UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

INVESTIGATING NON-MEDICAL ETHICS COMMITTEE MONITORING APPROACHES AND ITS EFFECTIVENESS

By

Shaun Schoeman

2324209

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Supervisor: Dr Caitlin Blaser-Mapitsa

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ABSTRACT

Ethics committee monitoring aims to ensure that research participants are protected throughout the research process and to ensure that research is conducted ethically. This study investigates monitoring approaches used by non-medical ethics committees within South Africa in a climate of limited resources and the relationship with the governing guidelines. The study further investigates the current monitoring approaches that are used and how effective these are in relation to participant protection. The study found that the current monitoring approaches used by non-medical ethics committees are passive as opposed to active. Non-medical ethics committees face challenges such as limited resources, funding, training, and ineffective guidelines that hinder their ability to monitor more effectively.

The governing monitoring guidelines for registered ethics committees are premised on medical ethics, which is not fit the purpose of non-medical ethics committee monitoring. The study proposes adjustments to these governing guidelines, taking limited resources and non-medical nuances into consideration. The study further suggests that passive monitoring be redefined to include more effective methods than just annual progress reporting. These methods include participant meetings or citizen monitoring to ensure that participants are protected, and that research is conducted ethically.

Key Words: Monitoring, Non-Medical Ethics Committees, Guidelines, Passive Monitoring, Active Monitoring.

DECLARATION

As a requirement for my Master of Management: Governance (Public and Development Sector Monitoring and Evaluation) at Wits School of Governance, I, Shaun Schoeman (Student No. 2324209), certify that this research paper is entirely original. Except in cases where I have made it clear otherwise, I did not submit it somewhere else.

Signed on the 24 February 2024 at Roodepoort.

DEDICATION

This research report is dedicated to my loving husband, son, and mom, who stood by my side throughout my study journey. I am grateful to my husband and son for supporting me and being my biggest cheerleader throughout this journey. I dedicate this research report to my mom, who sacrificed so much so that I could achieve my goals.

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1. CHAPTER 1: INTRODUCTION

1.1. Introduction and Background

The literature is premised on monitoring ethics studies within the medical sphere. However, within a South African context there is limited research regarding suitable monitoring frameworks for university non-medical monitoring, that successfully fulfils the role of effective monitoring beyond the clearance process. Chatfield et al. (2021), contend that medical studies often have sponsor-funded monitoring procedures in place to ensure adherence to ethical standards. However, numerous non-medical research studies have restrained budgets, resources, or inappropriate frameworks in place for adequate monitoring.

Any research study involving the collection of data from human participants must have ethical clearance. South African universities that review and approve ethics applications conform to and are registered with the National Health Research Ethics Council (NHREC) to ensure that ethical standards are adhered to throughout the data collection process. According to Davies (2020) research ethics committees are part of university administration and have become an integral review mechanism for universities to ensure research is conducted responsibly, while at the same time safeguarding human rights and guaranteeing scientific merit. An independent body with members with backgrounds in both science and nonscience, an Ethics Committee (EC) works to protect research participants' safety and human rights by adhering to six fundamental principles: justice, autonomy, beneficence, nonmaleficence, honesty, and confidentiality (Mehta et al., 2023).

Aspects such as confidentiality, anonymity, research instruments, participant information sheets, informed consent documents, etc., are all considered when ethics review and approval take place. However, to guarantee that ethical standards are maintained throughout the data collection process, the ethics committee's function should actively go beyond the review and approval procedure and be required to monitor research studies even after ethics clearance has been granted. Karunaratne et al. (2006), state that in addition to ethics committees reviewing and approving research proposals prior to the study commencing, they are also liable for monitoring studies as they progress. In support, Davies (2018) purports that the only way to ensure the safety of human participants in research studies is for ethics committees to monitor studies they approve. Dawson et al. (2019), who advance the notion of monitoring, argue that applying and receiving ethics clearance has seemingly become a tick-box exercise as a result,

fails to understand the seriousness of ethics and does not advance careful, considered thinking regarding the ethics involved.

Gauteng universities' non-medical ethics committees follow strict review and approval procedures as opposed of strict monitoring procedures to fulfil the duty of safeguarding human rights and safety after ethics have been obtained. According to Ochieng et al. (2013), globally there are many ethics committees that do not monitor studies for compliance with the necessary ethical values and scientific standards. As a result, there is an increased chance of nonconformity, which could jeopardise the safety and rights of research participants even more (Ochieng et al., 2013). Davis (2018) is of the same opinion, and states that active monitoring would allow ethics committees to recognise deviations from approved protocols that were not initially discovered in the progress or annual reports.

The NHREC specifies that registered university research ethics committees follow the Department of Health (DoH) 2015 guidelines, and monitoring (passive and active monitoring) approved research protocols are one of the responsibilities that ethics committees are liable for. According to DoH (2015) ethics committees are tasked with the responsibility to look after the interests (referring to rights and wellbeing) of participants who voluntarily participate in scientifically comprehensive studies. According to the DoH (2015) guidelines, annual reports outlining ethical concerns, the status of the project, and the outcomes at the end of the project must be submitted for post-approval monitoring. The guidelines recommend that additional monitoring activities be adopted, such as site visits, records of data collection methods, completed consent forms to be reviewed, etc. (DoH, 2015). At Gauteng universities, the ethics committee monitors by way of annual report submission, and researchers applying for amendments, if necessary, thereafter the monitoring documents are filed. The guidelines also delegate that non-medical ethics committees conduct active monitoring by way of site visits as part of their active monitoring efforts. However, this may not be applicable in the non-medical sphere, especially considering studies involving vulnerable participants, confidentiality, and anonymity concerns, and reflecting on the nuances in non-medical research.

According to Mulondo et al. (2022), the NHREC mandates that all registered ethics committees approving research that involves human participants conform to the same guidelines regardless of whether they review and approve medical research or social science research. The DOH (2015) guidelines are based on medical ethics and concentrate on the nuances of medical ethics, like clinical trials, with an emphasis on site visits for monitoring. Medical ethics is given preference in the DoH (2015) guidelines, and non-medical ethics committee processes and

procedures, particularly those related to monitoring, often must comply with these guidelines. Shetty et al. (2019) purport that medical ethics committees are responsible for monitoring clinical trials to guarantee that research is conducted ethically. However, monitoring by way of site visits may not be appropriate in terms of the non-medical research scope. This is re-iterated by Ramcharan and Cutcliffe (2001), who advance a need for a fair mechanism of adjudicating research of a qualitative nature, and it involves an appropriate monitoring process of the ethics all through the research. Ramcharan and Cutcliffe (2001) suggest that monitoring should be used as a way of adjudicating the ethics of qualitative research and further suggest that monitoring should take on the form of reviewing the research during and reviewing the outcome of the research. Investigating monitoring approaches and their effectiveness is relevant to the public sector as it contributes to broader research management and contributes to protecting members of society participating in research studies. Furthermore, considering the monitoring approaches and the guidelines that govern these approaches may be relevant to the public sector in terms of ensuring justice and guarding against any exploitation that may occur within research.

1.2. Study Aims

The study aims to investigate if the current monitoring strategies employed by university non-medical ethics committees are successful in ensuring human protection during the data collection process. More precisely, this research endeavours to explore how factors like institutional capability, appropriate guidelines, training, appropriate frameworks for monitoring, and the complexities of social science research influence how monitoring should be conducted in a non-medical setting that adequately fulfils the ethical requirements without impeding the research process. The study further aims to determine whether the monitoring guidelines should be modified to ensure that they are appropriate for non-medical research ethics committees. Finally, aims to ascertain if the current monitoring approach used if effective in terms of participant protection and ethics committee mandates.

