An evaluation of the ethical concerns of a Social Science Research Ethics Committee using the principles and benchmarks proposed by Emanuel et al. (2004)

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by

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DECLARATION

I, Sibusisiwe Bengu, declare that:

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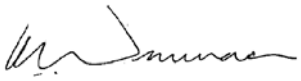

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ABSTRACT

Since the exposure of human rights abuses in research, there has over the years been extensive progress made in development of international ethical guidelines for conduct of ethical research and for protecting research participants.

Broadly, this research aimed at identifying the ethical issues that an REC considers important when reviewing protocols. The research also intended to bring about an understanding of whether the Emanuel et al. framework captures all the issues that an REC raises when reviewing protocols. More specifically, the study aim was to identify the main ethical issues raised during ethics review of research proposals and to assess their relative weight using Emanuel et al.'s (2004) recommended principles of ethics review of clinical research.

The study used content analysis of records of minutes of a social science research ethics committee (hereafter referred to as InstX) REC for the period of 2012 to 2013. In the sample of ten minutes, a total of 64 applications were reviewed by the InstX REC. The frequency of the principles used by the REC in reviewing protocols was identified.

The four most frequently raised concerns ranked in descending order: were informed consent, scientific validity, fair participant selection and respect for participants. Other ethical issues raised by the REC when reviewing protocols were social value, favourable risk-benefit ratio, independent review and collaborative partnership. A few issues considered not part of the Emanuel et al. framework, such as mistakes and missing information, were also identified.

Thus the Emanuel et al. (2014) framework is relevant to social science research, even though it was initially developed for clinical research.

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CHAPTER 1
INTRODUCTION AND BACKGROUND

1.1 Introduction

The importance of research in the development of interventions and improvement of quality of life cannot be underestimated. However, since the revelations of abuse of research participants in research during the 1940s and 1950s, and the public outcry for measures to protect human participants, there has been much attention given to ethics in research (Joffe, 2012). In particular, a great deal of attention has been given to the development of international guidelines for the protection of participants (Joffe, 2012).

One of the important mechanisms for protecting participants emerging from the guidelines is the establishment of research ethics committees (RECs), also known in the USA as institutional review boards (IRBs), that should review protocols before implementation of research (Joffe, 2012). As such, there has been a proliferation of RECs worldwide with developing countries lagging behind. Efforts have been made in the last decade aimed at creating or increasing capacity of ethical review in developing countries (Igoumenidis & Zyga, 2011). This is particularly important as there has been a phenomenal increase in research conducted in developing countries, in particular biomedical research (Nuffield Council on Bioethics, 2014).

It is important therefore to understand how these RECs in developing countries are reviewing protocols and the ethical concerns that emerge from their reviews. This will give a sense of the relevance of international ethics guidelines in enhancing the quality of research being implemented in the developing countries and will also identify areas for concern.

1.2 Background

Many international and national bodies require that all biomedical research studies involving human subjects must be reviewed by an independent REC (World Medical Association (WMA), 2013). RECs serve an important public function of oversight of research and as a public forum for the accountability of researchers (Ashcroft & Pfeffer, 2001).

Over the years, there has been an increase in biomedical and social research activities throughout the world, with particular emphasis on developing countries where the disease burden has been on the increase (Benatar & Fleischer, 2007; Tekola, Bull, Farsides, Newport, Adeyemo, Rotimi & Davey, 2009). There have been reports and concerns of incidents of unethical research and scientific misconduct in some of the research being conducted (Igoumenidis & Zyga, 2019). This has led to increased efforts towards the establishment of RECs in many institutions in the developing world. These efforts help to ensure that researchers adhere to the highest ethical standards with the ultimate goal of protecting research participants (WHO, 2009).

RECs rely on international and national guidelines to direct their review of research protocols (Zielinski, Kebede, Mbondji, Sanou, Kouvividila & Lusamba-Dikassa, 2014). All existing international guidelines strive to maximise protection of research participants and communities from potential harm and exploitation by researchers (Zielinski et al., 2014). In order to help RECs in their work, Emanuel and colleagues (2004) analysed existing ethical codes and produced a framework of eight principles and associated benchmarks to guide the review of research proposals.

However, there is little empirical research into the actual issues that RECs raise when reviewing research proposals. Recent papers present findings on three South African biomedical RECs, but there is no other data with which to compare such findings (Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2004). A closer and systematic examination of the ethical issues raised by a social science REC may shed more comparative light on this and reveal areas of concern raised during the review of study protocols which ultimately leads the REC to arrive at a particular decision. Using a qualitative approach, the minutes of REC meetings were analysed to evaluate their decision-making processes, according to the Emanuel, Wendler, Killen and Grady (2004) framework. This approach will thus also consider the applicability of the framework in an African context. This study forms part of a multinational study taking place in Ghana, Malawi, Nigeria and Zimbabwe.

CHAPTER 2
LITERATURE REVIEW

2.1 History of abuse of human research participants

There are numerous recorded incidents of human rights abuses in research and these include the Japanese and Nazi medical experiments. The Japanese experiments were carried out on prisoners of war, in which it is estimated that more than 3 000 people died (Goodwin, 2016). The Nazi experiments conducted on Jewish and other people were so horrendous that their exposure led to the international post-war trials generally referred to as the Nuremberg Trials. The threat of human rights abuse in research is still present as reports of abuse in research continue, especially in developing countries, but also in other parts of the world (Goodwin, 2016). Reported incidences of exploitation show that vulnerable groups are more at risk of harm than other sectors of the population (Goodwin, 2016).

2.2 International ethics guidelines

There are many international agreements and guidelines that have been developed in order to improve the treatment of research participants. This section will discuss some of the important contributions made by these guidelines.

The Nuremberg Code (1948) provided the first ethical standards for health research with research participants. It emphasises consent by research participants that is essential for all health research with human subjects. This underpins all measures that should be taken to limit harm to research participants.

The Declaration of Helsinki, signed in 1964 by the World Medical Association (WMA) and its later amendments, established ethical principles for medical research involving research participants. (WMA, 2013). It specifies that respect and protection of research participants should be considered in all research projects. The Helsinki Declaration also gives attention to risks and benefits of research, and protection of vulnerable groups. These ethical issues will be discussed in detail in the relevant sections of the literature review. Considerable attention was given by the Declaration of Helsinki to the importance of informed consent. It contends that participation in research must be voluntary, and prospective participants must

be adequately informed about all aspects of the research. Only when they have understood, should the researcher proceed to seek consent (WMA, 2013).

In 1979, the Belmont Report was published in the USA and this further outlines the ethical principles for protecting human subjects. The Belmont Report presents three universal principles for the protection of research participants:

- *Respect* for persons - this is based on the recognition that people/individuals are capable of making their own decisions. It also points out that not every human being is capable of 'self-determination' due to mental disability and people with restricted liberty. These groups need extra protection during research (Belmont, 1979).
- *Beneficence* - this is based on the ethical obligation to act without harming people during research. This can be achieved in research by minimising risks and maximising benefits to research participants (WMA, 2013).
- *Justice* is an ethical obligation to equitable distribution of benefits and burdens in research (Council for International Organisations of Medical Sciences (CIOMS), 2016). Justice is closely linked to the selection of research participants and it is important to ensure that selection is based on the research problem and not 'merely' on the availability of potential participants (WMA, 2013). Justice also relates to the benefits of research such as access to medical treatment (WMA, 2013).

These three principles are considered universal as they cover most of the ethical issues that arise during research and can be applied in any social context.

The increase of biomedical research and multinational studies spurred debate on the effectiveness of existing guidelines (CIOMS, 2016; Nuffield Council on Bioethics, 2014). These debates resulted in the revisions of the research ethics guidelines such as the Helsinki Declaration and the development of new guidelines with a specific focus on conducting research in developing countries. These guidelines include those of the Council of International Organisations of Medical Sciences (CIOMS) and the Nuffield Council on Bioethics.

The CIOMS, together with the World Health Organisation (WHO) report published in 1993 (revised in 2002), compiled a report to guide the development of national research ethics policies in developing countries (CIOMS, 2016). The CIOMS guidelines are comprehensive, covering various ethical issues in conducting research and different types of research, and give considerable attention to treatment of vulnerable groups during research. They also consider the role of RECs.

The Nuffield Council Report on Bioethics published in 2014 provides guidelines for externally sponsored research conducted in developing countries. The Nuffield Report addresses ethical issues related to unequal resources in terms of funding between developed and host (developing) nations, and identifies risks of exploitation. It recommends collaboration between the parties and the development of local expertise in the provision of health care in addressing some of these challenges (Nuffield Council on Bioethics, 2014). The Report recommends the establishment of an effective and independent system for the review of protocols (Nuffield Council on Bioethics, 2014). The Nuffield Report makes an important contribution to the ethics debate on the issues of standard of care and post-research support.

2.3 Emanuel et al. framework

In 2004, Emanuel, Wendler, Killen and Grady (2004) developed a framework for ethical conduct of health research in developing countries. The framework was developed in response to problems experienced with the application of existing ethical guidelines in terms of different interpretations, as well as the fact that they were not initially intended for application in developing countries. These contradictions presented difficulties for RECs in terms of applying these ethical standards.

The framework presents eight principles for application to all types of research, namely, collaborative partnership, social value, scientific validity, fair subject selection, favourable risk-benefit ratio, independent review, informed consent, and respect for recruited participants and study communities. The present study used the Emanuel et al. guidelines and the key principles are summarised below:

- Collaborative partnership: A collaborative partnership should be developed with local researchers and communities as this tends to enhance the researcher's awareness of particular community problems and facilitates their incorporation into the research (Emanuel et al., 2004). The involvement of the local community in all stages of the research should include the sharing of responsibility. The collaboration should work towards influencing policy making and allocation of resources. This value places emphasis on fair distribution of benefits and rewards from the research (Emanuel et al., 2004).

- Social value: The value of the research must be clearly explained in the proposal. This helps to ensure that the benefits of the study do not accrue to one particular group of people over those who took risks and participated in the research (Emanuel et al., 2004). One of the important aspects to social value is dissemination of research results to relevant stakeholders, which should include the local community and policy makers. In doing this, the language and format of the report should be appropriate to particular stakeholders (Emanuel et al., 2004). It is thus important to specify the beneficiaries of the research and the prospective value of the research to the participants (Emanuel et al., 2004).
- Scientific validity: All research on humans must generate results that are reliable, valid and can be interpreted and used by a specific group of people. Research that is not scientific is considered to be unethical as it exposes participants to risks with no benefits (Emanuel et al., 2004). It is important that the research is designed in such a manner that it responds to the research needs of the host community, whilst ensuring that the scientific objectives are met (Emanuel et al., 2004).
- Fair subject selection: There are three principles that should be considered in fair selection of subjects, namely: 1) use scientific reasons for selecting a particular group to ensure the scientific validity of the research; 2) select the target population to minimise risks; and 3) identify and protect vulnerable populations (Emanuel et al., 2004).
- Favourable risk-benefit ratio: The researcher should identify potential risks and benefits. On balance, the study should be beneficial to each participant and to the community that is targeted by the research (Emanuel et al., 2004). The social value for the study should justify the risks to participants.
- Independent review: Independent ethics review is important for all clinical research to enhance the public accountability of the researcher and minimise conflict of interest (Emanuel et al., 2004). Independent and transparent process of protocol review assures the community that the research is likely to be ethical. Reviews should be conducted by an independent and competent committee (Emanuel et al., 2004).
- Informed consent: There are five principles for assessing informed consent, namely: 1) involvement of the host community in identifying appropriate recruitment strategies and incentives for participants; 2) disclosure of information about the research must be culturally sensitive; 3) consent procedures should be utilised that are acceptable to the local community whilst ensuring voluntary consent by those individuals who participate in the research; 4) different levels of consent should be considered whilst not overlooking the importance of individual consent; and 5) prospective participants

should have the freedom to refuse to participate or to withdraw from the study (Emanuel et al., 2004).

- Respect for recruited participants and study communities: The REC must ensure that researchers understand that they have an obligation to participants and the host community to maintain confidentiality of information (Emanuel et al., 2004). This means that researchers need to be clear about how they will ensure confidentiality of maintained records and prevent conversations being overhead during interviews. It is important that the protocol specify how the health of the participant will be monitored and appropriate medical care provided or facilitated. Lastly, the protocol should explain clearly how the research results will be disseminated to participants and the host community (Emanuel et al., 2004).

2.4 Ethical considerations in research

This section reviews the ethical principles that have relevance to research conducted in developing countries. This section is influenced by the work of Emanuel et al. (2004) which is discussed below in section 2.7.

2.4.1 Community engagement and collaboration

'Collaboration with community' in research describes the process of working together with the community that involves a partnership (Tindana et al., 2007). The concept of research collaboration/partnership relates to community engagement which is a process involving working together with the community to achieve a common goal (Tindana et al., 2007). The idea of community engagement is based on the ethical requirement of involving participants in the research process.

The idea of community engagement places emphasis on partnering with stakeholders (individuals or groups) who can influence or are affected by the conduct or outcome of the research. Community engagement is used in the same context as community consultation (Tindana et al., 2007).

Dickert and Sugarman (2005) identify four ethical goals for community consultation: enhanced protection, legitimacy, enhanced benefits, and shared responsibility. Each will be described in turn:

- *Enhanced protection* of participants is based on the ethical obligation that researchers should minimise risk to research participants. Consultations with the community will provide the community with an opportunity to raise risks that may not have been identified by the researchers.
- Community consultation improves the *legitimacy* of the research project by giving an opportunity for the community to express their views about the project.
- Community consultation may *enhance benefits* from the research as the community gets an opportunity to include issues of its own concerns/needs, even though not all requests may be incorporated in the study. However, efforts are made to ensure that research is mutually beneficial to the community and the researcher/sponsor (Dickert & Sugarman, 2005).
- Community consultation encourages *shared responsibility* in the successful implementation of the research. The seeking of community assistance tends to enhance commitment to the study project and to its successful implementation (Dickert & Sugarman, 2005).

These goals of community consultation by Dickert and Sugarman (2005) are reflected in the Emanuel et al. framework (2004) in terms of the principle of collaborative partnership that needs to be established by researchers with host communities. Researchers have a responsibility to engage the community in a meaningful manner in the design, implementation, and monitoring of research, and in the communication of research results (CIOMS, 2016). Some communities may lack the capacity to assess the scientific quality and ethical obligations of the proposed research. Sponsors and researchers need to ensure that these disparities are resolved, and an equal partnership in decision-making is achieved (CIOMS, 2016).

Community engagement also addresses the ethical principle of respect for persons that refers to the researcher's obligation to act for the benefit of others (Simwinga & Kabero, 2014). This means that by consulting the community, the researchers have an opportunity to strengthen measures in the research project that maximise benefits for community and individuals (Simwinga & Kabero, 2014).

Collaborative partnership includes capacity building to enable the community to fully participate in the collaborative project as full partners and capacity to utilise the research results for policy making and/or improvement of health care (Benatar & Singer, 2016; Silaigwana 2017; Silaigwana & Wassenaar, 2019). Many studies identify what contributes to

meaningful engagements. These include the establishment of local residents networks, consultations with traditional/ community leaders and engagements with potential participants (Tindana et al., 2015).

2.4.2 Social value

The broad goal of all research should be to generate knowledge that will improve health and social conditions. It is thus important that the research produces quality information. The findings from the research are important for decision-making and these should be based on valid and reliable information (CIOMS, 2016). It is particularly important for clinical research that the social value of the research justifies the exposure of participants to risks. The promotion of social value requires prior engagement with the community to determine the social value of the research to the community. Lairumbi et al. (2008) argue that the moral of the principle of benefit sharing is widely recognised however the process of how these principles/ideas can be implemented still need further attention and clarity.

Habets, Van Delden and Bredenoord (2014) contend that there is no common focus on social value in research ethics, and these differences are reflected in the ethics guidelines on the issue of social value. There are those who regard knowledge production as providing social value whilst others consider social value as arising from improvement of health or social conditions (Habets et al., 2014). These interpretations influence what is considered ethical or unethical. Habets et al. argue that RECs should adopt the latter understanding of social value in their review of clinical trial protocols, that the proposed intervention should be evaluated against its anticipated social value, in terms of whether it will contribute to the well-being of patients and/or society (Habets et al., 2014). Stakeholders may have different views on social value of research to community. Lutge, Slack and Wassenaar (2017) in their study observed that researchers and gatekeepers had different perceptions of the social value of their research. Although all parties recognised the need to improve the health and well-being of the community, the researchers' perceptions were futuristic whilst the gate keepers on the other hand placed more emphasis current health needs (Lutge et al., 2017).

In addition, the research should be relevant to the community as there is a danger in externally sponsored studies that they may not add social value to the host community (Lindegger & Bull, 2002). Lairumbi et al's. (2008) study in Kenya showed that poor stakeholder partnership limited the social value of research. Therefore, it is important for RECs, when evaluating protocols, to ensure that the research is relevant to the host community and to determine if the implications of the research results have been considered by researchers (CIOMS, 2016; Wonkam, Kenfack, Muna & Oukem_Boyer, 2011).

Public accountability of research extends to obligations by researchers to publish their results and share the data on which the results are based (CIOMS, 2016). Research, particularly health-related research, is conducted to improve public health. Some of these studies are conducted with some risks to participants (CIOMS, 2016; Igoumenidis & Zyga, 2011). It is thus important that the results are shared to maximise benefits from the research, whether the studies were successful or unsuccessful (CIOMS, 2016). Therefore, public accountability can be enhanced through the use of trial registries, publication and data sharing.

