindu  
 $\Gamma_6$  Inkolo yeSintu yeNdabuko  
 $\Gamma_7$  Okunye (Sicela ucacise) \_\_\_\_\_  
 $\Gamma_8$  Akukho

5. Uzibona uwumuntu okholwayo kakhulu, okhalwayo ngokwanele, okholwa kancane, noma ongakhulwi?

$\Gamma_1$  Okholwayo kakhulu  
 $\Gamma_2$  Okholwayo ngokwanele  
 $\Gamma_3$  Okholwayo kancane  
 $\Gamma_4$  Ongakhulwi

6. Wagcinaphi esikoleni?

$\Gamma_1$  Angifundile  
 $\Gamma_2$  Isikole sebanga eliphansi (Ibanga 1 kuya kwiBanga 7)  
 $\Gamma_3$  Isikole sebanga eliphezulu (Ibanga 8 kuya kwiBanga 12)  
 $\Gamma_4$  Isitifiketi Esiphakeme  
 $\Gamma_5$  iDiploma  
 $\Gamma_6$  iBachelor's Degree  
 $\Gamma_7$  iPost-Graduate qualification  
 $\Gamma_8$  Okunye (Sicela ucacise) \_\_\_\_\_

7. Ingabe njengamanje?:

$\Gamma_1$  Uqashwe isikhathi esigcwele

$\Gamma_2$  Uqashwe etohweni  
 $\Gamma_3$  Awuqashiwe  
 $\Gamma_4$  Usuthathe umhlalaphansi  
 $\Gamma_5$  Okunye (Sicela ucacise)\_\_\_\_\_

10. Cishe uholo malini emva kokuthathwa kwentela (umholo, imali yokusizwa, impesheni) ?

$\Gamma_1$  Angiholi/ Ayikho  
 $\Gamma_2$  R1 to R400  
 $\Gamma_3$  R401 to R800  
 $\Gamma_4$  R801 to R1600  
 $\Gamma_5$  R1601 to R3200  
 $\Gamma_6$  R3201 to R6400  
 $\Gamma_7$  R6401 to R12800  
 $\Gamma_8$  R12801 to R25600  
 $\Gamma_9$  Ngaphezu kuka 25601  
 $\Gamma_{10}$  Angithandi ukusho  
 $\Gamma_{11}$  Angazi

11. Ungasikala kanjani isimo sakho sempilo?

$\Gamma_1$  Sihle kakhulu khulu  
 $\Gamma_2$  Sihle kakhulu  
 $\Gamma_3$  Sihle  
 $\Gamma_4$  Sihle ngokwanele  
 $\Gamma_5$  Asisihle

10. Wake walaliswa esibhedlela:

10a. Onyakeni odlule?

$\Gamma_1$  YEBO  
 $\Gamma_2$  CHA

10b. Eminyakeni eyisihlanu edlule?

$\Gamma_1$  YEBO  
 $\Gamma_2$  CHA

## **Ingxenye 5- Isiphetho**

Ngoba sesifika esiphethweni, ngicela ukubuza lemibuzo ephathelene nokuthi bekunjani ukuphendula imibuzo yami.

1. Kukudalele ubunzima obungakanani ukuphendula lemibuzo?

- $\Gamma_1$  A Ubunzima obukhulu
- $\Gamma_2$  Ubunzima
- $\Gamma_3$  Ubunzima obuncane
- $\Gamma_4$  Bebungekho ubunzima

2. Ungathi bekuwusizo olungakanani kuwena ukuphendula lemibuzo?

- $\Gamma_1$  Bekuwusizo olukhulu
- $\Gamma_2$  Bekuwusizo ngokwanele
- $\Gamma_3$  Bekuwusizo kancane
- $\Gamma_4$  Bekungelona usizo

3. Khona okukukhathazile ngalemibuzo engikubuza yona?

- $\Gamma_1$  YEBO
- $\Gamma_2$  CHA

3a. Yikuphi lokho?

Iyona yonke imibuzo ebengithanda ukukubuza yona lena. Ngiyabonga kakhulu ngosizo lwakho, kanye nokuthatha isikhathi sakho ukuze uphendule imibuzo yami. Izimpendulo zakho zizosiza ucwaningo oluphathelele nokuqoqwa kanye nokugcinwa kwama-sampula omuzimba (isb.: igazi, umchamo) ukuze asetshenziswe kucwaningo olusekhathini esizayo.