1.3. Problem Statement

Monitoring studies is an approach used to safeguard that participant interests, rights, and protection are taken into consideration during the data collection process. Monitoring studies approved by a registered South African university ethics committee can be classified as either passive and active, and using either active or passive is influenced by numerous aspects such

as capacity resources, study risk level identified, appropriate guidelines, an adequate framework to monitor, and the specified training needs for monitoring. Davis (2018) purports that there are numerous hindrances (capacity, insufficient training of committee members to conduct monitoring, and a lack of proper infrastructure and appropriate guidelines for monitoring) that influence the ethics committee's capability to monitor studies that they approve.

To guarantee that ethical standards are upheld throughout the data collection process, ongoing monitoring should be a crucial part of the ethics clearance process. This extends to how informed consent is obtained if a thorough explanation of the research is given (risk and benefits, if any) to participants and how, if applicable, any adverse events are managed and reported. The literature supports the responsibility of post-approval monitoring. However, there is a gap in the literature around specific and appropriate guidelines to be applied to monitoring in a South African university non-medical context, bearing in mind the constraints faced by non-medical ethics committees within South Africa. Thus, this research is focused on how monitoring is conducted, the form/framework it takes within the non-medical ethics committee sphere, and the relationship with the governing guidelines. Therefore, research is required regarding suitable non-medical monitoring frameworks in the context of limited capacity and limited financial resources, as well as the intricacies of social sciences research and the proper level of monitoring in this regard. The need to comprehend the current South African university monitoring approaches and how they translate into identifying ethical compliances or ethical deviations during fieldwork is therefore required.

1.4. Research Question

The research will emphasize the main and sub-research questions. The main research question for this study is:

How effective are university non-medical monitoring approaches and how do the current guidelines for non-medical research aided in ensuring ethical standards are adhered to during the data collection process?

The main research question will be addressed through the sub-questions in section 1.4.

1.5. Sub-questions

- How effective are the South African guidelines with regard to monitoring non-medical research in the context of limited resources and capacity?
- How can South African monitoring guidelines be adjusted to fit the non-medical research ethics space to ensure effective ethics compliance throughout the data collection process?

1.6. Research Purpose

The purpose of the study is to find out how effective the current monitoring are in relation to participant protection. The purpose of the study is to find out how experts, members, and chairs of non-medical ethics committees view the current monitoring guidelines and how well they fulfil the duty of guaranteeing ethical compliance during the data gathering process. The study also looks at how the guidelines could be modified to guarantee that monitoring is carried out in a way that satisfies the standards of non-medical research ethics while considering the financial and human resources constraints.

1.7. Key Findings

South African non-medical university ethics committees use the passive monitoring approach by way of submission of annual/progress reports by researchers, which is reliant on the researcher's integrity. The study found that the current guidelines for monitoring do not aid in ensuring researchers are ethical during data collection, and other factors may influence this sphere. As non-medical resources operate within a limited resources environment, the guidelines do not consider these aspects. Finally, the study found that the monitoring guidelines should be adapted to fit the scope and type of research that non-medical ethics committees review and approve.

1.8. Structure of the Report

Chapter 1: Introduction and Background

This chapter provides an overview and purpose of the research study. This section includes the study aims, problem statement, research question, and research sub-questions.

Chapter 2: Literature Review

This chapter discusses the literature on the functioning and monitoring of ethics committees, considering all factors that influence how ethics committees monitor the research they approve.

Based on earlier research, a conceptual framework has been created to achieve the study's goals.

Chapter 3: Research Methodology

This chapter outlines the research methodology undertaken in the study. A qualitative research methodology was used, and nine participants were interviewed.

Chapter 4: Data Presentation and Findings

This chapter presents the findings of the study. The main findings of the study are that monitoring is not effectively conducted at South African universities due to various factors such as limited resources and inappropriate guidelines for monitoring.

Chapter 5: Data Analysis and Findings

This chapter is dedicated to analysing the data from the interviews conducted, considering previous literature. Codes and themes have emerged based on the findings of the interviews and the conceptual framework.

Chapter 6: Recommendations and Conclusion

This chapter will outline recommendations, considerations for the field of monitoring, limitations of the study, and the conclusion.

2. CHAPTER 2: LITERATURE REVIEW

The literature review chapter outlines existing literature on ethics committee monitoring and the gaps that exist in the sphere of non-medical monitoring. This study will look at the challenges around non-medical university ethics committee monitoring and the relationship with the governing guidelines. Registered non-medical university ethics committees are registered with the National Health Research Ethics Council (NHREC), which stipulates the guidelines for all registered ethics committees. These guidelines are premised on medical research, and non-medical ethics committees are expected to follow these guidelines as well whether suitable or not. There are gaps in the literature around suitable guidelines and frameworks for monitoring non-medical research. The literature emphasises the importance of monitoring. However, challenges exist in executing monitoring effectively to protect human participants. Scholars speak to limited capacity, resources, appropriate guidelines, frameworks, and training as fundamental reasons for no monitoring or ineffective monitoring. This study will build on the literature in this space from a South African university perspective. The study will further engage with existing literature concerning how the guidelines governing monitoring affect how non-medical ethics committees conduct this function. This study builds on existing literature by proposing a conceptual framework that may aid in monitoring non-medical research. The study further challenges the requirement for active monitoring for non-medical ethics committees and contributes to the literature by looking at other methods that may fit between passive and active monitoring.

The need for additional research is growing as the world changes, and most of the time that means gathering data from human participants. Kaur et al. (2017), Davies (2020), and Head (2020) purport that a registered ethics committee must accept research studies involving human beings before they may start with data collection, as stated by the Declaration of Helsinki. To ensure that research conducted at South African universities are ethical, and complies with established ethical norms, research ethics committees are essential. Ethics committees oversee assessing research ideas and making sure that they adhere to moral standards and laws, particularly those governing the ethical treatment of human participants, and the ethical conduct of research.

Globally, research ethics committees serve the dual purpose of ensuring that research is conducted ethically, and protecting the rights, welfare, and interest of human participants during their participation in studies. Silaigwana and Wassenaar (2015), Grady (2015), Davies

(2020), and Moon et al. (2019) purport that in addition to protecting the rights of human participants, research ethics committees must make sure that research is carried out in an ethical and responsible manner.

2.1. Monitoring non-medical research in the South African context

2.1.1. Monitoring as an obligatory function of South African non-medical university ethics committees

Before to any data on human participants can be collected, all research involving human participants, whether it be in the medical field or within the social science field, it must undergo an ethics review, and be approved. Research ethics committees are required to carried out specific tasks to confirm that ethical standards and ethical conduct take place when collecting data from human participants. These tasks range from protocol review, protocol approval, and post-approval monitoring to ensure ethical principles were maintained during the data collection process. According to Kaur et al. (2017) and Owusu et al. (2022), the primary responsibility of the research ethics committee is to ensure that research is carried out in an ethical manner, and that research is scientifically adequate. Ethics committees may not have direct oversight during the data collection process, thereby relying on other forms of monitoring to ensure data was collected ethically, human protection was maintained, and the research was conducted as approved. Monitoring can be classified as either passive or active.

A mechanism to ensure that ethical standards and compliance are adhered to when collecting data from human participants is post-approval monitoring after a registered ethics committee has approved studies. Brown et al. (2013) argues that monitoring after a protocol has been approved can help identify research misconduct and ethical violations and prevent them from happening altogether. Kombe et al. (2014), who conducted a study on "Promoting research integrity in Africa", purport that monitoring is one element that could be used to foster research integrity whereby ethics committees should be given more capacity funding and should be strengthened to perform the function of monitoring approved studies to minimise research misconduct. However, universities do not view ethics committees as a high priority, and therefore, minimal funding and human resources are allocated to university ethics committees for their functions (Moodley and Myer, 2007).