2.4.3 Scientific validity

The attainment of social value from the research is dependent on the quality of the data that is produced (CIOMS, 2016). Research that is not appropriately designed will not be able to answer the research question(s) and thus will be of limited benefit for participants and the community (Emanuel et al., 2004). Scientific validity is based on the understanding that all health research should be based on extensive knowledge of scientific literature (WMA, 2013). This extensive knowledge of the subject matter should be reflected in the research design and it should be clearly described and justified in the protocol. It is therefore essential that the research design is scientifically sound and methods used are appropriate (CIOMS, 2016; WMA, 2013)

It is essential that the REC evaluate the scientific rigour of each research protocol submitted for ethics review. Slack, Lindegger, Vardas, Richter, Strode and Wassenaar (2000) argued that scientific rigour enhances the ethics of research. They show how studies that follow sound ethical principles also improve the scientific processes in the study. Emanuel et al. (2004) identify four considerations that RECs should consider in assessing scientific validity of proposed research:

- Whether the design enables interpretation of the results;
- Whether the design enables generalisation to the host community;
- Whether the research contributes to improvements in the provision of services and/ or addresses a health/social problem;
- Whether the study is feasible given the social, political and cultural context in which it is being conducted.

Adequate/appropriate training of researchers is another element that can contribute to the attainment of scientific validity (CIOMS, 2016). The Declaration of Helsinki, in its

commitment to protection of human subjects in medical research, emphasises appropriate training of researchers who conduct health research. The CIOMS guidelines also consider the competence of the research team as an important aspect of scientific validity to be considered by the RECs in reviewing protocols (CIOMS, 2016). However, the Emanuel et al. framework does not include the evaluation of competence of researchers as part of its requirement for scientific validity (Tsoka-Gwegweni & Wassenaar, 2014).

2.4.4 Fair participant selection and research with vulnerable populations

There is a perception that research that is of high risk is frequently conducted amongst populations who are poor and uneducated (CIOMS, 2016; Goodwin, 2016; Igoumenidis & Zyga, 2011). This is illustrated in a study by Igoumenidis and Zyga (2011) that cites cases where pharmaceutical companies tested new drugs in developing countries without the knowledge of participants. This tendency to conduct research on poor communities is reflected in Ndebele, Mwaluko, Kruger, Oukem-Boyer and Zimba's chapter that cites numerous examples of unethical research conducted in Africa. These include the testing of new drugs and clinical trials (Ndebele et al., 2014). These incidents highlight the importance of fair selection of participants in research.

The fair selection of participants in research relates to the ethical obligation of justice in research which is based on the understanding that a group of people should not be burdened unnecessarily with participating in research - unless the research is directly related to their conditions (U.S. Department of Health and Human Services, 1979). Thus, the selection of participants in research should be based on scientific reasons and not just on availability or social/economic status. Furthermore, groups that will not benefit from the research should not be unfairly exposed to the risks of the research (CIOMS, 2016).

The selection of participants is an important consideration in reviewing protocols. The selection of research participants should be fair and this means that the research question(s) must be directly relevant to the population. Furthermore, the knowledge generated from the study should be relevant to the research participant population (Horn, Sleem, & Ndebele, 2014).

All vulnerable groups should receive special protection in research studies. A vulnerable population is a concept commonly used in research ethics and refers to the inability or limited ability of particular individuals to protect their own interests (CIOMS, 2016). Children are considered vulnerable/special populations and researchers need to take special care in involving these groups in research (CIOMS, 2016). The research must demonstrate a direct

benefit to children to justify the conduct of a specific study (CIOMS, 2016). A parent or legally authorised person must give permission and the child, if possible, must agree (assent) to participate in research (CIOMS, 2016).

In reviewing this type of research, the REC should not only ensure that the risks to this group are minimal but should also ensure the protection of participants through an informed consent process (CIOMS, 2016). Targeting a specific group for a research study has a tendency to stigmatise or alienate vulnerable groups. Therefore, it is important that measures are taken by the research team to ensure confidentiality and anonymity of participants in the conduct of research (CIOMS, 2016).

A research protocol that includes vulnerable populations should demonstrate the following:

- The reasons the research cannot be done with another group;
- How the research is directly relevant to the needs of the group;
- How participants will have access to the benefits of the research (Horn et al., 2014).

Women are sometimes discriminated against in research (CIOMS, 2016). Women of childbearing age tend to be excluded from research due to concern that if they participate and become pregnant during the research, this could pose a risk to the foetus (CIOMS, 2016). By being excluded, women in this age group miss out on knowledge that could be gained from their participation in these studies (CIOMS, 2016). Women of childbearing age should be given an opportunity to participate in research and also be informed of the risks to the foetus, if any, associated with the research. This information must include options related to termination of pregnancy and medical support for the individual and the child (CIOMS, 2016).

2.4.5 Favourable risk-benefit ratio

The Declaration of Helsinki (1975) recognises that most medical research involves risks and advises that before research commences an assessment of possible risks to prospective participants should be undertaken. This Declaration recommends that research should be conducted if the value of the research outweighs the burden to participants (WMA, 2013). The commitment to minimising risks can be recognised in the ethical obligation of beneficence. Based on this principle, researchers are obliged to consider the maximisation of benefits and reduction of risks in their research (US DHHS, 1979).

Risks of harm to participants are not limited to medical research but apply to all types of research. This is demonstrated by Tyldum (2012) who found that many researchers who experience difficulties in recruiting adequate samples (low response rate) or in gaining access to certain groups of respondents during data collection may resort to the use of pressure. This takes many forms including economic, emotional or institutional pressures (Tyldum, 2012). It is thus important that researchers who resort to using these pressures ensure that the participants are not placed at risk of harm from participating in the research (Tyldum, 2012).

The assessment of risks and benefits of a research project is an important function of the REC. Risk refers to psychological, physical and social risks of harm as a result of participating in the research (Shah, Whittle, Wilford, Gensler & Wendler, 2004). Che Chi, Horn and Kruger (2014) have categorised the risks related to healthcare research into four categories. These categories are useful for RECs when reviewing protocols. The categories are:

- Research that involves no more than minimal risk, with the probability not greater than the risks participants may experience in daily life;
- Research that involves more than minimal risks, with potential risks justified by the benefit that the research participant will gain from participating in the research;
- Research that involves more than minimal risks, with no possible direct benefit but participation likely to produce generalisable knowledge;
- Other research not within the above three categories but will assist in enhancing knowledge of the health care problem (Che Chi et al., 2014).

There are two approaches that have been used by RECs to assess risk-benefit ratio in health research and these are component analysis and a net risks test. The component analysis approach involves separating the various procedures in the research study into therapeutic and non-therapeutic interventions (Che Chi et al., 2014). For therapeutic procedures to pass ethical clearance there should be sufficient evidence to support the expectation of potential benefit (Che Chi et al., 2014). The risks posed by the research must be acceptable in the context of anticipated benefits (Che Chi et al., 2014). For non-therapeutic procedures, the risks should be reduced to the minimum as far as possible in the study design; otherwise, the REC should consider alternative reliable procedures (Rid & Wendler, 2011).

The net risks test follows a different approach from component analysis in that it involves conducting a risk-benefit assessment (Rid & Wendler, 2011). This process involves the identification of all study interventions, and for each procedure or intervention, an alternative is identified and then assessed according to favourable or unfavourable risks, after which comparisons are made between the intervention and the alternative for each procedure (Che Chi et al., 2014). If the net risks of the research intervention are justified by the benefits of new knowledge, then the REC approves the study (Che Chi et al., 2014).

The framework of Emanuel et al. (2004) provides guidelines for RECs to review protocols for a favourable risk-benefit ratio in developing countries. First, the risk-benefit ratio must be favourable based on the context where the host community live. The context includes factors such as incidence of disease, drug resistance, and social and environmental factors. The assessment should be guided by the risk-benefit ratio principle that the greater potential of benefits to participants justifies their exposure to a higher level of risks (Emanuel et al., 2004). Secondly, the risk-benefit ratio for the community should be favourable. Thirdly, the potential risks and benefits of the research for the community should be assessed, and the community should be given an opportunity to decide whether the risks are acceptable in relation to the potential benefits to be derived from the study (Emanuel et al., 2004).

2.4.6 Independent review

The idea of oversight of research was first raised by the Helsinki Declaration of 1975. It calls for the establishment of independent research ethics committees and approval of research protocols by a research ethics committee (REC) before the study begins (IJsselmuiden, Marais, Wassenaar & Mokgatla-Moipolai, 2012). The idea of the REC was given further consideration by the Nuffield Council Report in its discussion of the functions of ethics committees, which is to primarily review research protocols (Nuffield Council on Bioethics, 2014). The Nuffield Report raises a number of issues that should be considered when reviewing externally funded research. The CIOMS guidelines published in 1979 (latest version CIOMS, 2016) discuss RECs, and the review of protocols is one of the principles considered by the CIOMS report. The CIOMS guidelines cover most of the issues covered by the other guidelines. In particular, they reflect on the management of multinational studies.

There is general agreement in all guidelines that all research protocols should receive independent ethics review before the commencement of the research. Independent ethics review of protocols is necessary in order to minimise any conflict of interest and enhance accountability (Emanuel et al., 2004). These conflicts of interest may affect the manner in

which the research is implemented, such as the formulation of research questions, recruitment of participants and interpretation of data. The review of protocols also enhances accountability. It is important that REC processes are transparent because this enhances accountability and assures the community that the research is not exploitative (Emanuel et al., 2004).

In some instances, supplementary reviews are necessary, especially for externally funded research (CIOMS, 2016). Ethics reviews of externally funded protocols should be conducted in both sponsoring and host communities (CIOMS, 2016). These committees may come to different conclusions regarding the proposed research which would require further engagements between parties (the RECs). These engagements should be geared towards an understanding of concerns of all parties particularly the views of those who will bear the risks of research.

The CIOMS guidelines recommend that multi-centre research studies should be implemented in each centre using an identical methodology (CIOMS, 2016). In addition, CIOMS recommends that the ethical review of research in a single jurisdiction should be conducted by one research ethics committee (CIOMS, 2016).

The Department of Health (2015) recommends the following process for independent review:

- Ensure that research will promote health and contribute to prevention diseases.
- Ensure that protocols are scientifically and ethically sound. This includes the protection of participants by weighing the risks of harm against the possibility benefits to participants.
- Independent and objective assessment of protocols and their possible effect on potential participants.

2.4.7 Informed consent

Informed consent is one of the important principles of ethical research. It is based on the ethical obligation of ‘respect for persons’ that recognises that participants are in the best position to express their interests and thus should be involved in decision-making about matters that affect them (Nuffield Council on Bioethics, 2014). Furthermore, the principle is based on the understanding that every individual is an autonomous agent capable of making his/her personal decision (Nuffield Council on Bioethics, 2014). The consent process

consists of disclosure, understanding/comprehension, decision-making capacity and voluntariness, and these will be described in the following sections.

2.4.7.1 Disclosure

The disclosure process involves communicating information about the proposed study to the participant by the researcher (Lindegger & Richter, 2000). The information that should be communicated to the participant is the following: rationale of the study, methodological issues, risks, benefits of participation in the study and available treatment alternatives (Siminoff, 2003). The format and language in which the information is communicated is important. The disclosure documents must be in the language of the participants, and the information should be simplified and avoid technical terms to improve understanding (Lindegger & Richter, 2000). The participants should be given an opportunity to ask questions and make a decision based on the information provided whether or not to participate in the study. The allocation of time to a disclosure process for questions and to discuss information has a positive impact on the comprehension of information by research participants (Cahana & Hurst, 2008).

2.4.7.2 Understanding/comprehension

There is increasing evidence that many participants do not fully understand the information provided to them. Siminoff (2003) asserts that there are serious gaps in informed consent processes, and many of the challenges are at the level of understanding of the participants (Siminoff 2003). Some authors relate this problem to consent forms containing technical language (Siminoff, 2003). These concerns are supported by the findings of a study by Montalvo and Larson (2014) who conducted a systematic review of published research to assess participant comprehension of the research in which they participated. They found that many research participants lacked a basic understanding of what the research entailed (Montalvo & Larson, 2014). These findings highlight the importance of presenting the information in a simplified manner so that it is understood by prospective participants.

The amount of information and the manner in which it is provided is another issue that has received much attention from researchers. Macklin (1999) argues that that too much information and too little information will have the same effect on the participant in terms of missing an understanding of what the project is about. Macklin recommends the provision of adequate information to enable an individual to make an informed decision about participating in the research (Macklin, 1999). There are various strategies that have been used in Africa to improve understanding such as administration of a comprehension quiz (Chaisson, Kass, Changeta, Mathebula, & Samandari 2011) and narratives tailored to local environment (Ndebele, Wassenaar, Munalula & Masiye, 2012).

There is a common problem in online studies where participants consent to participate in such studies without clearly understanding the information provided as part of the informed consent process (Antonacopoulos & Serin, 2016). Antonacopoulos and Serin (2016) suggest improving participant understanding of informed consent for online studies by improving the informed consent procedures and requiring participants to consent to each element of the study (Antonacopoulos & Serin, 2016).

2.4.7.3 Decision-making capacity

An important aspect of an informed consent process is the recording of it, which usually involves obtaining a signature from the research participant. The consent process can be complicated by the background of participants such as low literacy levels, and cultural and language barriers (Tekola et al., 2009). Cultural barriers can influence understanding of issues such as causes of diseases and decision-making processes (Wasunna, Tegli, & Ndebele, 2014). The informed consent process may be enhanced by the researcher making an effort to understand the community from which the participants are going to be recruited (Frimpong-Mansoh, 2008). The concept of community engagement and consent are interdependent as it is through community engagement that the researchers can understand how to adjust the consent process to context of the community (Participants in the Community Engagement and Consent Workshop, 2013). In an African context, important decisions like participation in the research may need consultation with community and family leaders (Frimpong-Mansoh, 2008). Emanuel et al. recommend the involvement of the community in developing appropriate procedures for recruitment of participants and determination of appropriate incentives for participants (Emanuel et al., 2004). In some communities, verbal consent may be necessary and in this case it should be documented, with witnesses to confirm the validity of the process (CIOMS, 2016).

In terms of child participants, the parent/legal guardian must give consent to permit the child to participate in the research and the child must give assent. The CIOMS (2016) guidelines emphasise that children must be involved in the decision-making. The researchers should take into consideration the age and personal circumstances of children in preparing appropriate information for participants (CIOMS, 2016).

It is essential for many studies that are conducted in an institutional setting to obtain gatekeeper permission to gain access to research participants and data for research (CIOMS, 2016). The concept of gatekeeper permission is based on the principle of autonomy that says that every institution or community has a right to control access to its

information, space, personnel and clients for research purposes (Singh & Wassenaar, 2016). Researchers should seek permission to access this information and people. The REC is also expected to assess the social value of the study, risks and benefits of the study to the institution as well as whether the research process will not impact negatively on organisational processes (Singh & Wassenaar 2016). Many RECs do not grant approval for ethics clearance until proof of gatekeeper permission is produced (Singh & Wassenaar, 2016).

2.4.7.4 Voluntariness

The decision to participate in research must be voluntary and free from any influence. There are many forms of influence that may negatively affect voluntary decision-making, including manipulation, coercion and undue influence (persuasion) (Wasunna et al., 2014). Coercion in research occurs when a person forces or threatens to harm another person as part of influencing the person to participate in the research (Wasunna et al., 2014). Undue influence, on the other hand, is when people are enticed to participate in research by being offered certain types of incentives that limit choice and which reduce consideration of risks posed by participating in the research process (Wasunna et al., 2014).

It is not easy to assess the reasons why people decide to participate in research; hence, Appelbaum, Lidz and Klitzman (2009) contend that voluntariness occurs in a spectrum from involuntary to voluntary action. Since one does not have much control over how decisions are made by individuals, the REC can ensure that other aspects of informed consent (i.e. disclosure of information about the research) are adequately addressed, to enable prospective participants to make an informed decision (Appelbaum et al., 2009). The REC's role is to assess the potential threats on a prospective basis and require special protection for groups of people that are vulnerable to offers, pressure or threats (Appelbaum et al., 2009). In some cases, some RECs may appoint consent monitors to observe the consent process (Appelbaum et al., 2009). Lema, Mbondo and Kamau (2009) recommend the evaluation of informed consent processes and procedures as part of clinical trial to identify issues that need improvement to ensure that informed consent is really voluntary.

2.4.7.5 Compensation and incentives

There is a common understanding amongst researchers that participants in research should be reimbursed for direct and indirect expenses incurred during the research (Appelbaum et al., (2009). These expenses include travel costs, lost earnings, inconvenience and time spent in research. The reimbursement may be in a monetary or non-monetary format (CIOMS, 2016; Nuffield Council on Bioethics, 2014). The debates are largely centred on the

amount or type of incentive that is appropriate to be used to compensate participants. Grant (2015) argues that incentives are a form of power as they may be used to get people to do what they would not otherwise do. It is essential that compensation is appropriate and not so large that participants are persuaded to get involved in the research when they would not otherwise have done so (CIOMS, 2016).