Isikhathi esikuthathe ukuze uphendule imibuzo: \_\_\_\_\_

## Appendix K: Codebook

### Subject Identification

Full variable name	SPSS variable name	Coding instruction
Identification	ID	0 - 150
Hospital	Hosp	1= Edendale Hoapital; 2= Grey's Hospital;

### Part 1 Research/ Clinical Experience

Question number	Full variable name	SPSS variable name	Coding instruction
1.	Have you ever had tests done using HBM?	TestHBM	1= yes; 2=no
2.	How long ago HBM test run?	LastHBMT	1= less than six months ago; 2= between 6 months and a year; 3= between 1 year and 2 years ago; 4= more than 2 years go; 999= skipped
3.	Received explanation/discussion about HBM test prior?	DiscPrior	1= yes; 2= no; 3= don't know; 999= skipped
4.	Why did you decide to do HBM test?	WhyDecd	1= explanation convinced; 2= already decided; 3= don't know; 999= skipped
5.	Anything not discussed prior to HBM test?	NotDiscPr	1= yes; 2= no; 999= skipped

5.1.	What not discussed prior to HBM test?	AddInfoPri	1=reason for test; 2= living with X disease; 3=what they were going to do with results; 4=no clarity language barrier; 999= skipped
6.	Discussion post HBM test?	PostDisc	1= yes; 2= no; 999= skipped
7.	How clear stated HBM test option not requirement?	TestOpt	1= very clearly; 2= clearly; 3= not very clearly; 4= not clearly at all; 5= was not discussed at all; 999= skipped
8.	How well results of HBM test explained?	ResExpld	1= very well; 2= well; 3= not very well; 4= not well at all; 5= was not discussed at all; 999= skip
9.	Discussion of how HBM test might affect family helpful?	TestFam	1= very helpful; 2= moderately helpful; 3= not very helpful; 4= not helpful at all; 5= not covered; 999= skipped
9.1.	Possibility of future research with HBM discussed?	FutRes	1= yes; 2= no; 3= don't recall; 999= skipped
10.	Scale of certainty of	ConfdRes	0 – 10: 0= no

	confidentiality of HBM test results		certainty at all; 10= complete certainty
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## Part 2- Consent

Question number	Full variable name	SPSS variable name	Coding Instruction
1.	Consent for residual identifiable clinical sample necessary?	ClinID	1= yes; 2= no; 3= don't know
1.1.	Consent for residual unidentifiable clinical sample necessary?	ClinUD	1= yes; 2= no; 3= don't know
2.	Consent for residual identifiable research sample necessary?	RschID	1= yes; 2= no; 3= don't know
2.1.	Consent for residual unidentifiable research sample necessary?	RschUD	1= yes; 2= no; 3= don't know
3.	Consent for different disease research on residual identifiable sample necessary?	RschDiffID	1= yes; 2= no; 3= don't know
3.1.	Consent for different disease research on residual identifiable sample necessary?	RschDiffUD	1= yes; 2= no; 3= don't know
4.	When to obtain consent for future research?	WhenCons	1= when samples are initially collected; 2= each time a new study is proposed; qualitative responses; 4= don't know
5.	Who should obtain consent?	WhoCons	1= the researcher or clinician for who

			samples collected for; 2= the researcher who intends to use your samples for proposed research; 3= Doctor or nurse; 4= don't know 5=LAB
6.	Is onetime general consent sufficient?	OTGenCons	1= yes; 2= no; other qualitative responses 4= don't know
7.	Should individuals be able to provide limits to use of samples	Limits	1= yes; 2= no; other qualitative responses 4= don't know
8.	Desirability of clinically significant results	ClinSigRes	1= yes; 2= no; 3= don't know
8.1.	Desirability to inform doctor of clinically significant results	ClinSigResDR	1= yes; 2= no; 3= don't know

### Part 3- Confidentiality

<b>Question number</b>	<b>Full variable name</b>	<b>SPSS variable name</b>	<b>Coding instruction</b>
1.	Confidential information most likely to be misused	InfMLMis	1= medical information; 2= credit history information; 3= employment history information; 4= don't know