Usually, ethics committees accumulate funds from external applicants who apply and pay for ethics reviews, and these are often used for training requirements (Moodley and Myer, 2007). This places ethics committees in a position of having to fulfil the ethics committees' mandates but not providing the adequate tools and funding to do so. Conducting sound research, and

protecting participants, and avoiding research misconduct should be a top priority for universities, and adequate resources should be allocated to ethics committees to perform these functions.

Funding and human resources impact how monitoring transpires for ethics committees at South African tertiary institutions. Grady (2015) and Pickworth (2000) argue that ethics committees are overburdened, and the nature of committee work is voluntary; excessive/active monitoring is seen as an added responsibility and may not be appropriate. According to Moodley and Myer (2007) there have been uncertainties raised about the possibility that ethics committees in underdeveloped nations may not support high standards of research participant security because of a lack of funding and properly qualified human resources. It's necessary to monitor studies that have been approved. However, because of a lack of funding and resources, it is rarely actively carried out, which poses a risk to research being conducted ethically. Boateng et al. (2014) and DeMets et al. (2006) argue that post-approval monitoring is viewed as fundamental and an essential duty to be conducted by ethics committees. However, for a variety of reasons, it's usually not done well enough, which makes it increasingly difficult to determine if the research was conducted as planned and approved by the research ethics committee (Boateng et al., 2014). This is confirmed by Wassenaar and Mamottee (2012), who argue that within the social science space, many research ethics committees have limited resources. As a result, post-approval monitoring is neglected, and ethical compliance is now dependent on the honesty of the researcher, with the research ethics committee playing a marginal role in ensuring that the authorised proposal is followed.

Research misconduct can range from protocol deviation without reporting it to the relevant ethics committee, faulty consent processes being used, and neglecting to report serious adverse events, which all lead to compromising participant safety and rights and research findings. Therefore, the monitoring strategy used to ensure research is carried out ethically is essential, and ought to be effective enough to result in sound ethical research being conducted in the field. Literature on the need for monitoring is extensive. However, debate exists around the extent of monitoring and the form it takes. Pickworth (2000) further argues that extensive monitoring may not be appropriate in a non-medical space because it could cause challenges between researchers and ethics committees as it is seen as a policing exercise and less trust is placed on the researcher.

Davis (2018) purports that monitoring to be conducted as prescribed by oversight boards often requires human resources, funding, adequate infrastructure, appropriate guidelines, and

adequately trained staff. This is often not the case at most South African universities. Funding is usually used for administration and training as opposed to monitoring functions (Pickworth, 2000).

2.1.2. Passive Monitoring

South African university's non-medical ethics committees opt for the passive approach to monitoring by way of submission of annual/progress reports because the review and approval process is rather rigorous. This process relies on the researcher's integrity. Researchers are often required to undergo an ethics training course to demonstrate that they are aware of and take into consideration ethical aspects of data collection. Ethics committees further categorise research studies into appropriate risk levels, which assists in determining how monitoring should be conducted. A high-risk study would require a more rigorous monitoring approach as opposed to a minimal-risk study. A high-risk study will require two or more annual/progress reports per year, whereas a minimal study requires one report per year.

An effective monitoring approach will assist ethics committees in detecting research misconduct and ethical violations early enough to prevent it or at least correct it without major repercussions. The validity of the passive monitoring approach is often questioned. According to Ochieng et al. (2013), ethics committees cannot only depend on annual reports submitted by researchers, as in many cases, researchers act unethically.

In contrast, some scholars argue that there may not be a need for an extensive monitoring approach because the review and approval processes are adequate in educating researchers on being ethical and protecting human research participants. Kombe et al. (2014) further argue that ethics committees cannot be the sole body that promotes good and ethical research conduct but that it should be a collective venture involving the entire research community (universities, schools, and supervisors). Each player within the research community has a responsibility to be aware and alert in preventing or reporting unethical behaviour and research misconduct (Kombe et al., 2014).

2.2. Adjusting South African monitoring guidelines to fit the non-medical research ethics space

In South Africa, registered university ethics committees are underpinned by the DoH (2015) guidelines established by the NHREC and serve the purpose of establishing a national minimum set of guidelines and standards for conducting ethical and accountable research (DoH, 2015). Monitoring approved studies forms part of what ethics committees are required

to do to ensure that participants are safeguarded and that ethical standards are met. Brown et al. (2013) purport that university ethics committees are liable to conduct post-approval monitoring because it warrants continued human participation protection.

The DoH (2015) guidelines are premised on health research, which established South African university-registered non-medical ethics committees must observe and comply by. Knight (2019) argues that ethics guidelines are informed by procedures and processes designed for, medical research and further argues that there are limitations in terms of the extent to which these guidelines can be suitable to non-medical research settings. Knight (2019), questions whether these guidelines are appropriate for non-medical research, because the guidelines do not speak to research methods primarily used within the social science field. In essence, guidelines are required to assist processes in achieving their purpose. However, if guidelines do not consider nuances within the process, it could result in the guidelines serving as a barrier rather than an enabler to research ethics committees. Although the guidelines cover an array of ethics committees, it cannot be a one-size-fits-all approach, as there are nuances that exist within each committee. These need to be catered for. For this reason, the study investigates ethics committee monitoring and how guidelines either aid or pose a barrier in this area.

Wassenaar and Mamotte (2012) and Head (2020), both state that ethics evaluation is becoming an increasing prerequisite for social science research globally. Head (2020) suggests that new ethical guidelines are required to address real-world ethical issues that arise in the social sciences sphere. Knight (2019) agrees and argues that new research methods and new participant groups are at the disposal of researchers, and this opens avenues to new ethical challenges related to ethical issues, such as consent, anonymity, discretion, and confidentiality, which are not addressed by the guidelines currently in place for social science research. Kombe et al. (2014) stated that Africa requires structures, policies, standards, guidelines, and governance arrangements that encourage ethical research, and ethical conduct. This raises the question of how appropriate the current norms are, and how progressive they are considering emerging standards in the field of social science research, which the study aims to address. A need to adjust the current guidelines is therefore required.

2.3. Theoretical Framework

University ethics committees in South Africa are primarily responsible for reviewing and approving research studies. Non-medical ethics committees place little emphasis on monitoring due to a lack of a suitable structure and monitoring procedures. This is further plagued by

limited resources to perform this function. There is no specialized training available in South Africa that addresses proper monitoring for non-medical research. A wealth of literature exists regarding the proper methods for conducting monitoring for medical and animal research studies, and most of them offer a useful framework and checklist for carrying out this task. Davies (2018) proposes a framework that enumerates specific elements that must be verified to fully satisfy the requirements for overseeing the ethics of a medical study following ethics approval.

Currently, university non-medical ethics committees do not have a suitable framework in place that guides committees in terms of what is required when monitoring non-medical studies. A universal checklist detailing exactly what must be checked and fulfilled in terms of ethics will provide a framework that non-medical ethics committees can use when monitoring to ensure participant protection.

The theoretical framework suggested by the researcher as the most suitable framework for this study is based on the framework developed by Davis (2018). Davis (2018) advances a process that ethics committees follow for continuing monitoring by way of a suitable checklist developed for monitoring approved studies. This process involves a checklist primarily used for on-site monitoring and captures the following domains: the consent form that was used, the availability of site standard operating procedures (SOP), the reporting of serious adverse events, protocol deviations and violations, and complaints received and how it is dealt with and managed (Davis, 2018). Although this checklist is premised on monitoring approved medical studies, some elements of this framework could be used for monitoring approved non-medical studies. The rationale for the process for continued monitoring by way of a checklist framework, is to ensure that monitoring is conducted in a way that is effective in ensuring human protection while taking non-medical ethics committee structures, guidelines, and constraints into consideration.