The ethics concerns around undue inducements relate to how certain types of incentives may limit the participant's choice (Appelbaum et al., (2009). The inducements are not so much of a concern when the risks from participating in the research are low (CIOMS, 2016). However, high inducements or offers are a concern when risks are high and research participants are from poor communities (CIOMS, 2016). In these cases, the ability to exercise voluntariness in decision-making may be weakened. Emanuel et al. (2004) identified four key elements of undue inducement: offer of something valuable in order to do something; the offer is so large that it becomes irresistible; the offer leads people to make poor judgements; and the risk of harm as a result of poor judgement (Emanuel et al., 2004). Emanuel et al. (2004) recommend that appropriate incentives should be determined in consultation with the host community. Koen et al. (2008) recommend that payment for participation in research should be based on time, inconvenience and expenses (TIE). Participants should be paid for their time and should be based on national unskilled labour rates whilst the payments for inconvenience should be determined based on the type of procedure followed (Koen et al., 2008). This means that participants with short visits and undergoing a simple procedure will receive less money than those participants with long visits and undergoing complex procedures (Koen et al., 2008). Participants should be reimbursed for their direct expenses such transport and food (Koen et al., 2008).

There are many ethical concerns around the payment of research participants who are children under the age of 18 years and who therefore cannot give consent (Wendler et al., 2002). The payment may induce the parent/legal guardian to consent to research participation for the child, without taking adequate consideration of the risks of the research to the child (Wendler et al., 2002). For example, the South African National Health Act 2003 mandates that a parent or guardian provide proxy consent for research with minimum risk. However, it excludes caregivers (Strode & Slack 2011). This proxy consent may arguably be abused by proxies who may not act in the best interest of the child (Strode, Toohey, Singh & Slack, 2015). Wendler, Rackoff, Emanuel and Grady (2002) propose guidelines for a payment process in research involving children, placing emphasis on lower payments or non-monetary forms of compensation for child research participants (Wendler et al., 2002).

The REC, when reviewing protocols, should pay careful attention to the provision of incentives/benefits for participating in research to ensure that they are appropriate to the local (social and economic) context (CIOMS, 2016; Emanuel et al., 2004; Nuffield Council on Bioethics, 2014). In reviewing protocols of research involving children, the REC should require clear justification for such payments in the protocol. Wendler et al. (2002) recommend that, in such research, payment should be given to the child who carried the burden of participating in the research and not to third parties.

2.4.8 Respect for participants

2.4.8.1 Confidentiality

Confidentiality is an important aspect in the use and storage of data. The data should be anonymised or coded and safely kept. Prospective participants should be informed of the safeguards that will protect confidentiality of the data collected as well as their limitations (CIOMS, 2016). One of the issues is that the key to coded data should not be kept with coded/anonymised data (CIOMS, 2016). Limits of confidentiality may be due to leaked data or data stolen by unauthorised parties; identification of individuals in anonymised or coded data in small sample sizes; or such limits as may be required by law (CIOMS, 2016).

The increase in the use of records and biobanks in research has brought the issues of consent and disclosure to the fore (CIOMS, 2016; Rothstein, 2002). The first issue of concern is the consent of participants for the use of their records. The question is the whether the material/data is “individually identifiable”; if the information is de-identified, then consent is not required (Rothstein, 2002, p. 106). In cases where records are in an identifiable form, then the consent of the person is required. The consent should specify the scope (possible uses of the data) and duration of use (CIOMS, 2016; Rothstein, 2002). In cases where researchers intend to use data collected from clinical records and have not obtained consent for future use, the REC may waive individual consent if the research has important social value and poses minimal risks to participants (CIOMS, 2016).

2.4.8.2 The sharing of results

The principle of respect for persons places an obligation on researchers to take into consideration the welfare of participants when conducting research. Apart from providing individuals with an opportunity to make decisions about their involvement in research this obligation requires sharing the results with research participants (USDHHS, 1979). Thus, the

sharing of research results/findings with participants is considered another important aspect of respect for participants (Emanuel et al., 2004; Fernandez, Kodish & Weijer, 2003), based on the principle that participants not to be treated as a means to an end (Fernandez et al., 2003). The sharing of results may take many forms, including publication, conference presentations, media releases and other forms of communication. The sharing of research results is important for all types of research, with special emphasis for health research. The sharing of results places the welfare of participants at the centre of the research, as the results may have implications for the participants (Fernandez et al., 2003).

The sharing of results sometimes presents a challenge of separating individual from aggregate study results in certain types of study, which therefore needs careful consideration from the beginning of the study (Gikonyo, Kamuya, Mbete, Njungana, Oloyu, Bejon, Marsh & Molyneux, 2013). Gikonyo et al. (2013) share their positive experience of giving feedback on research findings to malaria vaccine trial participants in Kenya. The community had an interest in receiving the report which contributed to the building of trust between parties and support for further research.

However, not all researchers share the same understanding of respect for persons that includes sharing research results with the participants. Miller, Hayeems, Bytautas and Bytautas (2012) question the assertion that sharing results is a means of fulfilling the principle of respect of persons. They argue that there are many ways of showing respect, and the guidelines should not be overly specific on how this obligation is fulfilled. The task of determining the means of fulfilling this obligation should rest with the researchers. They point out that research participants might have their own reasons for participating in the research and may not necessarily have an interest in the research results (Miller et al., 2012). However, the counter-argument by these authors failed to provide alternatives or examples of how this obligation could be fulfilled by researchers. Without clear suggestions from Miller et al. (2012), the sharing of results remains an important means of showing respect for participants.

The Nuffield Report identifies two important considerations for the principle of respect of research participants: standard of care and post-research commitment. These are discussed below.

2.4.8.3 Standard of care

The issues of standard of care and the level of treatment that should be provided to research participants in clinical trials is based on the ethical principle of justice which is concerned with the benefits of participating in research (Slack et al., 2000). There are opposing views on the matter between the providing of universal treatment available in other parts of the world or non-universal treatment available locally (Nuffield Council on Bioethics, 2014; Slack et al., 2000). The general view is reflected in the Nuffield Report which recommends that, where possible, research participants should be provided with the universal standard of care and where this is not possible, the minimum standard of care should be offered in line with the national public health system (Nuffield Council on Bioethics, 2014). A suitable standard of care should be determined in consultation with those who work in the host country (Nuffield Council on Bioethics, 2014). The issue of standard of care is linked to the treatment of participants and continued provision of health benefits to participants after the study has been completed (Slack et al., 2000).

This view is supported by Benatar and Fleischer's (2007) paper that reflects on the ethical issues of standard of care in low income countries. They recommend that attention be given to formulation of policies that link research and clinical care that will contribute to improvement of local standard of care. These can be realised through involvement of the host community in the planning of the study, forming partnership with specialists and non-governmental organisations (Benatar & Fleischer 2007).

2.4.8.4 Post-research commitment

Other researchers under this obligation of respect for persons have focused their attention on post-research commitments. The ethical obligation of post-research commitment requires the researcher to consider the sustainability of the changes to be introduced by the study Nuffield Council on Bioethics, 2014). The sponsors and the researchers need to consider these issues at the outset of their research studies (Nuffield Council on Bioethics, 2014). These considerations should include reflections of how adverse effects after the intervention will be treated and compensation of those injured or harmed as a result of the research Nuffield Council on Bioethics, 2014). Proponents of this view recommend that research participants should be given access to interventions that have proven success. Although this may be costly to the funder, these ideas should be considered before the research project commences (Igoumenidis & Zyga, 2011). Provision of the intervention to participants once the research is over is another area of contention.

In addition, the post-research commitment should be part of the investment in developing local capacity and expertise by all externally sponsored research (Nuffield Council on Bioethics, 2014). It is important that these initiatives of investment in local expertise are implemented in such a manner that they are sustainable once the research is over (Nuffield Council on Bioethics, 2014). The post-research commitments should be clear, and funding should be identified prior to undertaking the research. It is believed that this will avoid exploitation of poor communities, as they will not be exposed to research that will not directly benefit them (Bhutta, 2002).

However, there are some researchers who are wary of these requirements for research projects in that they may have negative effects for developing countries. This view is reflected in Bhutta's (2002) article that argues that these obligations may be difficult to implement by developing countries as sponsors of research, since they have limited resources. These obligations may also place a burden on Western countries' research sponsors, thus curtailing large-scale trials in developing countries (Bhutta, 2002; Igoumenidis & Zyga, 2011).

2.5 Criticism of research ethics committees

Wassenaar and Mamotte (2012) place critics of ethics review in two categories: principled and pragmatic objections. Principled objections refer to those people who regard ethics review as curtailment of academic freedom. They also regard ethics review as encompassing the standardisation of some of the ethical principles without consideration of local context. They also consider ethics review as derived from biomedical research, and thus unsuitable for social science research. They regard social science research as presenting lower risks to participants (Wassenaar & Mamotte, 2012). Pragmatic critics generally accept the need for ethics review, but are concerned about inefficiencies and inconsistencies of RECs, causing delays and bottlenecks in the conduct and completion of potentially socially valuable research (Wassenaar & Mamotte, 2012). One of the criticisms of ethics review is the bureaucracy of RECs. Over the years, there has been tremendous growth of RECs and their work of regulating the conduct of research, thus ensuring the protection of research participants (Grady, 2015). This has had a negative impact in terms of expanding bureaucratic procedures for gaining permission to conduct research, thus limiting the independence of researchers, to some extent (Schrag, 2011). Some researchers have gone as far as to accuse RECs of going beyond their originally intended mandate (Clapp, Gleason, & Joffe, 2017). There are many studies that find fault with the current system of

oversight of research (Joffe, 2012; Mamotte & Wassenaar 2009). Some of the reasons they cite are the incompetency and bureaucratic procedures associated with the work of RECs, which usually lead to delays in implementation of studies.

The effectiveness of RECs has been given attention by many studies. Some of these studies have focused mainly on the processes and their impact on the research. RECs have been criticised for inconsistency in decision-making. An example of this tendency is demonstrated in the findings of Abbott and Grady's systematic review study of institutional review boards (IRB) that found that there was inconsistency in the application of ethical guidelines and in decisions made by RECs (Abbott & Grady, 2011).

Some authors consider these variations to be a result of RECs using different guidelines or placing emphasis on one principle over others (Kruger & Mogkatla-Moipolai, 2014). The existence of many guidelines makes it difficult for RECs to determine which of the guidelines to apply (Kruger & Mogkatla-Moipolai, 2014). This leaves the RECs with difficult options when making decisions about which principles to apply for a particular research study, thus leading to some variation in REC decisions (McGuinness, 2008).

RECs are also criticised for often giving needless attention to mistakes and errors that are considered mundane and instead of focusing on substantive issues (Clapp, Gleason, Gleason and Joffe, 2017). Clapp et al. (2017) in their study of REC decision letters found that the ethics reviewers spent a substantial amount of their time highlighting proposal deficiencies such as spelling and typographical errors that are not related to ethics issues. They argue that this tendency influences the REC members' perception of the credibility of the researcher and his/ her work (Clapp et al., 2017).

Some of the concerns relate to multi-site reviews of a single study, conflict of interest amongst REC members and lack of relevant expertise of REC matters (Abbott & Grady, 2011). There have been challenges with the review of multinational studies as they need to be reviewed in both the host and the funding community. Barchi, Singleton and Merz (2014) identified four issues that pose a challenge in the review of multinational studies. These include:

- Lack of expertise and capacity in developing countries to conduct the reviews;
- Differences in the guidelines and ethical review criteria used by these committees;
- Differences in regulatory requirements;
- Lack of trust between the parties (Barchi et al., 2014).

There have also been concerns that many of these guidelines have been developed in Western contexts with limited evidence of the extent to which they are applicable to the developing world (Emanuel et al., 2004; Mkhize, 2006).

Bhutta's (2002) assessment of ethics in developing countries is that ethics debate has largely focused on regulatory issues, and little attention has been given to the needs of the developing countries and the vast inequalities in health and resources (Bhutta, 2002). These inequalities cannot be addressed by guidelines alone; they require greater involvement of other stakeholders and commitment in developing local capacity in ethical review of research, as well as the adoption and use of the ethical principles by developing countries (Bhutta, 2002). Given the criticism that has been levelled against the RECs, more attention needs to be given to RECs' effectiveness and quality of decisions (Grady, 2015; McGuinness, 2008).

Some studies focused on RECs' communication of their decisions. These include the study by Clapp et al. (2017) that analysed feedback provided to a sample of researchers by RECs in the United States. They found that RECs often did not provide reasons for requiring changes to the proposed research (Clapp et al., 2017).

Few studies have given attention to the actual discourse and interaction during the RECs' meetings. Fitzgerald, Phillips and Yule (2006) conducted ethnographic research on the ethics review process in five countries. They found that the narratives of reviewers set the tone of the discussions and influenced the decisions of the REC (Fitzgerald et al., 2006). Thus, the RECs' decisions are influenced by narrative rather than the researcher's application. Fitzgerald et al. (2006) thus draw attention to how narratives are influential in RECs' decisions and thus need to be well managed.

Notwithstanding the challenges encountered with REC review, the importance of REC oversight is still recognised by all authors. Some ways of improving effectiveness of the RECs have been suggested and these include the following:

- The requirements for the review of studies with minimal risks should be reduced.
- Duplication should be minimised by requiring a single review for multi-site studies (Abbott & Grady, 2011; Barchi et al., 2014).
- There should be collaborative review of multinational studies (Barchi et al., 2014).

2.6 Research ethics in Africa

Africa, as part of the developing world, has its own history in the development of ethics research. Kass, Chaisson, Chengeta, Mathebula and Samandari (2011) show that there has been relatively little, but growing scholarship on RECs in developing countries. Studies that have been conducted in Africa have highlighted the inadequate training in research ethics of REC members (Kass et al., 2011). These studies have also highlighted the inadequate funding and limited resources for RECs in African countries and note that this poses a threat to the RECs' independence as members face pressures to approve studies with economic benefits to local communities (Kass et al., 2011). Rwabihana, Girret and Duget's (2009) study of RECs in Africa found that many RECs had been established but that many of these committees were dependent on external funding for their operations (Rwabihana et al., 2009). Based on these findings, Rwabihana et al. (2009) argue for increased training of RECs that will strengthen the effectiveness and independence of these committees.

More recently, there has been growing interest in research ethics scholarship in Africa, amid concerns about exploitation of research participants. Ndebele et al.'s (2014) paper shows that researchers in Africa do not always follow ethical research guidelines, particularly when they are being funded by Western countries; this makes the African population vulnerable to exploitation. Ndebele et al. (2014) cite many examples of unethical research conducted in Africa. This situation is aggravated by the absence of an extensive ethical review system (Ndebele et al., 2014). These examples illustrate the need to strengthen research oversight to prevent the exploitation of research participants.

In light of the above-mentioned challenges, a number of initiatives have been undertaken to strengthen the RECs in Africa. These include the provision of training, ethics resource materials, books, funding and creation of ethics curricula in certain institutions, as well as the establishment of national systems and policies on the ethical conduct of research (Ndebele et al., 2014).

2.7 South African experience

Notwithstanding challenges mentioned above, there has been remarkable development of ethics in research in Africa in recent years. Many of these developments have taken place in South Africa. Several studies focused not just on the number of existing RECs but on the outcome of the reviews. Tsoka-Gwegweni and Wassenaar (2014) assessed ethical concerns raised during the review of protocols by a South African biomedical REC using the Emanuel et al. (2004) framework. The most frequent concerns were informed consent, scientific validity, fair participant selection and respect for participants (Tsoka-Gwegweni & Wassenaar 2014). In another study, Silaigwana (2017) investigated the commonly raised issues by two biomedical RECs in South Africa by sampling REC minutes and decision letters also using the Emanuel et al. (2004) ethical framework. The research show informed consent, respect for participants and scientific validity were the most frequently raised concerns and that all the issues identified were in accordance with international guidelines for review (Silaigwana, 2017: Silaigwana & Wassenaar, 2019).

In line with international developments in ethics of research, the South African government developed its own regulatory guidelines entitled *Ethics in health research: Principles, processes and structures*, based on international guidelines on research ethics. These guidelines were released by the Department of Health in 2004 and were replaced by the publication of the second edition in 2015. The *National Health Act No. 61 of 2003* (NHA) provided for the establishment of the National Health Research Ethics Council (NHREC), which is responsible for developing norms and standards for research ethics in South Africa and for promoting compliance by RECs. There are 30 RECs in South Africa that are registered with the NHREC as of 16 March 2018. The NHREC monitors the work of these committees through annual reports and audits. The growth in RECs is complemented by the various ethics training programs initiatives that are offered by certain institutions in South Africa.

The (InstX) REC is an institutional research ethics committee in South Africa; it has the responsibility to review all protocols at InstX before commencement of research. The REC also reviews applications from external researchers only in cases where no other suitable REC exists. InstX is a research organisation that agreed to participate in the present study on condition of anonymity, as applied to other related studies cited in this thesis. Like most social science RECs in South Africa, the InstX REC reviews research on a broad range of social science issues, some of which are health-related while others are focused on broader

social and economic concerns. InstX was selected for evaluation of its minutes partly because related studies to date had reported on the review outcomes of biomedical RECs (e.g., Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014) rather than on the review outcomes of an REC that had a social science focus. The InstX REC is one of several known social science-focused RECs in South Africa. Like the other studies mentioned above, this study sought to determine ethical issues arising from the ethics review process. InstX's REC concerns were assessed using the Emanuel et al. framework which is outlined briefly below.

2.8 The relevance of the framework to social science research

There has been a view that social science research does not need ethical review as it has minimal risks. Wassenaar and Mamotte (2012) argue that whilst social science research might not pose physical harm to participants, it may pose psychological harm such as invasion of privacy, emotional distress, loss of confidentiality, stigma, and other social ills. Thus, it should be reviewed and monitored (Wassenaar & Mamotte, 2012). Furthermore, these authors contend that the benefits and risks of social science research are not always tangible (unlike biomedical research); therefore, they require in-depth review (Wassenaar & Mamotte, 2012). In addition, the protection of privacy and confidentiality in research may be unsuitable for some social science methodologies, such as participatory research. The latter's main objective is empowerment of the community, and confidentiality of research participants is not one of its goals (Mutenherwa & Wassenaar, 2014).