2.	Confidential information least likely to be misused	InfLLMis	1= medical information; 2= credit history information; 3= employment history information; 4= don't know
3.	Scale of certainty of medical records being kept confidential	ConfMR	0 – 10: 0= no certainty at all; 10= complete certainty
4.	Risk of moving from paper to computerized records change	MRPprCom	1= increases the risk; 2= decreases the risk; 3= does not change the risk; 4= don't know
5.	Has confidentiality of your medical record ever been violated	ConfViol	1= yes; 2= no; 3= don't know
6.	Circumstances confidentiality medical record violated	CircmViol	1= assurance not given; 2= nurses disclosed; 3= dr disclosed pregnancy to parents; 4= space was not private 999= skip
7.	Avoided seeking psychical or mental help out of concerns of confidentiality	FearConf	1= yes; 2= no
8.	Medical information most sensitive	InfoSens	1= genetic information; 2= lab test information; 3= doctors notes from visits; 4= mental



			health information; 5= all are equally important; 6= don't know
9.	Medical information second most sensitive	Info2Sens	1= genetic information; 2= lab test information; 3= doctors notes from visits; 4= mental health information; 5= don't know

#### Part – Sociodemographic Information

<b>Question number</b>	<b>Full variable name</b>	<b>SPSS variable name</b>	<b>Coding instruction</b>
1.	Age	Age	Numerical age grouping
2.	Sex	Sex	1= male; 2= female
3.	Race	Race	1= African/Black; 2= Coloured; 3= Indian/Asian; 4= White; 5= other
4.	Religion	Religion	1= Muslim; 2= Christian; 3= Catholic; 4= Jewish; 5= Hindu; 6= African Traditional Belief; 7= Apostolic Church; 8= None
5.	How religious	Religious	1= very religious; 2=

			moderately religious; 3= not very religious; 4= not religious at all
6.	Level of Education	Education	1= No schooling; 2= Primary School (grade 1 to grade 7); 3= High School (Grade 8 to grade 12); 4= Higher Certificate; 5= Diploma; 6= Bachelor's Degree; 7= Post-Graduate qualification; 8= other
7.	Current employment	Employment	1= employed full time; 2= employed part time; 3= not employed; 4= retired; 5= student; 6= self employed
8.	Income before taxes	Income	1= None; 2= R1 to R400; 3= R401 to R800; 4= R801 to R1600; 5= R1601 to R3200; 6= R3201 to R6400; 7= R6401 to R12800; 8= R12801 to R25600; 9= Over 25600; 10=Refused; 11- don't know

9.	Rate personal health	Health	1= excellent; 2= very good; 3= good; 4= fair; 5= poor
10.1.	Hospitalisation in past year	Hospital1	1= yes; 2= no
10.2.	Hospitalisation past 5 years	Hospital5	1= yes; 2= no

#### Part 5= Conclusion

<b>Question Number</b>	<b>Full variable name</b>	<b>SPSS name</b>	<b>Coding instruction</b>
1.	Stressed caused by survey	Stress	1= a great deal of stress; 2= some stress; 3= a little stress; 4= no stress at all
2.	How helpful was survey	Helpful	1= very helpful; 2= moderately helpful; 3= a little helpful; 4= not helpful at all
3.	Anything that bothered you about survey	Bother	1= yes; 2= no
3.1.	What bothered you	WhatBother	1= salary question; 2= everything; 3= did not understand the point; 4= personal questions; 999= skipped

## 11. Tables

*Table 2. Frequency table of participants' clinical experience*

Question	Overall frequency (N=200)	Percentage (%)
<b>Have you ever had test done using your HBM</b>		
Yes	173	86.5
No	27	13.5
<b>How long ago were these HBM test run?</b>		
less than six months ago	57	28.5
between 6 months and a year	46	23.0
between 1 year and 2 years	43	21.5
more than 2 years ago	26	13.0
Missing (user defined)	28	14.0
<b>Received explanation/discussion about HBM test prior</b>		
Yes	151	75.5
No	14	7.0
Don't know	7	3.5
Missing (user defined)	28	14.0
<b>Why did you decide to do HBM test</b>		
Explanation convinced	85	42.5
Already decided	63	31.5
Don't know	16	8.0
Missing (user defined)	36	18.0
<b>Anything not discussed prior to HBM test</b>		
Yes	24	12.0
No	140	70.0
Missing (user defined)	36	18.0
<b>What not discussed prior to HBM test</b>		
reason for test	12	6.0
living with X illness/disease	8	4.0
what they were going to do with results	1	0.5
no clarity- language barrier	1	0.5
Missing (user defined)	178	89.0
<b>Discussion post HBM test</b>		
Yes	131	65.5
No	41	20.5
Missing (user defined)	28	14.0
<b>How well results of HBM test explained</b>		
very well	86	43.0
well	60	30.0
not very well	12	6.0
not well at all	3	1.5
Missing (user defined)	39	19.5
<b>How clearly stated HBM test is an option</b>		
very clear	81	40.5
clearly	52	26.0
not very clearly	16	8.0
not clearly at all	6	3.0
was not discussed at all	6	3.0
Missing (user defined)	39	19.5
<b>Discussion of how HBM test might affect family</b>		
very well	76	38.0
well	64	32.0
not very well	12	6.0
not well at all	5	2.5