Table 1: Onsite Monitoring Checklist for Institutional Ethics Committees/Institutional Review Boards

Table 1: On site monitoring checklist for Institutional Ethics Committees/institutional review boards

Monitoring domain	Methodology	Remarks
I. IC process and documentation		
a. IC form used	Inspect	• Site has used valid, contemporaneous and EC/IRB approved consent forms
b. AV recording documentation, storage/ archival	Observe, inspect and interview investigator and other delegated personnel	• Process of audio video recording of IC process is appropriate • Documentation of AV recording of IC is adequate • Patient privacy and confidentiality is respected • Storage area is well protected
II. Site documentation		
a. Availability of site SOPs	Observe, inspect Interview site personnel	Site conducts research according to SOPs
III. SAE management		
a. Reporting of SAEs	Inspect and interview site personnel	• Site has reported SAEs as required by current regulatory requirements • No discrepancy between the SAEs reported to ECs and that known to the site
b. Any unanticipated increase in SAE?	Observe and interviews	No increase in SAEs in the study than initial baseline assumed
c. SAEs/ SUSAR review	Ongoing review of documents submitted, interview investigator	No increase in SAEs at other sites; no increase in SUSARs in the study or any significant patient safety concerns
IV. Subject related		
a. Subject withdrawals after last EC site review	Review records, interview site personnel	Reasons for withdrawal are well documented
b. Protocol deviations and violations	Observe, interview investigator and site staff	• Site has SOP on how to manage protocol deviations and violations • Check if any of the protocol deviations violations are recurring in nature • Ascertain reasons for continued noncompliance with protocol and its impact on subject safety
c. Subject complaints received at site and how handled	Inspect, observe, interviews with Investigators/ site staff and subject	Subject complaints are handled as per SOP and discussed in team meetings, escalated to EC, etc.,

IC=Informed consent, AV=Audio visual, SOP=Standard operating procedures, SAE=Serious adverse event, SUSAR=Suspected unexpected serious adverse reaction, EC=Ethics Committee, IRB=Institutional review boards

Source: Davies, 2018;93

2.4. Conceptual Framework

The suggested conceptual framework for university non-medical ethics committee monitoring is premised on a process for continued monitoring by way of a checklist applicable to non-medical ethics committees' monitoring of studies they approve. This conceptual framework will guide how the research will proceed and provide a basis for how the results will be interpreted.

The following process for continued monitoring by way of a checklist that the researcher deemed appropriate will fall under the monitoring checklist for non-medical ethics committees.

The components for the process of continued monitoring by way of a checklist for non-medical monitoring are stipulated as follows:

- University ethics committee composition is required for functionality and responsibility for continued monitoring.
- Capacity and training required for continued monitoring.
- Monitoring.
- The use of consent forms, protocol deviation and reporting of serious adverse events.

- Continual monitoring aids in research being conducted ethically.
- Continual monitoring results in ethics compliance.
- Guidelines for ethics committee monitoring.

These domains will be investigated by means of additional literature analysis.

2.4.1. University ethics committee composition required for functionality and responsibility for continued monitoring

To guarantee the ethical guidance of research and complete protection of study participants, an appropriately established ethics committee should conduct a review and approval process. According to Kaur et al. (2017) and Davies (2020) the composition of university ethics committees, should be multidisciplinary, suitably established, and capacitated, which allows collective knowledge in the areas and disciplines believed necessary for understanding to give an all-inclusive assessment of moral difficulties that may occur throughout the research study. Different points of view must lead an ethical evaluation to increase its value and so assist universities' research obligations. Owusu et al. (2022) stated that ethics committees should comprise of chairs and members who are appropriately qualified or professionally capable, and they must be diverse in terms of race, gender, and cultural background. Owusu et al. (2022) further state that administrators have a substantial position in the ethics procedure and assist in facilitating the ethics review process, among other ethics tasks. According to Mulondo et al. (2022) ethics administrators are a crucial component of the governance structure that enables ethics committees to carry out thorough, timely ethics reviews.

Experts from a variety of diverse fields make up the membership of non-medical ethics committees in South Africa. The DoH (2015) guidelines specify that registered research ethics committees' membership should comprise of the following members: a minimum of one layperson, an expert in research ethics, a legal expert, a bio-statistician, a minimum of one member with experience and knowledge of counselling, professional care and health-linked treatment of humans, a qualitative research methods expert and quantitative research method experts all of which have a specified duty on the ethics committee. The guidelines (DoH, 2015) further state that nine members would form a quorum. This is supported by Kaur et al. (2017), who conducted a study on ethics committees in India and found that ethics committees must contain experts from multiple disciplines who are essential for appropriately judging a research project and membership that encompasses active members who represent a good mix of ethical, legal professional, cultural, educational, and community interests. However, challenges concerning capacity and membership exist, which impacts how ethics committee

responsibilities are carried out and as well as their ability to monitor approved studies. Ndebele et al. (2014) reported that inefficiently running ethics committees, under-resourcing, overworked ethics committee members, outmoded legislation, and low or non-awareness of guidelines are all factors that contribute to the ethics committee's ability to adjudicate and monitor research studies. These factors, as well as an increase in research being conducted, expose weakness to unequal research (Ndebele et al., 2014).

2.4.2. Capacity and training required for continued monitoring

According to Silverman et al. (2015) there are areas within research ethics committees that require improvement in lower to middle-income countries. These areas are classified as membership composition, a framework for monitoring, training, and a host of other aspects, which affect the effectiveness of an ethics committee to perform its duties (Silverman et al., 2015). In a study looking at administrative support for ethics committees, Mulondo et al. (2022) argue that currently, there is still no higher education institution in South Africa that provides research ethics capacity training for administrators at an undergraduate level, which is an indication that ethics administrators perform their job function with little to no training. Mulondo et al. (2022) determined that ethics administrators require training in areas such as (1) ensuring ethical compliance, (2) complaints received, (3) monitoring current research, and (4) preparation for audits.

The literature suggests that insufficient training for both ethics committee members and ethics committee administrative staff influences the ethics of research studies. This is supported by (Kadam and Karandikar, 2012), who state that ethics committees must contend with issues such as untrained staff, an excessive workload, space constraints for ethics committee work, a lack of administrative capacity, and insufficient compensation for members who sit on ethics committees. Thus, ethics committees work within the constraints they are faced with, resulting in some responsibilities being neglected or being completely overlooked. As ethics committees are understaffed and overworked, it results in reduced participant protection as research rapidly increases in South Africa (Dhai, 2005). Karunaratne et al. (2006) and Davies (2020) further purport that a lack of resources as well as specific monitoring training are repeatedly identified as barriers to more detailed monitoring processes and training. Guillemin et al. (2012) further quoted De Vries and Forsberg (2002), who stated that more capacity is required which would enable ethics committees to conduct their work sufficiently. The literature indicates there is a link between resources available and the ethics committee's ability to monitor approved studies, which is a requirement of ethics committees.