There is also an argument that much social science research is exploratory in nature and sometimes does not have well formulated questions before the interview (Mutenherwa & Wassenaar, 2014). In addition, sometimes the focus of the research may change based on the interaction between the researcher and research participant. This makes it difficult for the REC to review some exploratory studies in terms of assessing the appropriateness of research questions and sample size, for example (Mutenherwa & Wassenaar, 2014).

Mutenherwa and Wassenaar (2014) also raise the limitations of confidentiality in focus group discussions. The use of focus groups makes it difficult to protect research participants' confidentiality, especially in terms of any disclosures which may be made by participants during group discussions. Furthermore, it is difficult to protect the rights of the third party in the snowball sampling technique (Mutenherwa & Wassenaar, 2014).

Based on these arguments, social science research should be subjected to ethics review. This will improve the ethics and quality of social science research (Wassenaar & Mamotte, 2012). Indeed, Wassenaar and Mamotte (2012) recommend the application of the Emanuel et al. framework in reviewing protocols in all fields of social and health related research. They provide an adapted model of the Emanuel et al. framework, placing emphasis on issues arising in social science research. Since the InstX REC reviews mostly social science research, the Wassenaar and Mamotte (2012) model offers important guidelines for analysis of the InstX REC minutes. The key elements of this model are summarised in Table 1 below.

Table 1: The adapted model of Emanuel et al. framework

Principle	**Social science issues**
Collaborative partnership	• Research should be based on community needs and the community should be involved in all stages of research. The community's involvement should be fair. • Fieldworkers should be considered as key collaborative partners due to their important role in research, that of relating with participants and collecting data.
Social value	• The research should lead to knowledge that will be useful to participants. • The social value can be increased through a collaborative relationship and dissemination of results to participants and policymakers.
Scientific validity	• The methodology (quantitative and qualitative) should be rigorous. A quantitative design should have a scientifically acceptable sample size and qualitative studies, on the other hand, should have extensive methodology to ensure authenticity of findings. • Competence of fieldworkers in qualitative research is important as it may affect data quality.
Fair selection	• Selection of participants should be based on the research question. • Those who stand to gain the most from the research should be selected. • Purposive sampling should be transparent. • The community should be informed about how participants will be selected.
Favourable risk-benefit ratio	• The risk-benefit ratio of social science research should be carefully considered, as the benefits of such research are not easily determined. • Obligations to maximise benefits. • A plan should be in place to minimise possible harm and wrong doing.
Independent review	• RECs should be competent to review social science research, especially qualitative research.
Informed consent	• It is recommended that in some types of qualitative research, informed consent is negotiated at each stage of the research. • Special care should be taken in conducting research with vulnerable groups. This

	should include sensitising them about the scope and function of research, as they may have expectations of support or assistance that may influence their participation. • Research with children should include consent by the parent/legal guardian, with assent by children. Permission by an institution such as a school does not replace consent by legal guardian or parent.
Ongoing respect for participants	• Some qualitative designs (such as participatory research and focus group discussions) have limitations in terms of confidentiality. It is important that researchers inform participants of this and advise them not to disclose sensitive information. • Confidentiality might not be suitable for all types of research. In these cases, participants should be consulted. The REC will need to assess the risks of such action to participants. • Researchers are obliged to share their research findings with participants. This might not be comfortable for some participants, as they may need to identify themselves due to the small sample size of qualitative research.

Source: Wassenaar and Mamotte (2012).

The model highlights important issues for consideration by social science researchers and RECs. The model was used in the present study to complement and enhance the understanding of the Emanuel et al. framework, as it applies in a developing country and to social science research.

2.9 Criticisms of ethics principles/ frameworks

The Emanuel et al. framework is regarded as a useful instrument for use by RECs in assessing the quality of protocols (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014). It is comprehensive and applicable to all types of research (Silaigwana, 2017; Tsoka-Gwegweni & Wassenaar, 2014).

There are a few shortcomings with the Emanuel et al. framework that were identified by two studies conducted on biomedical RECs in South Africa (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014).

1. The principles do not include weightings that indicate the measure of importance of different principles (Silaigwana, 2017; Tsoka-Gwegweni & Wassenaar, 2014). This would be useful when faced with a conflict of which principle to prioritise in a particular research (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014).

2. Identified some ethical issues that are not considered by the Framework such as use of storage and transportation of biological samples (Silaigwana, 2017; Tsoka-Gwegweni & Wassenaar, 2014). Other issues identified that are not considered by the Framework and that may have a bearing on principles of social value and scientific validity was research funding and researcher expertise (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014).

2.10 Summary

This chapter provided an overview of ethical guidelines and principles that have been developed to improve the treatment of research participants. One of the important developments in this regard is the establishment of oversight committees (RECs) that review protocols of research that involve human participants before any studies are initiated. Strengthening research oversight in developing countries is one of important goals for many institutions to minimise risk of harm/abuse of research participants. Emanuel et al. developed a framework that consolidates different principles and highlights their relevance to developing countries. An overview of the Emanuel et al. framework was discussed and its relevance to RECs. The chapter concluded with a guideline of how the framework can be applied in the review of social science research.

CHAPTER 3
RATIONALE

3.1 Introduction

There is a growing appreciation that social science research should be subjected to ethics review. The last chapter highlighted several ethical risks for research participants in social science research. Ethics review of research protocols therefore will improve the ethics and quality of the research (Wassenaar & Mamotte, 2014).

3.2 Rationale of the study

Oversight structures such as RECs, which review protocols and monitor the implementation of research, are constituted to reduce harm and maximise benefits to participants. What ethical issues do RECs consider important and use for decision-making when reviewing protocols?

Although the Emanuel et al. framework is currently being used worldwide, it was initially developed to address ethical concerns arising from the implementation of clinical research in developing countries. It is important to understand whether the framework captures all the issues that arise in conducting research in developing countries, as well as identify possible ethical issues that are not covered by the framework. In addition, the ethical guidelines have been criticised by some people (Mkhize, 2006) for being based on Western values. It is important therefore to understand whether there are unique ethical issues emanating from the African continent.

3.3 Research questions

The questions that were asked are the following:

- What ethical concerns does the InstX REC raise when reviewing protocols?
- Is there a systematic prioritisation of some ethical issues over others?
- Is there an observable pattern to the ethical concerns raised by committee members? If so, what is the pattern?
- Are the concerns raised consistent with the framework developed by Emanuel et al. (2004)?

- Does any feature of the Emanuel et al. (2004) framework dominate the concerns? If so, which one?
- Are there other concerns raised by the InstX REC which are not consistent with the framework discussed by Emanuel et al. (2004)?

3.4 Aims and objectives

Aims:

The study aimed to identify the main ethical issues raised during ethics review of social science research proposals by a REC and to assess their relative weight, using Emanuel et al.'s (2004) recommended principles of ethical review of clinical research. This study is a replication of the study by Tsonga-Gwegweni and Wassenaar (2014) using a social science oriented REC instead of a biomedical REC.

Objectives:

The study objectives were the following:

- To study the minutes of the InstX REC's review meetings to identify and describe the ethical concerns and issues raised in their review of research proposals.
- To analyse the identified ethical issues and concerns using Emanuel et al.'s (2004) framework, by ranking and assessing how they do or do not fit the framework.

CHAPTER 4
RESEARCH METHODOLOGY

4.1 Research design

This study was based on a content analysis of archived written documents, namely the minutes of the meetings of the InstX REC. Content analysis is based on the qualitative research methodology approach (Mayring, 2014). This process involves interpreting meaning in the text using pre-determined rules of analysis referred to as categories (Mayring, 2014). The categories used were based on the Emanuel et al. (2004) framework.

Although the study was predominantly qualitative, a mixed method approach was followed which consisted of the qualitative aspect of assigning categories to text using Emanuel et al. framework. The quantitative part comprised of analysing the frequency of categories (Mayring, 2014).

The aim of the study was to understand the ethical issues raised during the review and thus a retrospective assessment of the minutes was conceptualised. Content analysis (Mayring, 2014) was considered suitable for the study. An assessment of minutes for a two-year period, 2012 and 2013, was selected and was considered adequate to be utilised as a sample size for the study since the study is mainly qualitative in nature.

4.2 Sampling strategy

Purposive selection is part of non-probability sampling which is the selection of research participants based on knowledge of the population (Babbie, 1994). The REC's responsibility is to review research protocols and identify issues of ethical concern for rectification before research projects are implemented. The minutes of the InstX REC reflect deliberations made during REC meetings.

Sampling in content analysis is not different from other research designs. However, the sampling techniques in content analysis tend to focus on two main issues: the topic area and the time period (Prasad, 2008). The time period for the study is 2012 and 2013. This time period was considered adequate to analyse the decisions of the REC. The study utilised a systematic sampling method to ensure that all REC minutes have an equal chance of being

selected. The InstX REC holds up to ten meetings each year and this translated to 20 records. Fifty percent of these records of minutes were systematically selected to form the sample for the study. Systematic sampling was used to select every second record in each year (2012 and 2013).

The inclusion criteria specified that only minutes recorded for all newly submitted protocols for full review should be included without any consideration of the type of study (clinical trial, social research, biomedical or behavioural study). Protocols submitted for continuing reviews, annual reports, and final reports were excluded. In the sample of ten REC meeting minute records, a total of 64 applications were reviewed by the InstX REC. Of these, 33 were discussed in the 2012 meetings, while 31 were reviewed during the 2013 meetings.

4.3 Unit of analysis

A unit of analysis refers to what is being analysed. There are two types of unit of analysis in content analysis: recording units and context units. The recording unit is the text which is counted (and maybe simplified) and placed into different categories (Prasad, 2008). The recording unit can be a word, sentence or a paragraph (Prasad, 2008). The context unit, on the other hand, is a 'large body of content' that represents the context for the recording unit (Prasad, 2008). The recording units for this research were minute records of the InstX REC.

This research utilised frequencies to record the number of times a particular phrase was recorded in the minutes within each category (Prasad, 2008). There are many ways of recording data in content analysis and these include the following quantification procedures:

- Space-time measures: recording the space and/or time that the category appears.
- Appearance: whether a particular category appears in the recording unit.
- Frequency: the frequency with which the given category appears in the context unit (Prasad, 2008).

The choice of the quantification procedure depends on the research questions to be answered. Frequency measurement is more commonly used (Singleton et al., 1993). Singleton et al. argue that its use should be based on an assumption that "frequency of a word or category is a valid indicator of importance, value, or intensity", while it also assumes that "each individual count is of equal importance" (Singleton et al., 1993, p. 384).

4.4 Developing content categories

Content analysis mainly involves developing categories of communication (Mayring, 2014). The quality of the analysis is dependent on having clearly identified categories (Mayring, 2014). The categories used for the analysis of the ten REC minute records were based on the eight principles and associated benchmarks of ethical research developed by Emanuel et al. and summarised in Section 2.7. The framework has eight principles:

- Collaborative partnership
- Social value
- Scientific validity
- Fair subject selection
- Favourable risk-benefit ratio
- Independent ethics review
- Informed consent
- Respect for participants and study communities.

These principles were defined in Section 2.7 to ensure that their ethical values were clearly understood.

The definitions show how the content categories are operationally defined. The definition of the categories establishes the understanding of what is being analysed and how each category is mutually exclusive, addressing different aspect of research ethics. The eight ethical principles of the Emanuel et al. (2004) framework were divided further into three or more categories within each principle. This aided the linking of content categories with communication in the minutes. The simplified categories were adapted from Tsoka-Gwegweni and Wassenaar (2014) and are presented in Table 2.

Table 2: Coding framework

	Principles	**Categories utilised**
1.	Collaborative partnership	Community representation
		Responsibility sharing
		Respect for local context
		Fair sharing of responsibility
		Sharing of products
2.	Social value	Research beneficiaries
		Research benefits
		Enhancing research benefits
		Impact on health system
3.	Scientific validity	Appropriate design and methods
		Applicability of results
		Impact on provision of healthcare services
		Study design feasibility
4.	Fair participant selection	Suitable study population
		Risk minimisation
		Benefits to study participants
		Vulnerability
5.	Favourable risk-benefit ratio	Risk identification and minimisation
		Type, probability and magnitude of benefits
		Comparison of risks and benefits
6.	Independent review	Regulatory compliance
		REC members' conflict of interest
		Transparent review
		Minimisation and reconciliation of multiple reviews
7.	Informed consent	Recruitment and incentive applicability to local context
		Appropriate disclosure documents and processes
		Presentation and accuracy of information
		Legally authorised representative
		Gatekeeper's permission
		Context of consent processes
		Respect for autonomy
8.	Respect for participants	Monitoring health and well-being
		Confidentiality and privacy
		Voluntariness
		Research results dissemination
		Post-research obligations

The division of content categories into specific activities helps to ensure that the content categories are mutually exclusive so that a particular word, phrase, sentence or paragraph can easily be placed into one of the selected categories (Mayring, 2014). Prasad (2008) shows that the quality of the content analysis is dependent on the categories; these should be clearly formulated and exhaustive. This means all communication being analysed should fit into one of the identified categories (Prasad, 2008).

4.5 Data collection

Provisional postgraduate and UKZN ethics approval for the study was received in September 2016 subject to InstX approval to use its REC for the study. Gatekeeper permission from the InstX leadership was obtained to access and analyse their REC minutes (see Appendix B – withheld to preserve anonymity). Subsequently, ethics approval for the study (No. BCA342/14) was obtained from the UKZN Biomedical Research Ethics Committee in 2017 (see Appendix A).

The minutes were accessed in electronic format after signing a confidentiality agreement with InstX. The minutes were coded using the eight principles and benchmarks of the Emanuel et al. (2004) framework to record the observable pattern in ethical concerns raised during ethical review of research proposals

The value of the content analysis is dependent on the clear identification of content categories and assigning of units to categories. Coding smaller units with less information is considered more reliable than coding larger units. There is also a danger of coding very small units in that they are too small to have meaning.

4.6 Data analysis

The data analysis process was systematic as it involved the selection of units of analysis, identification of categories, coding, analysis and reporting. The data analysis is explained below:

- The first step was to define coding categories. The Emanuel et al. framework was used to define categories. These were further simplified by Tsoka-Gwegweni and Wassenaar (2014) for use as a coding framework (Table 1).
- The second step was the piloting of the coding framework using one set of minutes. These were shared with a colleague to confirm consistency of interpretation and approach.
- The third step was to code all the minutes following the same approach.
- The fourth step was to capture the information from the coded minutes on a standard data capture sheet (Appendix B) to determine simple frequency counts made of each type of ethical issue raised in InstX's REC minutes. Thus, the frequency of occurrence per principle or category per minute was recorded. There were also provisions for 'other' categories of review comment not covered by the Emanuel et al. (2004) framework. These issues from the minutes were identified and the frequency of occurrence of these issues was recorded. The data obtained was captured using Microsoft Excel and analysed using simple descriptive analysis and the results are presented graphically.
- The fifth and final step was the analysis which entailed recording noticeable features, frequencies of coded categories and making interpretations.

4.7 Ethical considerations in conducting the research

The framework developed by Emanuel et al. for clinical research in developing countries guided the ethical considerations for this study. Although it was developed for biomedical research, it has been found relevant for use in social research (Wassenaar & Mamotte, 2012). The ethical issues considered in conducting this research are discussed below.

Collaborative partnership: This research is part of a bigger project concerned with analysing ethical issues raised by RECs in Africa. The research findings will help researchers to understand better the concerns raised by African RECs.

Social value: Emanuel et al. emphasise that the social value of the research for the host community must be clearly explained (Emanuel et al., 2004). The literature review in ethics and the experience of developing countries show the need for this type of research to be conducted in Africa. The research findings will highlight the ethical issues that the InstX REC considers when reviewing protocols. The findings will broaden understanding of whether the framework is useful to RECs in South Africa. The research findings will be shared with the InstX REC and published in a peer-reviewed journal.

Scientific validity: The research design for the study was scientific and sound based on a design already peer reviewed and published. The extensive literature review shows that the research design was appropriate for the analysis of ethical issues discussed by the InstX REC in their meetings. The principle of scientific validity includes demonstration of competence by the researcher to carry out the study. This involved the assessment by the REC of whether the researcher was qualified and competent to conduct the research. The researcher provided evidence of ethics training through registration on the South African Research Ethics Training Initiative (SARETI) programme. The Principal Investigator assured the REC of the role he would play in overseeing the research by ensuring implementation of the proposal and protection of participants.

Fair subject selection: This included consideration of how the researcher sampled the minutes and the inclusion and exclusion criteria thereof. No human participants were involved.

Favourable risk-benefit ratio: The research design involved content analysis which is regarded as an unobtrusive research method as it does not involve people directly. The research is thus considered minimal risk. The findings of this research may contribute to the understanding of how InstX reviews protocols and the ethical concerns that are raised during this process. These benefits outweigh the risk of confidentiality of research applicants that this research poses. Measures were taken to protect applicants by coding research protocols with numbers instead of using study or applicants names.

Independent ethics review: The protocol for this research was reviewed and approved by the KZN BREC approval number BCA342/14.