was not discussed at all	4	2.0
Missing (user defined)	39	19.5
<b>Possibility of future research with HBM discussed</b>		
Yes	25	12.5
No	95	47.5
Don't recall	42	21.0
Missing (user defined)	38	19.0

*Table 3. Frequency table of consent for research on stored human biological samples*

Question	Overall frequency (N=200)	Percentage (%)
<b>Consent for residual identifiable clinical samples</b>		
Yes	141	70.5
No	41	20.5
Don't know	18	9.0
<b>Consent for residual unidentifiable clinical samples</b>		
Yes	75	37.5
No	107	53.5
Don't know	18	9.0
<b>Consent for residual identifiable research samples</b>		
Yes	126	63.0
No	55	27.5
Don't know	19	9.5
<b>Consent for residual unidentifiable research samples</b>		
Yes	75	37.5
No	103	51.5
Don't know	22	11.0
<b>Consent for different disease research identifiable sample</b>		
Yes	140	70.0
No	44	22.0
Don't know	16	8.0
<b>Consent for different disease research unidentifiable sample</b>		
Yes	69	34.5
No	109	54.5
Don't know	22	11.0
<b>When to obtain consent for future research</b>		
When samples initially collected	111	55.5
Each time a new study is proposed	50	25.0
Other	9	4.5
Don't know	30	15.0
<b>Who should obtain consent</b>		
Researcher/clinician samples initially collected for	90	45.0
Researcher who intends to use samples	43	21.5
Doctor or nurse	17	8.5
Don't know	49	24.5
Lab	1	0.5
<b>Is one time general consent enough</b>		
Yes	106	53.0
No	56	28.0
Other	3	1.5
Don't know	35	17.5
<b>Should individuals be able to provide limits to the use of their samples</b>		
Yes	100	50.0

No	57	28.5
Other	6	3.0
Don't know	37	18.5

**Table 4. Frequency table of desirability of clinically significant results**

Question	Overall frequency (N=200)	Percentage (%)
<b>Desirability of clinically significant results</b>		
Yes	176	88.0
No	16	8.0
Don't know	8	4.0
<b>Desirability to inform doctor of clinically significant results</b>		
Yes	152	76.0
No	13	6.5
Don't know	35	17.5

**Table 5. Frequency table of confidentiality**

Question	Overall frequency (N=200)	Percentage (%)
<b>Confidential information most likely to be misused</b>		
medical information	110	55.0
credit history information	15	7.5
employment history information	22	11.0
don't know	53	26.5
<b>Confidential information least likely to be misused</b>		
medical information	29	14.5
credit history information	28	14.0
employment history information	74	37.0
don't know	69	34.5
<b>Risk of moving from paper to computerized records change</b>		
increases the risk	30	15.0
decreases the risk	88	44.0
does not change the risk	53	26.5
don't know	29	14.5
<b>Has confidentiality of your medical records ever been violated</b>		
Yes	17	8.5
No	160	80.0
Don't know	23	11.5
<b>Avoided seeking physical or mental help out of concerns of confidentiality</b>		
Yes	43	21.5
No	157	78.5
<b>Medical info most sensitive</b>		
genetic information	21	10.5
lab test information	43	21.5
doctors notes from visits	44	22.0
mental health information	8	4.0
all are equally important	63	31.5
don't know	21	10.5