Ikingura et al. (2007) noted that monitoring approved studies proved to be challenging for ethics committees in Tanzania, and the submission of progress reports was relied upon for monitoring purposes; this was credited to limited financial resources and limited capacity of chairs and members to conduct monitoring. The submission of annual reports relies primarily on the integrity of the researcher, as administrative staff are often limited, which limits their ability to follow up on the annual reports from the many applicants applying and receiving ethical clearance. This results in researchers failing to submit these annual reports, which in turn suggests that ethics committees have no oversight over research studies they approve. A lack of monitoring processes was also reported as a reason that influenced limited monitoring at research ethics committees in Tanzania (Ikingura et al. (2007). According to Davies (2020), many scholars have expressed worry that ethics committees in low- and middle-income countries may not be able to advance great ideals of human participant protection due to a deficiency of (1) financial and physical resources, (2) a lack of sufficiently trained ethics members, (3) a lack of diversity in membership, (4) ethics committee freedom, and (5) the incapacity to monitor approved protocols. As universities become more research intensive, the requirement to review and approve more protocols are evident. Sufficient capacity and qualified personnel, particularly those familiar with social science phenomena, are necessary for the efficient oversight of authorised research projects. Members voluntarily serve on ethics committees, and often do not have the time to conduct monitoring. The absence of appropriate guidelines, specific monitoring training and an appropriate framework to monitor makes the task of monitoring approved research studies more difficult and irregular. This is supported by Cox et al. (2023), who stated that there are definite benefits to monitoring approved studies, but challenges such as insufficient legislative support, lack of resources (financial and human), and organisational structures exist which affect this function. Ethics is a permanent role and requires full capacity and dedication, especially with its involving complexities and the importance placed on ethics, especially in a university setting.

The duties of research ethics committees include examining, approving, and overseeing ethically sound research projects. According to Eccles (2011), research including human participants requires a decision made by a fully registered ethics committee, because this decision cannot be made safely, and accurately by the researcher. The ethics committee is a body that will render an objective judgment based on the nature of the research, participant risks and benefits, consent requirements, and other safety measures (Eccles, 2011). According to Karunaratne et al. (2006) ethics committees spend a great deal of time and thoroughness on

ensuring the success of the ethics approval process. However, the monitoring activity continues to remain blurred and incoherent (Karunaratne et al., 2006). This is aggravated by the increasing workload placed on chairs, committee members, and administrators in performing the former action. The goal of increasing research and postgraduate enrolment at South African universities has been discussed; as a result, more ethical applications are being submitted for assessment, adding to the ethics committee's workload (Cleaton-Jones, 2019).

For instance, in 2015, the number of protocols submitted for review at a medical ethics committee at a Gauteng university doubled from 439 protocols in 2003 to 809 in 2015, and the amendments required after the initial review amounted to 671 which results in the total number of protocols reviewed in 2015 to 1480 (Cleaton-Jones, 2019). This is the result of South African universities becoming more research-intensive and an increase in the number of postgraduate students in recent years (Cleaton-Jones, 2019). This further speaks to the increased workload placed on chairs, committee members, and administrators in just one aspect of their responsibility (reviewing and approving protocols). The necessary revisions required following the original submission further demonstrate researchers' arbitrary approach toward ethics and further solicits a need for researchers to understand and treat ethics seriously. This reflects committees' limited ability to conduct proper monitoring as well as little emphasis placed on the framework for such monitoring, particularly with non-medical studies.

2.4.3. Monitoring

Ethics committees should monitor studies they approve, essentially to determine whether ethical standards were maintained throughout the process, as stated in the DoH (2015) guidelines. The monitoring guidelines speak primarily to researchers providing information to ethics committees by way of annual reports or progress reports (DoH, 2015). In an atmosphere where research is expanding quickly, approval and review processes are prioritised over monitoring. Non-medical research ethics committees are quite rigorous in the reviewing and approval stage, making every effort to ensure that researchers are aware that ethical standards are to be upheld during data collection and that researchers act ethically. The call for an annual report from researchers is, therefore, the most dependable way of monitoring the adherence to ethical standards, provided researchers firstly submit the annual reports and secondly, they are honest in the annual reports. However, there is debate in the literature regarding the nature of monitoring, its dependability, and its format.

Norton (2008) contends that the implementation of monitoring may not be difficult in developed nations like Canada. However, as research grows, scarce physical and financial

resources can present certain difficulties (Norton, 2008). Non-medical research ethics committees may not have the necessary infrastructure in place to carry out monitoring, and their meagre or non-existent budgets hinder their ability to do so. Time and compensation for members of the ethics committee also have an impact on the potential for monitoring to occur. Pickworth (2000) claims that chairs and members receive little to zero compensation for the time they spend reading and debating research applications. Many non-medical ethics committees, therefore, monitor in a passive manner. A research study's risk level will determine whether an ethics committee requires two progress reports annually. However, this process may not always be monitored or pursued. As a result, researchers may not even submit their progress reports for approval. This is corroborated by Pickworth (2000), Norton (2008), and Shetty et al. (2014), who stated that the most popular monitoring tasks consist of gathering yearly reports and looking into deviations from approved applications.

In the literature, there is overwhelming support for monitoring approved research studies. However, there is debate around appropriate monitoring frameworks, with consideration for current limitations faced by university ethics committees. According to Milford et al. (2006), there is a need for acceptable local ethics policies and guidelines to enable the training of ethics committee members, to promote ethics committee independence, range of membership, and post-approval monitoring of research ethics studies. The submission of annual reports by researchers is questioned as an appropriate form of monitoring, as it could not be sufficient because it might not reveal protocol violations, inaccurate reporting, or differences in the administration of consent and its records (Shafiq et al., 2021). Pickworth (2000) and Ochieng (2013) express a similar opinion, stating that annual reports may not provide sufficient monitoring since researchers may fail to disclose ethical transgressions, fraud, or material that participants may not understand. This, in turn, restricts participant protection and increases unethical research. Weijer et al. (1995) argue that although the submission of annual/progress reports is considered a minimal requirement of monitoring, it does not accomplish monitoring guideline requirements. Weijer et al. (1995) purport that monitoring approaches should be considered and established at the protocol approval stage of a project, and the process of monitoring the project should be included as a condition of approval.

There are debates around the extent of monitoring and at what point the ethics committee overstep their remit in terms of monitoring. There might be a need for supervisors to assist with the function of conducting monitoring of their own students' research. In a study conducted by (Guillemin et al., 2012) with ethics members and health researchers, the study revealed that

there was consensus in terms of an ethics committee's primary function of protecting participants. However, there was disagreement about the additional responsibilities conducted by ethics committees. The additional responsibilities described were the over-protectiveness of research participants, such as monitoring (Guillemin, 2012). Monitoring is also seen as a process that could have a negative effect on the relationship between the ethics committee and researchers and could be seen as the ethics committee policing researchers and research (Weijer et al., 1995). Researchers may feel that ethics committees should trust researchers to act with integrity and uphold ethical standards because, without trust, the research enterprise is questionable (Cox et al., 2023). According to Cox et al. (2023) there are perceptions that ethics committees are overstepping their remit by providing excessive oversight at the approval and post-approval stage, and at the same time, there are outcries regarding a need for a mechanism that would highlight research misconduct and unethical behaviour. This details a dilemma ethics committees are faced with in terms of monitoring and protecting human participants.

2.4.4. The use of consent forms, protocol deviation and reporting of serious adverse events

Douglass et al. (1998) undertook a study with the aim of testing an active monitoring system and analysing its suitability and effectiveness for the future of monitoring by research ethics committees. Interviews were conducted for this study, and monitoring documents were discussed with participants which centred around participant recruitment, protocol deviations, informed consent challenges, and challenges regarding adverse events were probed. According to the findings, the biggest departure from the approved ethics protocol concerned participant information (Douglass et al, 1998). According to the same study (Douglass et al., 1998), active monitoring would make it possible for ethical committees to recognise changes from the original approval. This extends beyond the annual report obligation and suggests that active monitoring should incorporate looking at signed consent forms and other relevant study material (Douglass et al., 1998). This demonstrates the necessity for a more sophisticated monitoring system that can identify ethical transgressions that an annual report might miss. Active monitoring should not just extend to site visits but more active ways in which ethics committees are able to protect participants.