Informed consent: Institutional permission was received from InstX and the letter is withheld to preserve confidentiality but is available for audit purposes. A summary of findings will be submitted to the InstX REC. An undertaking was made with the InstX leadership that all

information to be received will be treated as confidential. Furthermore the data will be analysed and reported in anonymised form ensuring that individuals, institutions and protocols are not mentioned. The protocols discussed in the minutes were allocated numbers to ensure anonymity. Assurance was given that the documents will be kept safe i.e. computer safety lock, passwords and locked cabinet for any hard copies. The data will be destroyed after five years.

Respect for participants and study communities: Every effort was made in this research to protect confidentiality by identifying research projects in the minutes with serial numbers instead of names and research titles. The minutes were stored safely in a lockable cupboard at home and a password was utilised to access the computer used to analyse data. The raw data will be submitted together with the dissertation to the University of KwaZulu-Natal for storage.

4.8 Validity, reliability and rigour

Reliability in content analysis refers to the likelihood that other researchers will re-code the same data in a similar fashion, that they will classify or categorise data in the same way and that the classification of texts corresponds with the established norms (Busch et al., 1994-2012). A sample of the coded minutes was shared with another researcher to confirm the approach utilised in coding the minutes. In this way, the reliability of the study was enhanced.

Validity in content analysis refers to the validity of categories and whether other researchers would define these categories in the same manner (Busch et al., 1994-2102). This study utilised the framework developed by Emanuel et al. (2004) for the analysis of ethics concerns. The framework incorporates eight ethical principles. The study adopted the coding framework utilised by Tsoka-Gwegweni and Wassenaar (2014) in their analysis of ethical concerns in a similar institution using the same framework. The coding framework was validated to ensure completeness and common understanding of the principles of the Emanuel et al. framework. In this way, the validity of the study was enhanced.

The issue of the validity of the study is linked to the ability to generalise based on the results. Coding rules were developed to guide the coding process. Busch et al. (1994-2012) contend that generalisation of results is dependent on the reliability of the categories that have been developed and how accurately they measure the item under study. Busch et al. (1994-2012)

thus recommend the development of the coding rules as essential to conceptual analysis. The coding rules developed for this study thus addressed the concerns about generalisability of the results.

Criteria used to assess the quality of qualitative research are credibility, transferability, confirmability and dependability. The widely used criteria for assessment of credibility are internal validity, external validity, reliability and objectivity which are sometimes not considered suitable for qualitative studies (Anney, 2014). Trustworthiness in the findings of this study can be assessed using the criteria of credibility and dependability.

The credibility criterion addresses issues of internal validity in qualitative research - that of assessing whether the study achieved its objective (Shenton, 2004). The credibility of the research findings in this study can established in three levels. Firstly, it can be assessed through the manner in which research method was presented in the report which provides extensive details to enable replication of the study by another researcher. Secondly, the random sampling approach used in selecting minutes for the study enhanced the credibility of study as it demonstrates that the researcher had minimal influence on the types of minutes selected. Thirdly, credibility was enhanced through the examination of two previous studies of RECs in South Africa which utilised the same research approach (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014.

Dependability relate to the issue of reliability of whether the study if repeated can produce the same results (Shenton, 2004). Dependability in this study can be established through the manner which the minutes were coded that ensured that there is consistency and uniformity in the manner which the minutes were coded.

The results are presented in the following section.

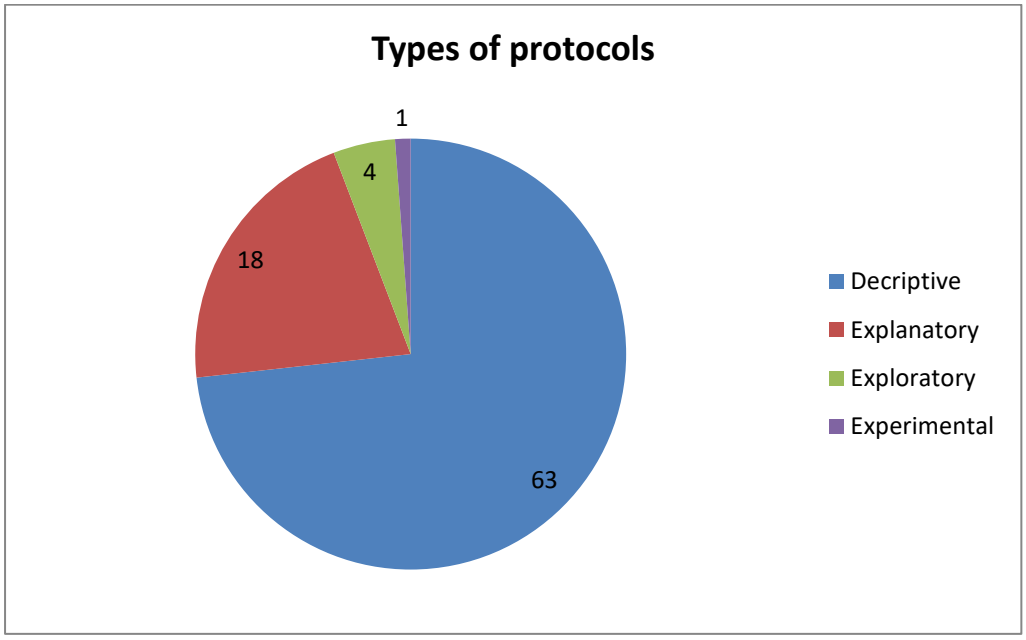
CHAPTER 5
RESULTS

5.1 Profile of minutes assessed

A sample of ten records of minutes of the InstX REC was sampled for the study, out of a total of 20 records for the period of two years (2012-2013). Systematic sampling was used to select every second record in each year. The ten sets of minutes selected reflect the review of 63 protocols of which 33 were discussed in 2012 InstX REC meetings and 31 in 2013 InstX REC meetings. The average number of protocols reviewed in each InstX REC was six and the highest number of protocols reviewed in one meeting was ten, whilst the minimum was four protocols. More than half (55%) of the protocols reviewed during the study period were from external researchers while, 45 percent were from internal researchers working in different research units within the InstX. Twelve of the 63 protocols reviewed were multinational studies submitted by non-South African researchers. All were social science protocols, mainly in the fields of education and primary health care.

The protocols that were reviewed by the InstX REC were, as mentioned above, mainly social science studies as expected. The majority of the protocols reviewed (63) had a descriptive design. The second most commonly used design (18) was an explanatory design covering different types of evaluation studies. There were only four studies that used an exploratory design and only one study that used an experimental design. Furthermore, the majority of protocols reviewed by the InstX REC during this period planned to utilise primary data sources, seven studies planned to use only secondary data sources, and four protocols planned to use both types of data sources (secondary and primary data). Likewise, a majority of the protocols planned to use secondary data in identifying suitable participants. The most commonly identified secondary data source was routine data collected by government institutions such as registers, databases and reports. This information is presented in Figure 1 and comprehensive list in Appendix D.

Figure 1: Types of protocols reviewed by InstX REC



The research focus/topics of protocols reviewed by the InstX REC during the period under study varied with the most frequent areas of discipline being health, education and training. The target population also varied; the majority (46) protocols planned to use adult participants, four targeted youth, and eleven targeted children as participants in their research studies.

The results below are presented in order of the research questions posed in section 3.3.

5.2 Ethical concerns raised by InstX REC in reviewing protocols

The concerns raised by the InstX REC in meetings when reviewing protocols were categorised in the following manner using the Emanuel et al. framework, also as done by Tsoka-Gwegweni and Wassenaar (2014): collaborative partnership, social value, scientific validity, fair participant selection, favourable risk-benefit ratio, independent ethics review, informed consent and respect for participants. All the Emanuel et al. framework categories were reflected in the concerns raised by the InstX REC when reviewing protocols. The main concerns are summarised below.

5.2.1 Collaborative partnership

Collaborative partnership was categorised into five themes, namely: community representatives, responsibility sharing, respect for local context, fair research benefits for community, and sharing research products. The InstX REC inquired about the relevance of

some of the studies to South African context. The InstX REC recommended a collaborative relationship that is characterised by the sharing of responsibilities in various aspects of the research such as planning, capacity building, conducting research and dissemination of results.

5.2.2 Social value

Many concerns that were raised in the InstX REC minutes highlighted the importance of research having social value; these concerns were categorised into five themes: research beneficiaries, research benefits/value, enhancing research benefits and impact on health system. Some of the concerns related to inadequate information provided by researchers indicating the beneficiaries of the studies and prospective research participants. Others were concerned about titles of the research studies that were not aligned with the objectives or in some cases were too broad.

5.2.3 Scientific validity

Many concerns raised by the InstX REC in this category related to the quality of the data collection instruments and data analysis plan.

5.2.4 Fair participant selection

Numerous comments were made by the InstX REC in several protocols on sampling method, sample size and lack of justification for choosing a method.

5.2.5 Favourable risk-benefit ratio

The InstX REC was concerned that many protocols did not give adequate attention to potential harm to individuals participating in group discussions. Other concerns by the InstX REC in this category were related to researchers that did not indicate how they would deal with information that constitutes reportable offenses.

5.2.6 Independent ethics review

Independent review of InstX REC concerns were categorised into four themes: regulatory compliance; REC members' conflict of interest; transparent review; and minimisation and reconciliation of multiple reviews. The InstX REC was concerned with multinational and multi-site study applications that did not indicate or provide ethical clearance letters showing approval by the REC of the host country or institution.

5.2.7 Informed consent

There were many InstX REC concerns related to informed consent. These concerns were categorised into: recruitment and incentives; appropriate disclosure, presentation and accuracy of information, legally authorised representative, gatekeeper permission, context of consent process, and autonomy. Many of the InstX REC comments on informed consent were related to appropriate disclosure, with a focus on the information provided to prospective participants. The issue of getting information translated to the language spoken by participant was emphasised.

All the concerns that were raised by the InstX REC in the theme of recruitment and incentives were related to incentives. It was observed that there was confusion between reimbursement for expenses and payment for effort of participating in the research (which the committee regarded as not an incentive).

The InstX REC was concerned with the protocols not clearly explaining the process they would use in gaining children's assent and site permission from the institutions where they would recruit the participants.

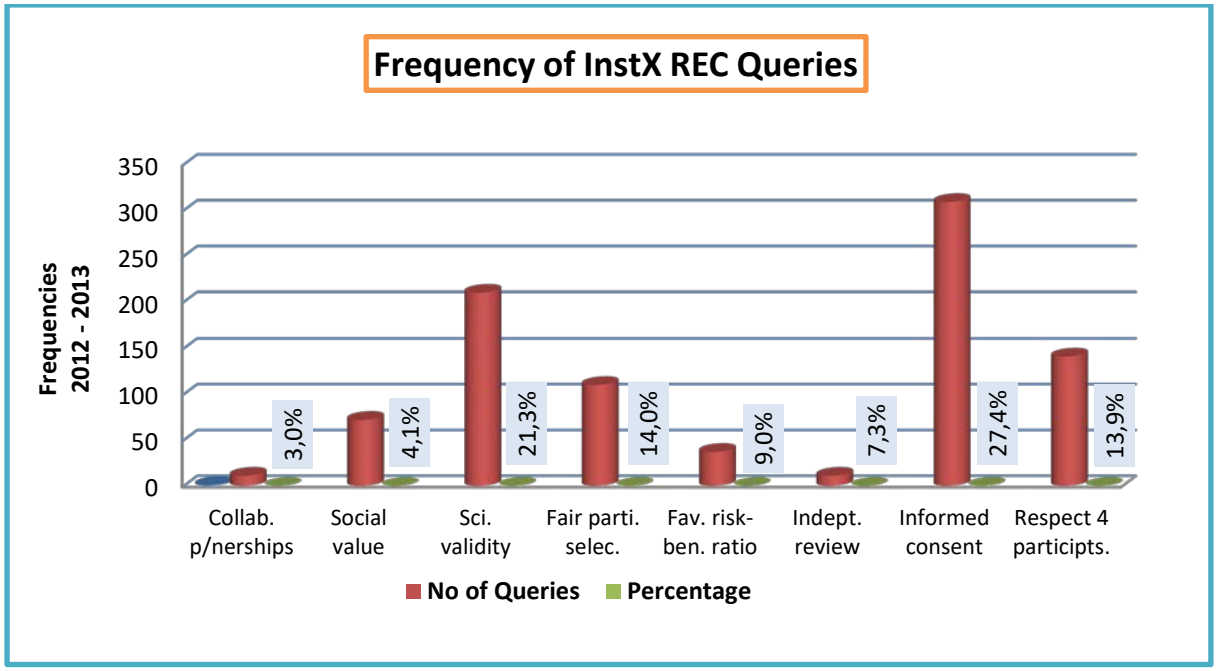
5.2.8 Respect for participants

The InstX REC was concerned whether insurance had been arranged to cover adverse reactions for those patients agreeing to participate in the study, formalising possible further referrals for some participants and provision of counselling for individuals who would be identified to be at risk of contracting the disease under study. The REC was also concerned about the confidentiality of data collected and anonymity of participants in the eventual research report.

5.3 Systematic prioritisation of some ethical issues over others

The concerns raised by the InstX REC minutes covered a wide range of ethical issues. A closer analysis of the minutes showed prioritisation of certain ethical issues over others. Figure 2 shows the frequency of the ethical issues raised in the REC minutes during the period of study (2012/2013).

Figure 2: Frequency of ethical concerns raised in the InstX REC meetings



The four most frequently raised ethical concerns by the InstX were informed consent (27.4%), scientific validity (21.3%), fair participant selection (14%), and respect for participants (13. 9%). These are discussed in more detail below ranked according to frequency. The minutes were further analysed to determine which concerns were raised most frequently within these four themes.

5.3.1 Informed consent concerns

Figure 3: Frequency of informed consent concerns raised by the InstX REC

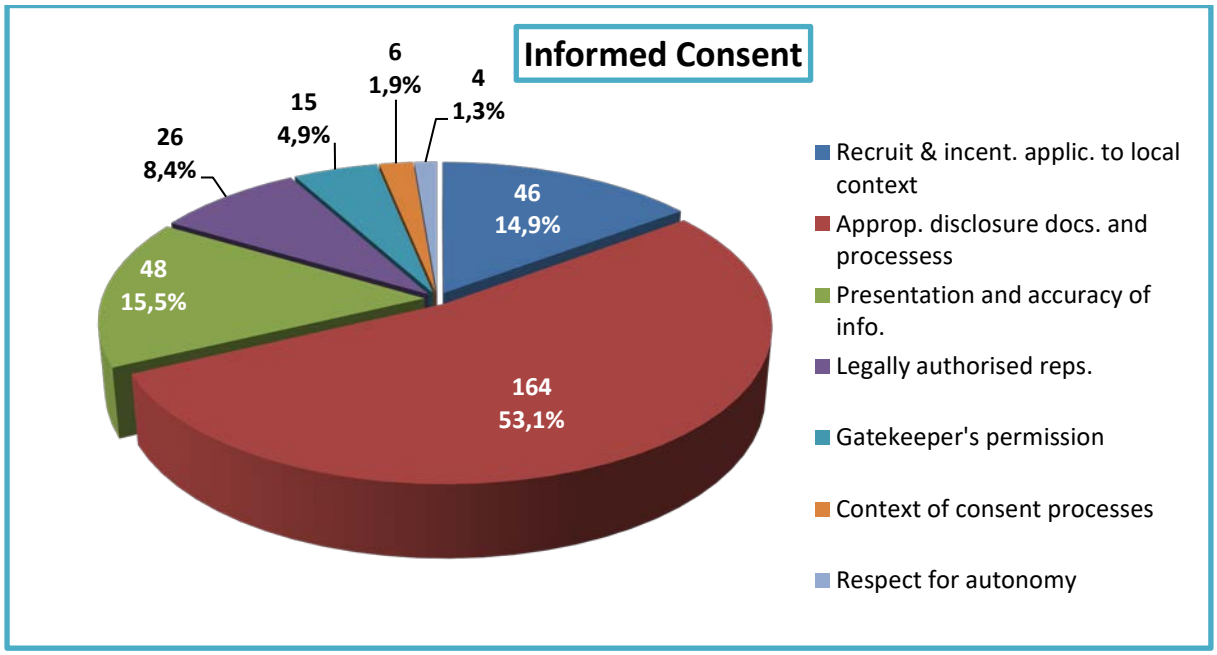
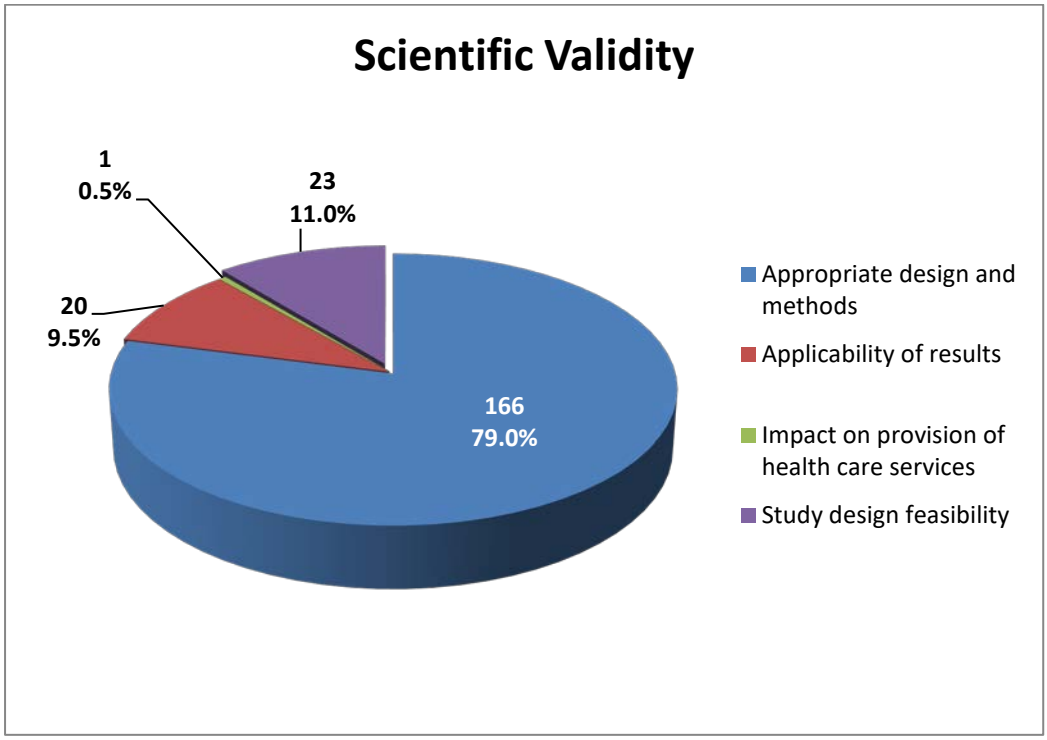


Figure 3 shows the frequency table of REC concerns on the theme of informed consent. The most frequently discussed informed consent concern was the availability of appropriate disclosure documents and processes (53.1%) that would be used for recruiting research participants. The presentation and accuracy of information (15.5%) provided to participants was the second most frequently raised concern within the theme of informed consent. This is followed by applicability of recruitment and incentives (14.9%) provided to participants, then legally authorised representatives (8.4%) and lastly, gatekeeper permission (4.9%) respectively.