## 11. Figures

**Figure 1- Consent for residual identifiable clinical samples \* current employment**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	21.440 <sup>a</sup>	10	.018
Likelihood Ratio	<b>24.886</b>	<b>10</b>	<b>.006</b>
Linear-by-Linear Association	.338	1	.561
N of Valid Cases	200		

a. 8 cells (44,4%) have expected count less than 5. The minimum expected count is ,18.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal		
Phi	.327	.018
Cramer's V	<b>.232</b>	<b>.018</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 2- Consent for residual identifiable clinical samples \* income before taxes**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	36.406 <sup>a</sup>	20	.014
Likelihood Ratio	<b>33.957</b>	<b>20</b>	<b>.026</b>
Linear-by-Linear Association	.708	1	.400
N of Valid Cases	200		

a. 21 cells (63,6%) have expected count less than 5.  
The minimum expected count is ,09.

	Value	Approximate Significance
Nominal by Nominal	Phi	.427
	Cramer's V	<b>.302</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**(b) Symmetric Measures**

**Figure 3 - Consent for residual identifiable clinical sample \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	<b>10.433<sup>a</sup></b>	<b>2</b>	<b>.005</b>
Likelihood Ratio	11.902	2	.003
Linear-by-Linear Association	4.976	1	.026
N of Valid Cases	200		

a. 0 cells (,0%) have expected count less than 5. The minimum expected count is 8,46.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal	Phi	.228
	<b>Cramer's V</b>	<b>.228</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.



**Figure 4 - Consent for residual unidentifiable clinical samples\* current employment**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	17.181 <sup>a</sup>	10	.070
Likelihood Ratio	<b>20.058</b>	<b>10</b>	<b>.029</b>
Linear-by-Linear Association	.195	1	.658
N of Valid Cases	200		

a. 9 cells (50,0%) have expected count less than 5.

The minimum expected count is ,18.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal Phi	.293	.070
Cramer's V	<b>.207</b>	<b>.070</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 5 - Consent for residual unidentifiable clinical samples \* income before taxes**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	29.923 <sup>a</sup>	20	.071
Likelihood Ratio	<b>34.102</b>	<b>20</b>	<b>.025</b>
Linear-by-Linear Association	.689	1	.407
N of Valid Cases	200		

a. 19 cells (57,6%) have expected count less than 5.

The minimum expected count is ,09.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal Phi	.387	.071
Cramer's V	<b>.274</b>	<b>.071</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 6 - Consent for residual unidentifiable clinical samples \* how long ago HBM test run**

(a) Chi-Square Tests				(b) Symmetric Measures		
	Value	df	Asymp. Sig.		Value	Approx. Sig.
Pearson Chi-Square	13.665 <sup>a</sup>	6				
Likelihood Ratio	<b>13.970</b>	<b>6</b>		Nominal by Nominal	Phi	.282
Linear-by-Linear	3.965	1			Cramer's V	<b>.034</b>
Association				N of Valid Cases	172	
N of Valid Cases	172					

a. Not assuming the null hypothesis.

a. 4 cells (33,3%) have expected count less than 5. The minimum expected count is 2,27.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 7- Consent for residual unidentifiable clinical sample \* Discussion post HBM test**

(a) Chi-Square Tests				(b) Symmetric Measures		
	Value	df	Asymp. Sig. (2-sided)		Value	Approx. Sig.
Pearson Chi-Square	6.053 <sup>a</sup>	2	.048			
<b>Likelihood Ratio</b>	<b>6.245</b>	<b>2</b>	<b>.044</b>	Nominal by Nominal	Phi	.188
Linear-by-Linear	1.140	1	.286		<b>Cramer's V</b>	<b>.048</b>
Association				N of Valid Cases	172	
N of Valid Cases	172					

a. 1 cells (16,7%) have expected count less than 5. The minimum expected count is 3,58.

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 8- Consent for residual identifiable research sample \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	<b>7.943<sup>a</sup></b>	<b>2</b>	<b>.019</b>
Likelihood Ratio	8.336	2	.015
Linear-by-Linear Association	.627	1	.429
N of Valid Cases	200		

a. 0 cells (.0%) have expected count less than 5.  
The minimum expected count is 8,93.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal <b>Phi</b> <b>Cramer's V</b>	.199 <b>.199</b>	.019 <b>.019</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 9- Consent for residual unidentifiable research sample\* hospital**