Informed Consent

The DOH (2015) guidelines make provision for ethics committees to look at signed consent forms as a measure of monitoring research they approved. Apau Bediako and Kaposy (2020) found that the use of meaningful informed consent contributes to the protection of participants, and at the same time, assists in alleviating any conflict-of-interest issues. In instances where

ethics committees are not at the means to conduct site visits, reviewing informed consent forms could highlight issues that could otherwise have been missed in annual reports (Apau Bediako and Kaposy, 2020). Issues such as whether the correct consent form was signed or whether the consent form was amended in any way from the approved protocol.

For a consent form to be considered as an adequate consent form, it should include the following aspects: full information about the study, risks and benefits associated with the study, their full involvement, produced or translated in a language they can read and comprehend, and that they can withdraw from the study at any time without any negative consequences. The primary role of the informed consent document is to protect the rights and welfare of participants taking part in research (Sugarman et al., 2005). Consent forms are pivotal documents when collecting data because participants must voluntarily consent to participate by signing a consent form acknowledging that they are fully aware of what the research is about and that they are at the capacity to give their consent to be involved in the research being conducted. Borovecki et al. (2018) explain that obtaining consent is a process whereby people intending to participate in research are fully informed about what the research is about, and they are fully capable of deciding to consent. A consent form will detail all aspects of the study, and a participant based on all the information given, will either agree or disagree to partaking in the research study.

In monitoring consent forms, the committee should ascertain that consent forms exist that they were signed, and what was agreed to transpired (Weijer et al., 1995). The consent form should be checked against the consent form approved for the study to ascertain if the consent form is the accurate consent form for the study. Sharmila et al. (2016) explains that the most frequent research misconduct relating to consent forms are failure to acquire consent, backdating informed consent forms, and the use of a different study's consent form. Sharmila et al. (2016) further elucidates that it is the responsibility of the ethics committee to provide adequate oversight that ensures informed consent is obtained properly.

Reviewing signed consent forms, as a form of monitoring, could reveal if participants were fully aware of what they were agreeing to and if all pertinent information were relayed to participants as stated in their approved study. Researchers are obligated to ensure that participants are fully competent to provide consent. Otherwise, it could be considered faulty consent. This is substantiated by Sugerman et al. (2005), who mentioned that for informed consent to meet the goal is autonomous authorisation, it is pivotal that researchers establish if the participants providing consent are competent to provide such consent and that such consent

is, in fact, voluntary. This type of monitoring of consent forms could reveal whether informed consent has been obtained (Weijer et al., 1995). However, the checking consent forms may not reveal if any unethical behaviour has taken place after the signing of the consent form.

Protocol Deviations

Protocol deviation is when researchers deviate from what was approved by an ethics committee, which could have consequences depending on the severity of the deviation. Gajbhiy et al. (2020) state that for a research project to comply with ethical standards, the investigators should adhere to the ethics-approved protocol documents thoroughly. Jalgaonkar et al. (2016) and Gajbhiy et al. (2020) purport that deviating from approved research protocols could lead to participants being at risk, their rights and protection being compromised, and unreliable, contradictory, deceptive, and invalid results. In medical studies, protocol deviation could lead to participant benefits being reduced or the treatment failing (Gajbhiye et al., 2020). Jalgaonkae et al. (2016) conducted a study involving reported protocol deviations from different sectors: government studies, pharma studies, investigator-initiated studies, and dissertation studies. The results found that the most reported studies came from pharma studies, and the fewest reported deviations came from dissertation studies (Jalgaonkae et al., 2016). It was concluded that the most reported deviations were because of sponsor monitoring that was able to pick up these deviations (Jalgaonkae et al., 2016). The lack of reporting deviations in dissertation studies does not necessarily mean it does not happen; it could allude to it not being reported or under-reported, which is why Jalgaonkae et al., 2016 and Gajbhiye et al. (2020) elude to the fact that ethics committees should make a concerted effort to create awareness of ethical standards and guidelines because researchers may not be properly trained and adequately knowledgeable of ethical standards. Thus, it is the ethics committees' responsibility to monitor approved research studies and provide sufficient ethical standards information to avoid protocol deviations that may occur. There may be cases where protocol deviations are necessary and may aid with study results. However, protocol deviation should be reported, and should follow the proper ethics committee channels.

Should a researcher deviate from the approved protocol, it is commonly reported as an amendment to the approved protocol. The amendments should be submitted, reviewed, and approved by a registered ethics committee. This process will enable researchers to continue with their studies ethically without putting participant protection and research results at risk. The amendments process could be considered as part of the monitoring process because it provides an avenue for researchers to report any protocol deviations using the appropriate

avenues as opposed to not reporting it at all. This process further allows ethics committees to ascertain the progress of approved studies as well as monitor studies they approve. In instances where protocol deviations are severe, ethics committees can provide corrective action and provide researchers with specific recommendations pertaining to the specific deviation (Jalgaonkae et al., 2016). Therefore, Gajbhiye et al. (2020) and Cox et al. (2023) call for a need for ethics committees to monitor approved studies more rigorously to detect protocol deviations and a host of other ethical misconduct in the form of faulty consent, unapproved recruitment processes, and elements of non-compliance, that could often cause serious harm to participants, as well as the impact on the research results. Therefore, relying on researcher integrity and submitted annual reports may not always reveal deviations from the approved protocols and are often seen as a tick-box practice.

Apau Bediako and Kaposy (2020) reported that some researchers backed ethics committees conducting continual monitoring and stated that it prevents researchers from deviating from their approved studies if they were aware of continual monitoring. In a non-medical ethics committee space, the framework for monitoring may be challenging, as it may not be appropriate for non-medical ethics committees to conduct site visits because of the nature of social science research, the location, as well as resource constraints.

Serious adverse events

Tripathi et al. (2016) purport that the primary measure of participant safety throughout the research is how serious adverse events are managed. There are instances where serious adverse events are not reported to the research ethics committee, resulting in participants not being safeguarded and protected, and ethics committees may not be able to guide researchers on how to rectify problems detected. Medical research ethics committees primarily conduct site visits in a bid to ensure ethical standards are being upheld and participants are being protected, and aspects such as protocol deviation and serious adverse events might be revealed. Monitoring by way of site visits is useful for the detection of serious adverse events because people conducting the site visits have or should have expertise and training in detecting serious adverse events. However, adverse events can take place within the non-medical ethics space and require appropriate monitoring mechanisms that are able to detect serious adverse events or at least mechanisms in place where investigators are able to report adverse events that may occur during fieldwork. Site visits for non-medical research may not be appropriate because, firstly, it is costly, and secondly, some studies span different continents, which makes it impossible to conduct site visits. As part of monitoring, ethics committees are required to evaluate the serious

adverse events, and further take the required action to safeguard human participant protection (Tripathi et al., 2016). However, with passive monitoring, serious adverse events are not often reported, therefore resulting in the required action not being taken to protect the welfare of human participants, which goes against ethical principles.

2.4.5. Continual monitoring aiding in research being conducted in an ethical manner

University ethics committees and the ethics procedure serve the dual purpose of guaranteeing that researchers have ethical approval prior to beginning data collection, and that research is conducted ethically by making sure study participants are protected throughout the study. There is a debate about how the ethics process ensures research is conducted ethically, with varying views and beliefs in this regard. According to Head (2020) and Coleman and Bouësseau (2008), there is evidence in the literature that the ethics process helps researchers carefully consider their research methods and steer clear of research misconduct. Another study conducted by (Shafiq et al., 2021) found that researchers welcomed continual monitoring, which is part of the ethics process, by ethics committees because it revealed deficiencies within their studies, which otherwise would not have been detected, within time, which allowed them to take corrective action, thus, enabling ethical research. Makhoul et al. (2014) further found that, firstly, the ethics process aids in research being conducted ethically because it undergoes a rigorous approval process in terms of ensuring participant protection. Secondly, it improves publication possibilities; thirdly, the ethics process enhances study credibility. However, there is also debate about the ethics committee's role in ensuring research is conducted ethically.