5.3.2 Scientific validity concerns

The ethical principle that received the second highest attention from the InstX REC was scientific validity. The ethical issues that received attention within the principle of scientific validity were appropriate design, applicable results, study design feasibility and impact of the results. Figure 4 presents the frequency of these concerns raised in REC minutes.

Figure 4: Frequency of scientific validity concerns raised by the InstX REC

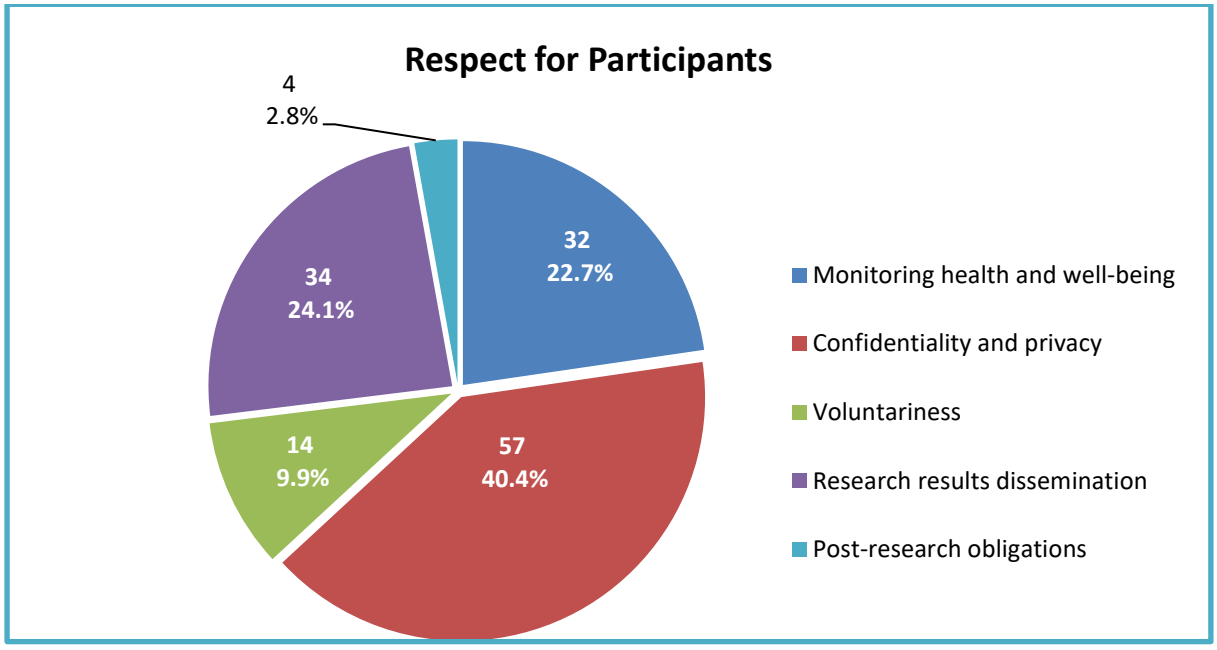


According to the findings, utilisation of appropriate design and methods accounted for 79% of the scientific validity concerns, followed by study design feasibility (11%). Applicability of results is at 9.5 percent, while impact on provision of health care services constitutes a mere 0.5 percent.

5.3.3 Respect for participants' concerns

The third most frequently raised ethical principle was respect for participants. This principle is divided into five themes, namely: monitoring of health and well-being, confidentiality, voluntariness, research results dissemination and post-research obligation. Figure 4 displays the frequency of respect for participants' concerns raised in the InstX REC minutes.

Figure 5: Frequency of Respect for participants concerns raised by the InstX REC

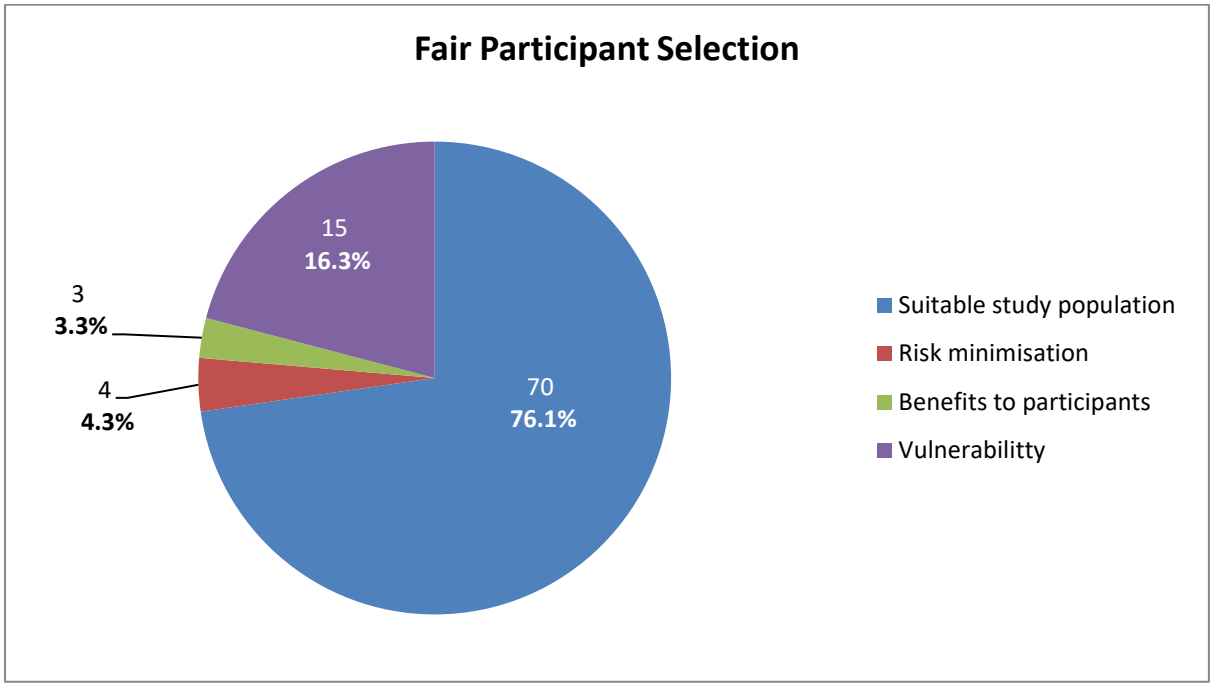


According to figure5, the sub-themes for the respect for participants theme were distributed as follows: Confidentiality and privacy of research participants (40.4%); research results dissemination (24.1%); monitoring of health and well-being (22.7%); voluntariness (9.9%); and post-research obligations (2.8%).

5.3.4 Fair participant selection concerns

The fourth most frequently discussed ethics concern by the InstX REC was fair participant selection. It is divided into four themes: selection of suitable participants, minimisation of risks, benefits to participants and vulnerability. Figure 6 presents the frequency of the themes within fair participant selection.

Figure 6: Frequency of fair participant concerns raised by the InstX REC



The selection of suitable study population was the most frequently discussed concern (76.1%); followed by vulnerability (16.3%), risk minimisation (4.3%), and benefits to participants (3.3%).

5.4 Consistency of InstX REC concerns with Emanuel et al. framework

The concerns raised by the InstX REC in their meetings were consistent with the Emanuel et al. framework. Issues raised by the InstX REC covered each of the principles of the framework. However, the ethical issues of informed consent and scientific validity dominated the InstX REC's concerns. Table 3 shows the frequency of concerns of raised by the InstX REC. Out of the 998 concerns identified, 309 of these were related to informed consent and 210 to scientific validity. The fewest concerns related to collaborative partnership (1%) and independent review (1%).

Table 3: Frequency of concerns raised the InstX REC (Descending)

Principles	No of Queries	Percentage
Informed consent	309	31%
Sci. validity	210	21%
Respect for participants	141	14%
Fair particip. selection	110	11%
Other	98	10%
Social value	72	7%
Fav. risk-benefit ratio	37	4%
Indept. ethics review	11	1%
Collab. partnerships	10	1%
Grand Total	998	100%

5.5 Other concerns raised by the InstX REC

There were 98 concerns (10%) identified that are not covered by the framework. These comments have been placed in the category of other. They relate to the following comments by the InstX REC: abbreviation/ acronyms, spelling mistakes, rectify clarity, timeframes and budget concerns.

5.6 Summary

This chapter provided study results and these are presented in sequence corresponding to study questions. The ethical concerns raised by the InstX REC when reviewing protocols were discussed in relation to the eight principles of Emanuel et al. framework. It was observed that the InstX REC gave priority to following ethical principles, ranked in descending order, when reviewing protocols: informed consent, scientific validity respect for participants and fair participant selection. The analysis also revealed a pattern of how the InstX REC dealt with certain types of research such as multinational studies and research with vulnerable groups.

CHAPTER 6
DISCUSSION

6.1 Ethical concerns raised by the InstX REC

6.1.1 Introduction

The InstX REC reviewed predominantly social science studies, as expected. This was confirmed through the number and type of studies that the committee reviewed during the study period (2012 to 2013). The InstX REC reviewed a broad range of quantitative and qualitative studies.

Numerous ethical challenges were identified by the REC reviewing these protocols. These challenges were coded using the Emanuel et al. (2004) framework. The findings showed that the Emanuel et al. framework is an applicable and useful guide for reviewing protocols because most of the issues raised in the REC's minutes could be accommodated by the Emanuel et al., (2004) model as adapted for the review of social science research by Wassenaar and Mamotte (2012).

Further findings are discussed below, in the sequence of the standard Emanuel et al. (2004) framework.

6.1.2 Community engagement and collaboration

Community engagement and collaboration principles encourage the consultation/ involvement of the community in all aspects of the research. The ethical concerns of collaborative partnership were ranked eighth (3%) out of the overall ethical concerns raised in the minutes. The ethical concerns raised were mainly related to multinational and multisite studies.

These findings are comparable to the findings of previous studies in South Africa on RECs. Tsoka-Gwegweni and Wassenaar (2014) found that collaborative partnership was the least raised concern whilst it ranked as the fifth concern in Silaigwana's (2017) study (Silaigwana & Wassenaar, 2019).

Community consultation is particularly important for multinational studies as it will not only enhance the researchers' understanding of the community but will give the community an

opportunity to raise concerns with that particular research and needs (Dickert & Sugarman, 2005; Simwinga & Kabero, 2014). Several guidelines recommend that researchers establish collaborative partnerships with host communities (CIOMS 2016; Emanuel et al., 2004). The REC therefore understands the value of collaborative partnership in enhancing legitimacy of research studies and enhancing benefits for participants.

6.1.3 Social value

The findings of study revealed that social value was ranked seventh (4.1%). This shows that the issues about social value were not frequently raised. Issues raised in this principle of social value relate to research benefits and possible impact of research on the research population or society at large.

These findings are comparable to the findings of previous studies in South Africa on RECs. The studies by Tsoka-Gwegweni and Wassenaar (2014) and Silaigwana and Wassenaar (2019) both found that social value was the least raised concern.

The issue of social value of research is an important ethics issue that RECs should take into consideration when reviewing protocols. They need to assess the potential benefit of the research to the wellbeing of participants or society. Sometimes it might not be easy for RECs to review social science research because their value may not be quantifiable. Exploratory studies might present a unique challenge for RECs because some aspects of the research design may not be fully formulated before research commences (Mutenherwa & Wassenaar, 2014). This would make it difficult for the REC to review some of the study protocols. It is also possible that the REC did not raise this item because it was satisfactorily dealt with in the protocol being reviewed.

6.1.4 Scientific validity

The findings of the study show scientific validity as the second (21.3%) most frequently raised concern by the REC. This is comparable to previous studies in South Africa which had similar findings. Scientific validity was second most frequently raised concern in Tsoka-Gwegweni and Wassenaar's (2014) research. Similarly the issue of scientific validity was also rated second most frequently raised concern in Silaigwana's (2017) study (Silaigwana & Wassenaar, 2019).

The REC also raised a number of concerns regarding the qualifications and experience of the researchers. Appropriate experience and expertise is another element that can contribute to the attainment of scientific validity (Tsoka-Gwegweni & Wassenaar, 2014). The CIOMS guidelines (2016) recommend that RECs consider competence of the research team when reviewing protocols.

A majority of concerns in this category were related to the utilisation of appropriate designs and methods. These ratings show that the RECs placed an important value on scientific validity. These findings are supported by the ethics guidelines (CIOMS, 2016) that emphasise the importance of scientific validity in the attainment of social value.

6.1.5 Fair participant selection

The findings show that issues related to fair participant selection were third (14.0%) most frequently raised concern. Some of the common ethical concerns in this category related to the selection of suitable study populations and the vulnerability of study participants.

These findings were confirmed by a previous study in South Africa which also ranked fair participant selection as the third most frequently raised concern by a REC (Tsoka-Gwegweni & Wassenaar, 2014). These RECs' concerns reflect an appreciation by RECs of the importance of appropriate selection of participants and that it must be linked to the research question. These RECs' efforts would help reduce the tendency of high risk research being indiscriminately targeted at poor communities (Ndebele et al., 2014).

6.1.6 Favourable risk-benefit ratio

The findings showed that the REC's concerns relating to favourable risk-benefit ratio was ranked fifth (9.0%). One of the issues frequently raised in these concerns was protection of individuals participating in focus group discussions. These findings are supported by published concerns about the limitations of confidentiality in focus group discussions (Mutenherwa & Wassenaar, 2014).

These findings are comparable to two previous studies in South Africa which ranked the risk benefit ratio fourth among concerns raised by South African RECs (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014). This shows the importance the REC efforts in getting researchers to reduce risks and maximise benefits (US

DHHS, 1979). The assessment of risks and benefits is an important function of the REC when reviewing protocols.

6.1.7 Independent review

Independent review issues were ranked seventh (4.1%). These findings are comparable to previous studies in South Africa in which independent review was one of the least frequently raised concerns (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2015). The main concerns related to multinational and multisite study applications that did not have ethical clearance showing approval of REC in sponsor/donor countries. These findings support the call by other researchers for strengthening the role of RECs in developing countries (Igoumenidis & Zyga 2011; Ndebele et al., 2014). Ethics guidelines recommend that research protocols should receive independent ethics review before commencement of research (CIOMS, 2016; Nuffield Council on Bioethics, 2014) and this include the South African Department of Health (2015) research guidelines. In cases of externally funded research, supplementary review in the host country are necessary (CIOMS, 2016).

6.1.8 Informed consent

These study findings highlight that informed consent was the most (27.4%) frequently raised concern by the REC. These findings are comparable to results reported in previous studies in South Africa. The research by Tsoka-Gwegweni and Wassenaar (2014) and Silaigwana and Wassenaar (2019) also ranked informed consent as the most frequently raised concern by RECs. These findings highlight that RECs are committed to ensuring that research participants are protected by ensuring that their decisions to participate in research are well informed and voluntary.

Many issues raised by the REC were related to inadequate information provided to participants as part of disclosure and the language in which this information was presented to prospective participants. There were also several concerns regarding incentives and processes of recruiting children in research.

These findings highlight the need for attention to be given to information disclosure and decision making process during informed consent process (CIOMS, 2016; Macklin, 1999;

Siminoff, 2003). Particular attention also needs to be given to involvement of children in research and the securing of assent and parental consent.

6.1.9 Respect for participants

Ongoing respect for participants was the fourth (13.9%) most frequently raised concern by the REC in this study. This finding is comparable to results reported in previous studies in South Africa that ranked respect for participants fourth amongst the concerns raised by the REC (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014).

The issues under respect for participants were counselling and insurance provided to study participants who are at risk, confidentiality of data and anonymity of participants in the reports. These findings show that the RECs recognised their important role of ensuring the welfare of participants during and after the research, and possibly that applicants underestimated their importance. One of the issues for consideration is confidentiality in the use and storage of data (CIOMS 2016; Rothstein, 2002). There is a growing interest in RECs and researchers to include standard of care and post-research commitment to participant's welfare in research projects (Nuffield Council on Bioethics, 2014).