**(a) Chi-Square Test**

	Value	df	Asymp. Sig. (2-sided)
<b>Pearson Chi-Square</b>	<b>6.425<sup>a</sup></b>	<b>2</b>	<b>.040</b>
Likelihood Ratio	6.772	2	.034
Linear-by-Linear Association	1.248	1	.264
N of Valid Cases	200		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 10,34.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal <b>Phi</b> <b>Cramer's V</b>	.179 <b>.179</b>	.040 <b>.040</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 10- Consent for residual unidentifiable research samples \* Discussion post HBM test**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	7.541 <sup>a</sup>	2	.023
Likelihood Ratio	<b>7.868</b>	<b>2</b>	<b>.020</b>
Linear-by-Linear Association	.479	1	.489
N of Valid Cases	172		

a. 1 cells (16,7%) have expected count less than  
5. The minimum expected count is 4,53.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal Phi	.209	.023
<b>Cramer's V</b>	<b>.209</b>	<b>.023</b>
N of Valid Cases	172	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 11- Consent for research studying a disease other than what the sample was initially collected for using unidentifiable human biological samples\* personal health**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	15.960 <sup>a</sup>	8	.043
Likelihood Ratio	<b>15.693</b>	<b>8</b>	<b>.047</b>
Linear-by-Linear Association	5.029	1	.025
N of Valid Cases	200		

a. 2 cells (13,3%) have expected count less than  
5. The minimum expected count is 2,09.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal Phi	.282	.043
<b>Cramer's V</b>	<b>.200</b>	<b>.043</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 12- Consent for research studying a disease other than what the sample was initially collected for using unidentifiable human biological samples \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	<b>11.751<sup>a</sup></b>	<b>2</b>	<b>.003</b>
Likelihood Ratio	13.046	2	.001
Linear-by-Linear Association	8.326	1	.004
N of Valid Cases	200		

a. 0 cells (.0%) have expected count less than 5.  
The minimum expected count is 10,34.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal	Phi	.242
	<b>Cramer's V</b>	<b>.242</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 13- Consent for research studying a disease other than what the sample was initially collected for using unidentifiable human biological samples \* How long ago last HBM test**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	13.901 <sup>a</sup>	6	.031
Likelihood Ratio	<b>13.712</b>	<b>6</b>	<b>.033</b>
Linear-by-Linear Association	2.654	1	.103
N of Valid Cases	172		

a. 2 cells (16,7%) have expected count less than 5. The minimum expected count is 2,87.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal	Phi	.284
	<b>Cramer's V</b>	<b>.201</b>
N of Valid Cases	172	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 14- When should consent be obtained \* personal health**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	34.526 <sup>a</sup>	12	.001
Likelihood Ratio	<b>34.418</b>	<b>12</b>	<b>.001</b>
Linear-by-Linear Association	1.238	1	.266
N of Valid Cases	200		

a. 8 cells (40,0%) have expected count less than  
5. The minimum expected count is ,86.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal	Phi	.415
	Cramer's V	<b>.240</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 15- When should consent be obtained \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.527 <sup>a</sup>	3	.002
Likelihood Ratio	<b>15.113</b>	<b>3</b>	<b>.002</b>
Linear-by-Linear Association	13.799	1	.000
N of Valid Cases	200		

a. 2 cells (25,0%) have expected count less than  
5. The minimum expected count is 4,23.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal	Phi	.270
	Cramer's V	<b>.270</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 16- Should individuals be able to provide limits to the use of their samples \*  
religious**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	31.046 <sup>a</sup>	21	.073
Likelihood Ratio	<b>35.254</b>	<b>21</b>	<b>.026</b>
Linear-by-Linear Association	10.427	1	.001
N of Valid Cases	200		

a. 21 cells (65,6%) have expected count less than  
5. The minimum expected count is ,06.

**(b) Symmetric Measures**

	Value	Approximat e Significance
Nominal by Nominal	Phi Cramer's V	.394 <b>.073</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null  
hypothesis.

**Figure 17- Should individuals be able to provide limits to the use of their samples \*  
How religious**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	29.741 <sup>a</sup>	9	.000
Likelihood Ratio	<b>28.978</b>	<b>9</b>	<b>.001</b>
Linear-by-Linear Association	11.043	1	.001
N of Valid Cases	200		

a. 4 cells (25,0%) have expected count less than 5. The  
minimum expected count is ,90.

**(b) Symmetric Measures**

	Value	Approximat e Significance
Nominal by Nominal	Phi Cramer's V	.386 <b>.000</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null  
hypothesis.