Makhoul et al. (2014) found that there are views among scholars that ethics committees often overdo their job, police research, add burden, and question the researcher's integrity. Head (2020) and Coleman and Bouësseau (2008) contend that the ethics review process is not enough to ensure that research is conducted ethically, particularly in the qualitative realm, and that larger ethical issues may be overlooked because the review is focused on rewriting ethics forms. Since the primary ethical concerns were overlooked, this could lead to a situation in which research is not conducted ethically. Ethics committees might not even be aware that participant protection is at risk as monitoring ethics may not receive the same priority as reviewing and approving procedures.

According to Tsan and Nguyen (2019), ethics committees can ensure participant safety and protection by monitoring research, yet noncompliance in this area persists as an issue despite its importance. Hyder et al. (2009) purport that the Institute of Medicine highlighted the following four vital tasks of review committees in protecting participants: 1) application

review, 2) investigator-participant interactions that are ethical, 3) continuous monitoring to ensure safety, and 4) quality enhancement and compliance. It is determined that adequate monitoring is essential to carrying out moral research and safeguarding human subjects. This is substantiated by Shetty et al. (2014), who argue that as research expands, ethical issues arise regarding inconsistencies in consent processes, deviations from what was approved in the ethics process, which affects research being conducted ethically, and advocates for continued appropriate monitoring to ensure research is conducted ethically.

2.4.6. Continual monitoring results in ethics compliance

In addition to providing clearance certificates, university ethics committees are also concerned with researchers adhering to ethical standards, particularly while conducting research in the field. Hutchings and Michailova (2022) argue that when researchers deviate or do not follow ethical guidelines and procedures, there is a danger of strained relationships between establishments and universities, which can damage the reputation of the university, the student, and the supervisor. Cox et al. (2023) argue that monitoring is not only concerned with compliance but also research integrity and aids in providing consultative support as well as educational support for researchers. Research that does not adhere to ethical guidelines may not be used, and the results may not be published, and this could lead to the loss of important data (Hutchings and Michailova, 2022). A need exists to ensure ethical principles are practised when conducting fieldwork, a space in the research process where ethics committees have less control. Dawson et al. (2019) argue that a retrospective review process of research studies aims to improve the way research is conducted and assist in enriched ethical practice that fosters deeper thought and concern for the safety and welfare of participants. Using appropriate monitoring techniques helps to safeguard human participants during the data collection process by enabling the prompt detection of aberrations that minimise potential harm to the university's reputation and enable corrective action.

2.4.7. Guidelines for non-medical ethics committee monitoring

There is a distinct difference between medical and non-medical university ethics committees. Medical university ethics committees primarily focus on studies involving humans that take place within a hospital setting and often involve intrusive procedures, such as prodding, poking, or drawing blood from participants etc. Non-medical university ethics committees focus on studies involving humans but are not physically intrusive or life-threatening (De Wet, 2010). However, non-medical study participants may experience psychological distress, unmet

expectations, deception, unexpected or inaccurate portrayals, and differing perceptions, to name a few potential harms (De Wet, 2010). Hence, the need for ethics approval is essential.

Ethics committees (Non-Medical, Medical, and Animal university ethics committees) registered with the NHREC are required to follow the DOH 2015 guidelines, and this pertains to all responsibilities of ethics committees. Guidelines for monitoring are listed within the DOH 2015 guidelines. However, most of these guidelines are geared towards medical ethics and clinical trials. It is plausible to claim that these statutory norms and recommendations were written primarily for research ethics committees whose work is related to biomedicine and health and does not consider community-based participatory research, primarily conducted within non-medical research (Davies, 2020 and Flicker et al., 2007). All ethics committees registered with the NHREC are, therefore, subject to the same guidelines for research involving human participants. As these guidelines are medically inclined, it makes it difficult for non-medical ethics committees to monitor appropriately, as these guidelines do not accommodate research methods used within the non-medical space.

To ensure participant protection and avoid any research misconduct, guidelines for monitoring non-medical research should be fit for purpose. Literature promotes the need for appropriate guidelines which will fulfil the function of monitoring. Haire et al., (2014) argue that to have comprehensive monitoring processes in place, it calls for a need to strengthen monitoring frameworks and guidelines to avoid research misconduct and that protocols are conducted as it was approved. This is indicative of guidelines for monitoring being suitable for the types of research being conducted. Kass et al. (2007) conducted a study on ethics committees within Africa, and respondents participating in that study cited that a deficiency of national guidelines and standard operating procedures affects the quality of work of ethics committees. De Wet (2010) further elucidate that the establishment of a successful ethics committee, together with appropriate guidelines, will foster insightful conversations and debates within the non-medical ethics committee, which filters down to approval and the monitoring stage. In the study conducted by De Wet (2010), participants echo this by stating that there is a necessity to have good guidelines for ethics committees that will enable committees to judge fairly and correctly. Guidelines that will protect all participants vulnerable participants, and participants that are minors.

Appropriate and suited guidelines allow for ethics committees to work within a framework that works for adjudicating and monitoring non-medical research appropriately that ticks the boxes of protecting human participants that participate in non-medical research. According to Knight

(2019), technological advancements have allowed for new types of interactions between researchers and human participants, which have significantly changed the landscape of human research in non-medical study fields. As a result, conducting ethical research has become more challenging, especially when it comes to issues like confidentiality and anonymity. Knight (2019) identified this gap within the guidelines and called for it to be addressed in the social science ethics sphere. This calls for a need to tailor or add appropriate guidelines for non-medical research, which will enable committees to monitor non-medical research appropriately and sufficiently ensure human protection during data collection processes.

2.5. Conclusion

The responsibility of ethics committees is to monitor research studies they approve. However, university ethics committees' ability to carry out this monitoring is hampered by a lack of appropriate guidelines, The role of overseeing approved protocols is one of the many tasks performed by the ethics committee, and in most cases, the committees are unable to totally fulfil this task due to a lack of ethics committee assistance (Dhai, 2005). Ethics committees are confronted with the challenge of being accountable for monitoring participant protection but lack the infrastructure and the necessary resources that would allow them to do so (DeMets et al., 2006). Therefore, ethics committees' resort to following the bare minimum of monitoring, which might not be adequate for ensuring the safety and protection of human participants throughout data collecting. It is argued that with a more meticulous and extensive monitoring and ongoing assessment system, many problems that are associated with existing research techniques may have been avoided (Dhai, 2005). South African university ethics committees are required to adhere to national guidelines stipulated by the NHREC for human participant protection. This is indicative that ethics committees are no longer just restricted to the institution, but function as a custodian of human participant protection that participate in research (Dhai, 2005). Therefore, university ethics committees and research ethics as a profession must receive the proper recognition and backing (Dhai, 2005). This speaks to appropriate guidelines, support, and frameworks given to ethics committees by regulatory bodies.

3. CHAPTER 3: RESEARCH METHODOLOGY

3.1. Introduction

The methodology chapter outlines the methodology that was undertaken for this study. The chapter further outlines the research approach used, the data collection instrument used, and how it was applied, the research sampling method used, and the data analysis technique that was employed. The chapter concludes with an in-depth discussion of the limitations that were revealed within the study, the feasibility related to the study, and ethical considerations that were considered, followed by the validity and reliability aspects.