6.2 Systematic prioritisation of some ethical issues over others

There were a total of 998 queries in ten sets of minutes sampled that reviewed 63 protocols. The four most frequently raised concerns by the InstX REC were ranked in descending order: informed consent (27.4%), scientific validity (21.3%), fair participant selection (14%) and respect for participants (13.9%). Other ethical issues raised by the REC when reviewing protocols included issues not part of the Emanuel et al. framework (10%), social value (7%), favourable risk-benefit ratio (4%), independent review (1%) and collaborative partnership (1%).

These findings are comparable with other studies conducted in United Kingdom and South Africa. The most frequently raised concerns in the UK study were informed consent, scientific designs, patient care and application mistakes (Dixon-Woods, 2008). The REC studies in South Africa using the Emanuel et al. (2004) framework had similar findings. Tsoka-Gwegweni and Wassenaar's (2014) study identified the following issues as the most frequently raised concerns by a biomedical REC: informed consent, scientific validity, fair participant selection and ongoing respect for participants. Silaigwana's (2017) study of two biomedical RECs had similar findings of four most frequently raised issues: informed consent, respect for participants, scientific validity and collaborative partnerships. These studies show that ethical issues about informed consent, scientific validity and respect for participants are the most frequently raised concerns by RECs.

Informed consent was the most frequently raised concern by the InstX REC. Within informed consent, the InstX REC was particularly concerned about information disclosure. The disclosure of information in the informed consent process relates to the information about what is being researched and how this information is communicated to participants. These findings are consistent with the international guidelines, which give emphasis to informed consent as a moral obligation of respect for persons (WMA, 2013; Nuffield Council on Bioethics, 2014).

The InstX REC gave particular attention to informed consent when it reviewed studies with children. Children are considered vulnerable which means they are unable to protect their own interests and thus need extra protection (CIOMS, 2016). When reviewing studies involving children, the InstX REC ensured that the risks to participants were minimised and that the decision-making process involved the child participants. The InstX REC also gave particular attention to informed consent in health studies.

The payment of incentives under informed consent was another ethical issue that the InstX REC gave attention as it may easily be abused by researchers to induce people to participate in the research when they would not otherwise do so (Grant, 2015). In raising these concerns, the InstX REC was in line with CIOMS whose guidelines advise RECs to ensure that incentives are appropriate and not too large, as this may lead to poor judgement (CIOMS, 2016; Emanuel et al., 2004). In line with these sentiments, Koen et al. (2008) recommend that participants should be paid for time, inconvenience and expenses. The payment of time should be based on the national unskilled labour rate whilst the payment for inconvenience should be based on type of procedure and this means that patients/ participants with short visits and simple procedures should receive less money than patients/ participants with longer visits and complicated procedures (Koen et al., 2008).

The issue of incentives requires particular attention by the REC if the research participants are children. The parent/guardian may be induced to consent for a child to participate in research without properly considering the risks of the research (Wendler et al., 2002). The InstX REC thus has the responsibility to assess the justification for involvement of minors and ensure that payments that will be given to children are appropriate.

The second most frequently discussed ethics concern was the scientific validity of studies. As Emanuel et al. (2004) explain, poorly designed research will not be able to respond to the research question; as a result, the social value will not be attained. There were a number of issues that were raised within scientific validity and the InstX REC's concern was primarily with the utilisation of an appropriate research design. The research proposals should demonstrate an understanding of the literature and provide justification of the research design (WMA, 2013). Qualitative studies should include extensive methodology which should be presented in the protocol (Wassenaar & Mamotte, 2012).

The third ethical issue that received attention from the InstX REC was respect for participants and this relates to researchers' responsibilities after the research has been completed. Within the respect for participants' principle, the two most frequent InstX REC concerns were confidentiality, and monitoring of the health and well-being of research participants.

Many studies that were reviewed by the InstX REC during this period had qualitative designs. The InstX advised some qualitative researchers to be careful in reporting their results, as the small sample size of qualitative research meant that it could be easy for

people to identify responses. The REC's view is supported by literature that indicates the limitations of confidentiality in participatory and action research (Wassenaar & Mamotte, 2012).

The other InstX REC concern was with regard to the storage and later use of data in ways that do not reveal the identity of participants. The InstX REC requires that all data from studies approved by the REC should be stored for future use. The InstX is a research institution and has capacity for data-sharing that enhances the social benefits of research conducted (CIOMS, 2016).

The fourth highest concern was fair participant selection. These concerns were mainly related to the selection of a suitable study population and research with vulnerable groups. The InstX REC was concerned about selection of participants not being based on scientific reasons, while in some cases, the protocol was lacking a justification of the sampling method and the inclusion and exclusion criteria. The selection of participants should be based on scientific reasons. The InstX REC's concerns are supported by literature that REC protocol review should consider the research question and study objectives in terms of whether they link to the selected study population (Horn et al., 2014).

The InstX REC was also concerned about the lack of attention given to gender issues in the research design and data collection of some studies. The CIOMS guidelines show that the exclusion of women may result in this group missing out on the knowledge that could have been gained from their participation. The inclusion of woman and other vulnerable groups requires researchers to provide special protection by ensuring that their involvement does not further stigmatise or alienate them (CIOMS, 2016).

6.3 Consistency of InstX REC concerns with Emanuel et al. framework

The ethical concerns raised by the InstX REC in its meetings were consistent with the Emanuel et al. (2004) framework. The common features are described below.

The social value principle was identified in many REC comments. In attending to the issue of social value, relevant comments were grouped into four categories: identification of research beneficiaries; the benefits of research; enhancing social value; and impact of the research findings on the host health system. Although overall there were not many comments relating

to this principle, attention was given by the InstX REC to the identification of research beneficiaries and research benefits. Therefore, the social value of proposed research was considered by the InstX REC as proposed by the Emanuel et al. (2004) framework.

Scientific validity was given major consideration by the InstX REC in the ethics review of protocols. The InstX REC concerns on scientific validity were divided into four categories: utilisation of appropriate design; applicability of results; impact on provision of health care services; and study design feasibility. A majority of comments by the InstX REC were related to the utilisation of appropriate design and methods. The InstX REC comments reflect understanding of scientific validity similar to the framework.

The fair selection of participant is an important aspect in reviewing protocols as it ensures that the selection of participants is fair and it is directly relevant to the research population. The concerns around participant selection were divided into four categories: scientific reasons for the selection of participants; minimisation of risks in selection of participants; target population selected for collaborative partnership; determination if the community selected is vulnerable or some individuals within the community need special measures taken to protect those individuals. The concerns raised by the InstX REC covered all these categories with a majority relating to the selection of participants and minimisation of risks in the selection of participants. The concerns were mainly related to studies with vulnerable population. The InstX REC recognised the importance of selection of participants in a similar fashion as the framework by Emanuel et al. (2004).

The commitment to minimising risks is an ethical obligation for all researchers. In analysing the InstX REC concerns about favourable risk-benefit ratio, three categories were used: risk identification; type, probability and magnitude of benefits; and comparisons of risks and benefits. Most of the comments recorded under this principle related to risk identification and minimisation of risks. There were not many comments under this principle, as many of the studies that were reviewed had low risks.

The general principle that research protocols should receive ethical review before commencing with research is reflected in the InstX REC comments. The concerns of the InstX REC on independent review were relatively few and they were mainly related to issues of transparent process of reviews of multinational studies. The international ethical guidelines indicate that ethical reviews for externally funded studies should be conducted in both funding and host communities.

Informed consent is one of most important principles of research, and the large number of concerns within this principle reflects that the InstX REC regards it as an important issue in research ethics. In analysing the InstX REC concerns relating to the principle of informed consent, the following categories were used: recruitment and incentives; use of appropriate disclosure documents and processes; presentation and accuracy of information; consultations with legal representatives for children; and gatekeeper permission in context of consent and autonomy. Many concerns around informed consent were directed to studies that involved children.

The principle of respect for persons in research can be shown in concerns about monitoring the health of participants, confidentiality, voluntariness, results dissemination and post-research obligations. All these categories received attention from the InstX REC, with confidentiality receiving the highest number of concerns. These concerns were mainly directed to qualitative data and use of databases/records.

6.4 Features of Emanuel et al. framework that dominate the concerns

The features that dominated the InstX REC concerns were informed consent and scientific validity. In terms of informed consent, the committee gave much attention to the ethical obligation of gaining valid informed consent from prospective participants. There were also a considerable number of concerns raised by the InstX concerning the principle of respect for participants; these reflect the ethical issues of ensuring confidentiality of data, the right to withdraw, monitoring the health of participants and informing the community of the results of the research. Although the principles of informed consent and respect for participants were analysed separately, they are part of one ethical obligation of respect for participants in research. As Emanuel et al. (2004) argue, ethical conduct does not end with recruiting participants (i.e. gaining informed consent), but should also guide the treatment of former research participants and the host community.

The InstX REC also gave considerable attention to the quality of research design as reflected in the principle of scientific validity. This is based on the understanding that a poorly designed study will not achieve its intended social value. The other ethical issue that received attention from the InstX REC was fair selection of participants, which should be based on scientific reasons and ought to benefit research participants.

6.5 Other concerns raised by InstX REC

The analysis shows that 10 percent of the InstX concerns were not directly aligned to the framework of Emanuel et al. Issues identified in the minutes that are not consistent with the framework were categorised as other and they relate to spelling errors, use of abbreviations, requests for clarity, timeframes and budgetary issues. These findings indicate that the InstX REC gives greater attention to ethical concerns, substantive issues and less attention to issues of errors and formatting. This finding is contrary to comments by Clapp et al. (2017) that raise concerns about RECs spending too much of their time in ethics review focusing on minor mistakes or errors instead of giving attention to substantive issues (Clapp et al., 2017).

6.6 Study limitations

Content analysis was time consuming as it involved the tedious process of analysing (identification and coding) communications. The process was manual and, taking into consideration the amount of data that was processed, the process may have been vulnerable to error.

Content analysis tends to ignore context; thus one may read the text out of context or read too much out of it (Prasad, 2008). Having not been present in the InstX REC meetings and not having had access to the actual proposals that were reviewed may have led to some aspect of the analysis being read out of context.

There were some overlaps in some of the aspects of the principles that made it not easy to categorise some of the concerns from the minutes. This meant that some of the concerns were relevant to more than one principle. In these cases the concern was placed in one category and counted once. This suggests that the data may contain some coding errors and these should be managed by using multiple coders seeking consensus to improve reliability of similar future studies.

6.7 Summary

This chapter discussed the study findings and these were presented in context of the literature review. A pattern was observed of how the InstX REC dealt with certain types of research, and these include multinational studies and research with vulnerable groups. The findings show that the concerns raised by the InstX REC were aligned to the eight principles of the Emanuel et al. framework. There were only 10 percent of concerns identified from the minutes that were not part of the framework. This shows that ethical concerns are the main issues discussed by the InstX REC during the review of protocols.

CHAPTER 7
CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

A content analysis of the minutes of the InstX REC was conducted to understand the ethical issues that arose when as sample of protocols from 2012 and 2013 were reviewed. The InstX REC concerns when reviewing protocols were many, and included a broad range of issues covered by the Emanuel et al. framework, which was used as a guide in the analysis.

The study findings reveal that most of the protocols reviewed by the InstX REC were social science research. This is not unexpected because the InstX REC was established to review the organisation's social science research protocols. The importance of ethics review for social science research was demonstrated in the ethical concerns raised by the InstX REC. Thus, as suggested by Wassenaar and Mamotte (2012), the Emanuel et al. (2004) framework is relevant to social science research, even though it was initially developed for clinical studies.

The study aims were to identify the main ethical issues raised during ethics review by the Instx REC and assess their relative frequency using Emanuel et al.'s recommended principles for ethics review of clinical research. The four most frequently raised concerns by the InstX REC ranked in descending order: were informed consent (27.4%), scientific validity (21.3%), fair participant selection (14%) and respect for participants (13.9%). Other ethical issues raised by the REC when reviewing protocols were social value (7%), favourable risk-benefit ratio (4%), independent review (1%) and collaborative partnership (1%). Issues considered not part of the Emanuel et al. framework such as mistakes and missing information were also identified and accounted for 10% of the issues raised by the REC.

The four most frequently raised concerns by the InstX REC when reviewing protocols were comparable to ethical concerns of other RECs in South Africa, despite the present study focusing in a REC which reviewed mainly social science protocols, rather than biomedical protocols. The comparison of findings with two published studies using the same methodology on biomedical RECs shows no major difference in the type and frequency of the concerns raised during protocol review. These RECs focused on protecting the rights of participants through informed consent and enhancing the care for participants during and

after research than on other ethics principles. These efforts include ensuring that the selection of research participants in planned research is scientifically motivated.

It was observed from the study findings that the InstX REC raised ethical concerns of community engagement mainly during the review of multinational studies. However, it needs emphasising that this principle applies to all research, irrespective of locality. Evidently, the ethical issue of community engagement is essential for multinational studies in terms of understanding of social context of community and its priorities. Consultations with host community in research will help to ensure that the research is beneficial to the community.

This study is the first known research in South Africa that analysed concerns raised by a social science REC using the Emanuel et al. (2004) framework. The study results will need to be tested using a larger sample of RECs than was the case in this research.

7.2 Recommendations for future research

First, this study focused on an evaluation of ethics concerns of one REC. Further studies of ethical issues of other social science RECs in South Africa, using the same standard methodology, would be useful to get a broader view of the concerns raised by these RECs and the applicability of the Emanuel et al. (2004) framework to assess their reviews.

Second, this study relied on retrospective analysis of REC minutes. Future research should to consider conducting similar studies utilising direct observational methods or designs to eliminate errors that might arise in minute-taking.

Third, a future study could conduct in-depth analysis to assess the extent to which REC decisions/ queries, using he Emanuel et al. (2004) framework, are influenced by ethics committee members' research ethics training and experience.

REFERENCES

Abbott, L., & Grady, C. (2011). A systematic review of the empirical literature evaluating IRBs: What we know and what we still need to learn. *Journal of Empirical Research on Human Research Ethics*, *6*(1), 3-19. doi: 10.1525/jer.2011.6.1.3

Anney, V.N. (2014).Ensuring the quality of the findings of qualitative research: looking at trustworthiness criteria. *Journal of Emerging Trends in Education Research and Policy Studies*, *5*(2), 272-281.

Antonacopoulos, N., & Serin, R. (2016). Comprehension of online informed consents: Can it be improved? *Ethics and Behavior*, *26*(3), 177-193. doi:10.1080/10508422.2014.1000458

Ashcroft, R., & Pfeffer, N. (2001). Ethics behind closed doors: Do research ethics committees need secrecy? *British Medical Journal, 322*, 1294-1296. doi:322.7297.1294

Appelbaum, P., Lidz, C., & Klitzman, R. (2009). Voluntariness of consent to research: A conceptual model. *Hastings Center Report*, *39*(1), 30-39.

Babbie, E. (1994). *The practice of social research*. Belmont, CA: Wordsworth Publishing.

Barchi, F., Singleton, M., & Merz, J. (2014). Fostering IRB collaboration for review of international research. *American Journal of Bioethics*, *14*(5), 3-8. doi:10.1080/15265161.2014.892168

Benatar S., & Fleischer T. (2007). Ethical issues in research in low-income countries. *International Journal of Tuberculosis and Lung Disease, 11*(6), 617-623.

Bhutta, Z. A. (2002). Ethics in international health research: A perspective from the developing world. *Bulletin of the World Health Organisation*, *80*(2), 114-120.

Cahana, A., & Hurst, S. A. (2008). Voluntary informed consent in research and clinical care: An update. *World Institute of Pain*, *8*(6), 446-451.

Chaisson, L., Kass, N., Changeta, B., Mathebula, U., & Samandari, T. (2011). Repeated assessments of informed consent comprehension among HIV-infected participants of a three year clinical trial in Botswana. *PLoS ONE*. *6*(10) 1-9.

Che Chi, P., Horn, L., & Kruger, M. (2014). Risk-benefit assessment. In M. Kruger, P. Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 63-70). Stellenbosch, South Africa: SUN Press.

Clapp, J., Gleason, K., & Joffe, S. (2017). Justification and authority in institutional review board decision letters. *Social Science and Medicine*, *194*, 25-33.

Council for International Organisations of Medical Sciences (CIOMS). (2016). *International ethical guidelines for biomedical research involving human subjects*. Geneva: Author.

Dickert, N., & Sugarman, J. (2005). Ethical goals of community consultation in research. *American Journal of Public Health*, *95*(7), 1123-1127.

Dixon-Woods, M. (2008, October). What troubles research ethics committees? *Clinical Discovery*, 14-15.

Department of Health Republic of South Africa. (2015). *Ethics in Health Research*. Pretoria: Author.

Emanuel, J. E., 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.

Fernandez, C., Kodish, E., & Weijer, C. (2003). Informing study participants of research results: An ethical imperative. *IRB: Ethics and Human Research*, *25*(3), 12-19.

Fitzgerald M., Phillips P., & Yule E. (2006). The research ethics review process and ethics review narratives. *Ethics and Behavior*, *14*(4), 377-395.

Frimpong-Mansoh, A. (2008). Culture and voluntary informed consent in African health care system. *Developing World Bioethics*, *8*(2), 104-114.