**Figure 18- Desirability of clinically significant results \* discussion post HBM test**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.497 <sup>a</sup>	2	.106
<b>Likelihood Ratio</b>	<b>7.502</b>	<b>2</b>	<b>.023</b>
Linear-by-Linear Association	2.219	1	.136
N of Valid Cases	172		

a. 3 cells (50,0%) have expected count less than 5. The minimum expected count is 1,19.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal <b>Phi</b> <b>Cramer's V</b>	.162 <b>.162</b>	.106 <b>.106</b>
N of Valid Cases	172	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 19- Desirability to inform doctor of clinically significant results \* sex**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	7.408 <sup>a</sup>	2	.025
<b>Likelihood Ratio</b>	<b>7.167</b>	<b>2</b>	<b>.028</b>
Linear-by-Linear Association	2.474	1	.116
N of Valid Cases	200		

a. 1 cells (16,7%) have expected count less than 5. The minimum expected count is 4,81.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal <b>Phi</b> <b>Cramer's V</b>	.192 <b>.192</b>	.025 <b>.025</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.



**Figure 20- Desirability to inform doctor of clinically significant results \* level of education**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	24.516 <sup>a</sup>	12	.017
Likelihood Ratio	<b>21.371</b>	<b>12</b>	<b>.045</b>
Linear-by-Linear Association	4.562	1	.033
N of Valid Cases	200		

a. 12 cells (57,1%) have expected count less than 5. The minimum expected count is ,33.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal	Phi	.350
	Cramer's V	<b>.248</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 21- Desirability to inform doctor of clinically significant results \* rate personal health**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	18.101 <sup>a</sup>	8	.020
Likelihood Ratio	<b>21.090</b>	<b>8</b>	<b>.007</b>
Linear-by-Linear Association	.009	1	.924
N of Valid Cases	200		

a. 7 cells (46,7%) have expected count less than 5. The minimum expected count is 1,24.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal	Phi	.301
	Cramer's V	<b>.213</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.  
b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 22- Desirability to inform doctor of clinically significant results \* have you ever had tests run using your human biological samples**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	7.209 <sup>a</sup>	2	.027
Likelihood Ratio	<b>6.421</b>	<b>2</b>	<b>.040</b>
Linear-by-Linear Association	6.895	1	.009
N of Valid Cases	200		

a. 2 cells (33,3%) have expected count less than  
5. The minimum expected count is 1,76.

**(b) Symmetric Measures**

	Value	Approx. Sig.
Nominal by Nominal	Phi	.190
	<b>Cramer's V</b>	<b>.190</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 23- Confidential information most likely to be misused \* religion**

**(a) Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)
Pearson Chi-Square	30.680 <sup>a</sup>	21	.079
Likelihood Ratio	<b>33.912</b>	<b>21</b>	<b>.037</b>
Linear-by-Linear Association	6.053	1	.014
N of Valid Cases	200		

a. 21 cells (65,6%) have expected count less than  
5. The minimum expected count is ,15.

**(b) Symmetric Measures**

	Value	Approximate Significance
Nominal by Nominal	Phi	.392
	<b>Cramer's V</b>	<b>.226</b>
N of Valid Cases	200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 24- Confidential information most likely to be misused \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	<b>22.966<sup>a</sup></b>	<b>3</b>	<b>.000</b>
Likelihood Ratio	23.763	3	.000
Linear-by-Linear Association	22.035	1	.000
N of Valid Cases	200		

a. 0 cells (.0%) have expected count less than 5.

The minimum expected count is 7,05.

**(b) Symmetric Measures**

		Value	Approx. Sig.
Nominal by Nominal	Phi	.339	.000
	<b>Cramer's V</b>	<b>.339</b>	<b>.000</b>
N of Valid Cases		200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

**Figure 25- Confidential information least likely to be misused \* hospital**

**(a) Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	<b>9.386<sup>a</sup></b>	<b>3</b>	<b>.025</b>
Likelihood Ratio	9.471	3	.024
Linear-by-Linear Association	3.196	1	.074
N of Valid Cases	200		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 13,16.

**(b) Symmetric Measures**

		Value	Approx. Sig.
Nominal by Nominal	Phi	.217	.025
	<b>Cramer's V</b>	<b>.217</b>	<b>.025</b>
N of Valid Cases		200	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