Gikonyo, C., Kamuya, D., Mbete,B., Njungana, P., Olotu, A., Bejon, P., Marsh, V., & Molyneux, S. (2013). Feedback of research findings for vaccine trials: Experiences from two malaria vaccine trials involving healthy children on the Kenyan coast. *Developing World Bioethics*, *13*(1), 48-56.

Goodwin, M. (2016). Vulnerable subjects: Why does informed consent matter? *Journal of Law, Medicine and Ethics, 44*, 371-380. Retrieved from 10.1177/1073110516667935Grant, R. W. (2015). Rethinking the ethics of incentive. *Journal of Economic Methodology*, *22*(3), 354-372.

Grady, C. (2015). Institutional review Boards: Purpose and challenges. *Chest, 148*(5), 1148-1155.

Habets, M., Van Delden, J., & Bredenoord, A. (2014). The social value of clinical research. *Biomedical Central Medical Ethics*, *15*(66), 1-7.

Horn, L., Sleem, H., & Ndebele, P. (2014). Research vulnerability. In M. Kruger, P. Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 3-10). Stellenbosch, South Africa: SUN Press*.*

Igoumenidis, M., & Zyga, S. (2011). Healthcare research in developing countries: Ethical issues. *Health Science Journal*, *5*(4), 243-250.

IJsselmuiden, C.B., Marais, D., Wassenaar, D.R., & Mokgatla-Moipolai, B. (2012). Mapping African ethical review committee activity onto capacity needs: The MARC initiative and *HRWeb's* interactive database of RECs in Africa. *Developing World Bioethics, 12,* 74-86. doi:1111/j.1471-8847.2012.00325.x

Joffe, S. (2012). Revolution or reform in human subjects research oversight. *Journal of Law, Medicine and Ethics*, *40*(4), 922-928.

Kass, N. E., Chaisson, L. H., Chengeta, B., Mathebula, U., & Samandari, T. (2011). Repeated assessments of informed consent comprehension among HIV-infected participants of a three-year clinical trial in Botswana. *PLoS ONE*, *6*(10). doi:10.1371/journal.pone.0022696

Koen, J., Slack, C., Barsdorf, 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.

Kombe, F., Anunobi, E., Tshifugula, N., Wassenaar, D., Njadingwe, D., Mwalukore, S., . . . Ranaiyo, N. (2014). Promoting research integrity in Africa: An African voice of concern on research misconduct and the way forward. *Developing World Bioethics*, *14*(3), 158-166.

Kruger, M., & Mokgatla-Moipolai, B. (2014). Children as research participants. In M. Kruger, P. Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 91-98-71). Stellenbosch, South Africa: SUN Press.

Lairumbi, G., Molyneux, S., Snow R. W., Marsh, K., Peshu, N., & English M. (2008). Promoting the social value of research in Kenya: Examining the practical aspects of collaborative partnerships using an ethical framework. *Social Science and Medicine*, *67*(5), 737-747.

Lema, V. M., Mbondo, M., & Kamau, E.M. (2009). Informed consent for clinical trials: A review. *East African Medical Journal*. *85*(3), 133-142.

Lindegger, G., & Bull, S., (2002) Ensuring valid consent in a developing country context. Retrieved from http://www.scidev.net/dossiers/ethics/erpolicy_lidegger_bull.html

Lutge, E., Slack, C., & Wassenaar, D. (2017) Defining and negotiating the social value of research in public health facilities: Perceptions of stakeholders in a research-active province of South Africa. *Bioethics*, *31*(2), 128-135.

Mayring, P. (2014). *Qualitative Content Analysis: Theoretical foundation, basic procedures and software solution*. Retrieved from www.beltz.ze

McGuinness, S. (2008) Research Ethics Committees: The role of ethics in a regulatory authority. *Journal of Medical Ethics*, *34*(9), 695-700.

Macklin, R. (1999). Understanding informed consent. *Acta Oncologica*, *38*(1), 83-87.

Miller, F., Hayeems, R., Bytautas, L., & Bytautas, J. (2012). What does 'respect for persons' require? Attitudes and reported practices of genetics researchers in informing research participants about the research. *Journal of Medical Ethics*, *38*(1), 48-52.

Mkhize, N. (2006). Communal personhood and the principle of autonomy: The ethical challenges. *Continuing Medical Education*, *24*(1), 26-29.

Montalvo, W., & Larson, E. (2014). Participant comprehension of research from which they volunteer: Systematic review. *Journal of Nursing Scholarship*, *46*(6), 423-431.

Mutenherwa, F., & Wassenaar, D. R. (2014). Ethics review of social and behavioural research in an African context. In M. Kruger, P. Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 117-124). Stellenbosch, South Africa: SUN Press.

Ndebele, P., Mwaluko, G., Kruger M., Oukem-Boyer, O. O. M., & Zimba, M. (2014). History of research ethics in Africa. In M. Kruger, P. Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 3-10). Stellenbosch: Sun Press.

Ndebele, P., Wassenaar, D., Munalula, E., & Masiye, F. (2012) Improving understanding of clinical trial procedures among low literacy populations: an intervention with a micrbicide trial in Malawi. *BMC Medical Ethics*, 13(29), 1-14. Retrieved from www.biomedcentral.com/1472-6939/13/29

Nuffield Council on Bioethics. (2014).*The ethics of research related to healthcare in developing countries*. Nuffield Council Report on Bioethics. Retrieved from www.nufflieldbioethics.org

Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya. (2013). Consent and Community in diverse research contexts. *Journal of Empirical Research on Human Research Ethics, 8*(4), 1-18.

Prasad, B. (2008) Content analysis: A method of social science research. In D. Lal Das, & V. Bhashkharan (Eds.), *Research methods for social work*. (pp. 173-103). New Delhi: Rawat.

Rid, A., & Wendler, D. (2011). A framework for risk-benefit evaluations in biomedical research. Zurich Open Repository and Archive, University of Zurich, 140-179. Retrieved from https://doi.org/10.1353/ken.2011.0007

Rothstein, M. A. (2002). The role of IRBs in research involving commercial biobanks. *Currents in Contemporary Ethics*, *30*(1), 105-109.

Rwabihana, J., Girre, C., & Duguet, A. (2009). Ethics committees for biomedical research in some African emerging countries: Which establishment for which independence? A comparison with the USA and Canada. *Journal of Medical Ethics*, *36*(4), 243-249. Retrieved from http://www.jstor.org/stable/20696772

Schrag, Z. M. (2011). The case against ethics review in the social sciences. *Research Ethics*, *7*(4), 120-131.

Shah, S., Whittle, A, Wilford, B., Gensler, G. & Wendler, D. (2004). How do Institutional Review Boards apply the federal risk and benefit Standards for pediatric research? *Journal of American Medical Association*, *291*(4), 476-482.

Shenton, A.K. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information*, *22*, 63-75.

Slack, C., Lindegger G., Vardas, E., Richter, L., Strode, A., & Wassenaar D. (2000). Ethical issues in HIV vaccine trials in South Africa, *South African Journal of Science*, *96*, 291-295.

Silaigwana, B. (2017) *Empirical investigation of ethical issues raised by two research ethics committees reviewing biomedical research in South Africa*. Unpublished PhD thesis, Pietermaritzburg: University of KwaZulu-Natal.

Silaigwana, B., & Wassenaar, D. R. (2019). Research ethics committees' oversight of biomedical research in South Africa: A thematic analysis of ethical issues raised during ethics review of non-expedited protocols. *Journal of Empirical Research on Human Research Ethics* DOI: 10.1177/1556264618824921

Siminoff, L. A. (2003). Toward improving the informed consent process in research with Humans. *IRB: Ethics and Human Research*, *25*(5), S1-S3. Retrieved from http://www.jstor.org/stable/3564115

Simwinga, M., & Kabero, C. (2014). Community engagement. In M. Kruger, P. Ndebele, & L. Horn (Eds). *Research ethics in Africa* (pp. 143-152). Stellenbosch, South Africa: SUN Press.

Singh, S., & Wassenaar, D. (2016). Contextualising the role of the gatekeeper in social science research. *South African Journal of Bioethics and Law*, *9*, 142-46.

Singleton, R. A., Straits, B. C., & Straits, M. M. (1993). *Approaches to social research.* New York, NY: Oxford University Press.

Strode, A. E., & Slack, C. M. (2011). Using the concept of parental responsibilities and rights to identify adults able to provide proxy consent to child research in South Africa. *South African Journal of Bioethics and Law, 4*(2), 69-73.

Strode, A. E., Toohey, J., Singh, P. & Slack, C.M. (2015) Boni mores and consent for child research in South Africa. *South African Journal of Bioethics and Law, 8*(1), 22-25.

Tekola, F., Bull, S., Farsides, B., Newport, M., Adeyemo, A., Rotimi, C., & Davey G. (2009). Tailoring consent to context: Designing an appropriate consent process for a biomedical study in a low income setting. *PLoS Neglected Tropical Diseases, 3*(7). doi: 10.1371/journal.pntd.0000482

Tindana, P., Singh J., Tracy, S., Upshur, R., Daar, A., Singer, P., & Lavery, J. (2007). Grand challenges in global health: Community engagement in research in developing countries. *PLOS Medicine*, *4*(9), 1451-1455.

Tsoka-Gwegweni, J., & Wassenaar, D. R. (2014). Using the Emanuel framework to examine ethical issues raised by a biomedical research ethics committee in South Africa. *Journal of Empirical Research on Human Research Ethics, 9*(5), 36-45.

Tyldum, G. (2012). Ethics or access? Balancing informed consent against the application of institutional, economic or emotional pressures in recruiting respondents for research. *International Journal of Social Research Methodology*, *15*(3), 199-210. doi:10.1080/13645579.2011.572675

U.S. Department of Health and Human Services (USDHHS). (1979). *Belmont Report*. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

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, NY: Oxford. DOI: 10.1093/oxfordhb/9780199739165.013.0019

Wasunna, C., Tegli, J. & Ndebele, P. (2014). Informed consent in an African context. In M. Kruger, P., Ndebele, & L. Horn (Eds.), *Research ethics in Africa* (pp. 57-6271). Stellenbosch, South Africa: SUN Press.

Wendler, D., Rackoff, J., Emanuel, E., & Grady, C. (2002). The ethics of paying for children's participation in research. *Journal of Paediatrics, 141*(2), 166-171.

Wonkam, A., Kenfack, M. A.,Muna, W. F. T. & Oukem-Boyer, O. (2011). Ethics of human genetic studies in Sub-Saharan Africa: The case of Cameroon through a bibliometric analysis. *Developing World Bioethics*, *11*(3), 120-127.

World Health Organization. (2009). *Research ethics committees: Basic concepts for capacity-building.* Geneva: World Health Organization. Retrieved from http://www.who.int/ethics/publications/9789241598002/en/

World Medical Association (WMA). (2013). *Declaration of Helsinki: Ethical principles for medical research involving human subjects*. *JAMA*, *310*(20), 2191-2194. doi: 10.1001/*jama*.2013.281053

Zielinski, C., Kebede, D., Mbodji, P. E., Sanou, I., Kouvividila, W., & Lusamba-Dikassa, P. (2014). Research ethics policies and practices in health research institutions in sub-Saharan African countries: results of a questionnaire-based survey. *Journal of the Royal Society of Medicine*, *107*(IS), 70-76.

APPENDIX A

COPY OF UKZN ETHICS CLEARANCE LETTER

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

09 May 2017

Dr Sibusisiwe Bengu (Student No: 215080965) (RSA)
c/o Prof D Wassenaar
Discipline of Psychology
School of Applied Human Sciences
wassenaar@ukzn.ac.za

CLASS APPROVAL

Protocol: Ethical issues raised by African Research Ethics Committees.
***BREC reference* number:** BCA342/16 *(HSS/1450/014CA)*

The Biomedical Research Ethics Committee has considered and noted your application dated 31 May 2016.

The conditions have been met and the study is given **full ethics approval with effect from the date of the original full approval by UKZN HSSREC (*HSS/1450/014CA*). Your response dated 03 May 2017 in response to BREC letter dated 13 September 2016 has been noted by BREC.**

This approval is valid for one year from **09 May 2017.** 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 **13 June 2017.**

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: **Dr Sibusisiwe Bengu**
Postgraduate officer: khanyilet@ukzn.ac.za

Biomedical Research Ethics Committee
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APPENDIX B

DATA COLLECTION PRO FORMA (DATA COLLECTION SHEET)

REC Codename: _____

For minutes of each protocol reviewed, code the frequency with which the following issues were raised (some issues can occur several times in the review of a single protocol).

Protocol no:	Collaborative Partnership	Social Value	Scientific Validity	Fair Selection	Risk-Benefit Ratio	Informed Consent	Independent Ethics Review	Other 1	Other 2	Other 3

APPENDIX C

COPY OF InstX PERMISSION LETTER

(Withheld to preserve anonymity; Copy available for audit purposes)

APPENDIX D

PROFILE OF PROTOCOLS

Year	Study design	Participants	Data source
2012			
1 (external)	Descriptive (health-related study) retrospective	Children and adults	Secondary data
2 (external)	Descriptive (health-related study) retrospective	Adults	Secondary data
3 (internal	Descriptive (Indicators)	Adults and children	Primary data
4 (external)	Explanatory (testing eye health service)	Youth and adults (16-20 years)	Primary data
5 (internal)	Descriptive (comparing roles)	Adults	Primary data
6 (multinational)	Explanatory (effectiveness of a training model)	Adults	Primary data
7 (external)	Descriptive (barriers to enrolling)	Adults (clinicians)	Primary data
8 (internal)	Exploratory study (exploring)	Adults	Primary data
9 (internal)	Descriptive (tracking system)	Adults	Primary data
10 (external)	Descriptive (monitoring - education)	Adults and children	Primary data (identified through school register)
11 (internal)	Explanatory (design assessment)	Adults	Primary data
12 (multinational)	Explanatory (impact evaluation)	Adults	Primary data
13 (external)	Exploratory (health-related study)	Youth	Primary data
14 (internal)	Descriptive	Adults	Primary data
15 (internal/ multinational)	Descriptive (health-related study)	Youth	Primary data
16 (multinational)	Descriptive (towards and understanding)	Adults	Primary data
17 (multinational)	Explanatory (health-related study)	Adults and children	Secondary data (clinical records and publications) and blood samples analysis)
18 (external)	Explanatory (evaluating/health-related study)	Adults	Primary data (retrospective

Year	Study design	Participants	Data source
			identification of clients based on client clinic records)
19 (external)	Explanatory (evaluation/health-related study)	Adults	Secondary data (stored samples of routine testing, records)
20 (multinational)	Exploratory	Youth 16 -18 years (High school children)	Primary data
21 (external)	Explanatory (evaluating/health-related study)	Adults	Primary data
22 (external)	Explanatory (evaluating/health-related study)	Youth 16-19 years	Primary data
23 (internal)	Descriptive (health-related study)	Adults	Primary data
24 (internal)	Descriptive (health-related study)	Adults	Primary data
25 (internal)	Descriptive (Chinese presence)	Adults	Primary data
26 (internal)	Descriptive (alcohol advertising)	Adults	Primary data
27 (internal/ multinational)	Descriptive (health-related study)	Adults	Primary data
28 (external)	Descriptive (education)	Adults	Primary data
29 (internal)	Explanatory (evaluation study)	Adults	Primary data
30 (internal/ multinational)	Descriptive (education)	Adults	Primary data
31 (internal)	Descriptive (education)	Adults	Primary data
32 (internal)	Descriptive (strategy)	Adults	Primary data
2013			
33 (internal)	Descriptive (programme)	Adults 12	Primary data
34 (internal)	Descriptive (education)	Children (11 to 13 years)	Primary data
35 (internal)	Descriptive (migration)	Adults	Primary data
36 (external)	Descriptive (health-related study)	Children and adults	Primary data
37 (multinational)	Explanatory (health-related study)	Adults	Primary data
38 (external)	Experimental/explanatory (health intervention study	Adults	Primary data
39 (external)	Descriptive (profiling migrant	Children	Primary data

Year	Study design	Participants	Data source
	children)		
40 (internal)	Descriptive (education)	Adults	Primary data
41 (external)	Explanatory (evaluation/health-related study)	Children and adults	Primary data
42 (external)	Explanatory (health-related study)	Children	Primary data
43 (internal)	Explanatory (diagnostic study)	Adults	Primary data
44 (external)	Explanatory (evaluation/health-related study)	Youth	Primary data
45 (multinational)	Explanation (evaluation/health related study)	Adults	Primary data
46 (internal)	Descriptive	Adults	Primary data
47 (internal)	Descriptive	-	Secondary data
48 (multinational)	Descriptive (health-related study	Adults	Primary data
49 (internal)	Descriptive	Adults	Primary data
50 (internal)	Descriptive	Adults	Primary and secondary data
51 (internal)	Exploratory	-	Secondary data
52 (internal)	Descriptive	Adults	Primary and Secondary data
53 (internal)	Descriptive	Adults	Primary and Secondary data
54 (internal)	Explanatory (health-related study)	Adults	Primary data
55 (external)	Descriptive	Adults	Primary data
56 (external)	Descriptive (education)	Adults	Primary and Secondary data
57 (internal)	Descriptive	Adults	Primary data
58 (external)	Exploratory and descriptive		Secondary data
59 (external)	Explanatory	Children and adults	Primary data
60 (internal)	Descriptive	Adults	Primary data
61 (multinational)	Descriptive (evaluation/health-related study)	Adults	Primary data
62 (external)	Descriptive	Adults	Primary data
63 (external)	Descriptive	children	Primary data