3.2. Research Approach

The purpose of this study was to examine the methods that university non-medical ethics committees employ for monitoring and assess their efficacy in maintaining ethical compliance during the data collection process. The study also sought to determine how guidelines stipulated for non-medical research affect how ethical compliance is adhered to during fieldwork. The study relied on the positivist research paradigm because it allowed the researcher to determine functional correlations between explanatory and causative factors (independent variables) and outcomes (dependent variables) (Park et al., 2020). According to Park et al. (2020), positivist research aims to produce causal linkages or explanatory correlations that, in the end, enable prediction and control of the phenomenon under study. The positivist paradigm usually relies on quantitative techniques (Park et al., 2020). However, the positivist paradigm can also be appropriate for an experimental study that uses qualitative analysis to assess the impact of an intervention (Park et al., 2020). It is relevant to the study because, the study sought to ascertain the relationship between ethics committee monitoring and factors associated with this function. The researcher came from a position that non-medical ethics committees should monitor but may not have the proper resources and guidelines to fulfil this function properly. A qualitative strategy was used to investigate the effects of monitoring through experimentation, which is consistent with the positivist paradigm (Park et al. 2020). By using this method, the researcher was able to better comprehend the study problem and help address the research questions from the perspectives of the chosen set of participants inside the ethics committee arena.

3.3. Research Design

According to Sileyew (2019), the purpose of the research design is to give a study an acceptable structure. This study adopted a cross-sectional design as it allowed the researcher the gather relevant information at a specific moment, usually the time during the data gathering or shortly after that (Kesmodel, 2018). The researcher collected data from chairpersons, co-chairs, members, and experts from university non-medical ethics committees, which provided an outline of their knowledge and perceptions around ethics committee responsibilities and tasks. The data further provided insight on their perspective on monitoring non-medical studies, and how the governing guidelines for monitoring influenced how monitoring is conducted, especially in a climate of limited capacity. Therefore, this design did not necessitate that data be collected multiple times from a single participant, but only once. This study espoused a qualitative strategy. The rationale for the use of a qualitative strategy is that qualitative research encompasses the perspectives and opinions of the intended participants and, simultaneously, acknowledges that many sources of data may be relevant rather than relying just on one (Yin, 2016). According to Creswell (2014), qualitative research is a method for examining and understanding the significance of individuals or groups placed in a social or human context.

The research probed the opinions and meanings from experts in ethics concerning the role of monitoring and how it is conducted to ensure ethical compliance and further gathered data from various members as their backgrounds and ethics experiences are different and vast, which resulted in in-depth and valuable information around this topic. According to Rahman (2020) the use of a qualitative research strategy results in a dense portrayal of participants' thoughts, feelings, and experiences, as well as an interpretation of the motivations behind their behaviour. The study examined opinions regarding the suitability of guidelines overseeing the monitoring of non-medical research, the suitability of monitoring through annual reports, the suitability of monitoring in an area with limited resources, and the suitability of monitoring taking non-medical nuances into consideration.

3.4. Data collection instrument and its application

The proposed study used primary data sources using semi-structured interviews which allowed the researcher to prepare questions but also allowed the researcher to probe as well. According to Longhurst (2003) and Ahlin (2019), a semi-structured interview is a dialogue in which the interviewer uses questions to try to elicit information from the study participants and provides data from multiple perspectives. The use of a semi-structured interview allowed for more of a

conversation to take place and provided participants with the chance to explore issues they believed were pertinent despite the researcher having prepared a list of planned questions to gather more insight into the research topic (Longhurst, 2003). Another reason for the use of semi-structured interviews is that it is a flexible technique of data gathering, which allowed the researcher to examine discrepancies in participants' narratives and obtain a deeper understanding of the research issues (Fylan, 2005). The interview schedule was piloted first, with a member of an ethics committee to ascertain whether any of the questions were ambiguous and needed to be changed, and the timing for the interviews were ascertained. Following the pilot study, the researcher finalised seven in-depth questions and follow-up questions were asked where the researcher felt that participants could provide more in-depth information. The topic on the use of signed consent forms as a measure of monitoring was further probed as this was deemed necessary.

The research questions and the literature review served as the foundation for the questions that were included in the semi-structured interview guide so that it could better answer the research questions and gather as much data on the topic as possible. The questions asked to participants were open-ended, accompanied by follow-up how and why type questions (Adams, 2015). The interviews were conducted via the MS Teams platform, and interviews were audio recorded and transcribed with the permission of the participants. As the interviews were transcribed, field notes were not necessary, and it allowed the researcher to be more engaged in the interview.

3.5. Research Sampling

Selecting participants who would most effectively contribute to the study by offering rich and in-depth knowledge on the issue is essential for qualitative research (Fossey et al., 2002). Thus, purposive sampling was used for this research. The sample specifically consisted of chairpersons, co-chairs, members, and experts of non-medical university ethics committees because they have detailed and considered knowledge of the topic and produced the most useful and in-depth data on the topic (Yin, 2016). Purposive sampling was used for this study since it is meant to enhance understanding of participants' experiences or for the creation of ideas and theories (Devers & Frankel, 2000).

3.6. Description of the sample that was interviewed.

The sample population were individuals who have extensive experience with human ethics and have served on research ethics committees. These individuals serve on university research ethics committees in the capacity of a chairperson, co-chairperson, expert or member. These individuals have extensive knowledge regarding reviewing, approving, and monitoring research that the committee approved.

To access the participants, gatekeeper permission was applied for and obtained from two university registrars in Gauteng. This made it possible for the researcher to interact with the study participants. Once, permission was sought, participants were contacted via email and sent an invitation email with the inclusion of the participant information sheet, and consent form. All participants approached were over the age of 18. Interested participants were asked to complete the consent form and send the signed consent form back to the researcher via email. A suitable date and time were agreed upon, and an MS Teams meeting was scheduled. The initial sample size was twelve (12). However, only nine participants agreed to participate in the research study. The interview sample comprised nine (9) individuals who were chairs, co-chairs, members, and experts involved with non-medical ethics committees with more than five years of ethics experience. There were six females and three males who participated in the research study. The reasoning for a sample size of twelve was that the study was focused on in-depth understanding and insight into this phenomenon. A larger sample would not yield an in-depth, case-oriented analysis and would be cumbersome to manage and analyse (Bobby, 2016). Studies focused on theoretical saturation found that saturation can be reached at six to twelve in-depth interviews (Bobby, 2016). Interviews were conducted on MS Teams and lasted between 30 minutes to one hour. Seven in-depth questions were asked and completed within the timeframe. Follow-up questions were asked by the researcher where necessary, which allowed for further engagement. The table below outlines the categories of participants that participated in the study.

Table 2:Categories of participants involved in the study:

Participants	**Number**
Chairs	2
Co-chairs	3

Members	2
Experts	2
Total	9

3.7. The process of data analysis

Thematic analysis was used in this study, which resulted in the data being coded, and themes pertaining to the research emerged from the data collected. According to Kiger and Varpio (2020), thematic analysis is a method of coding the data, creating themes, and summarising the findings. Themes can be described as repeated ideas that emerge from the data collected (Bryman, 2016). The data collected from the interviews (audio recorded data, and transcripts) were actively read and re-read so that the themes and subthemes rose from the collected data (Bryman, 2016).

After each interview, the researcher transcribed and analysed each interview before moving on to the next interview. Themes emerged as interviews were transcribed and analysed. This process also required that the researcher move back and forth between the transcripts (Abdul et al., 2018). To identify themes related to the study's research questions, the researcher looked for similarities and differences, recurrences, metaphors and equivalencies, and missing data (Bryman, 2016). While conducting the interviews, themes such as the type of monitoring, the responsibility of monitoring, how monitoring aids in ethical behaviour, and the role of the guidelines became prominent. The interview questions were the same for all participants, except for a few additional questions where further probing was required. Themes were established from the answers given by participants that were the same or similar. Based on the interview answers, the researcher established the themes for the study.

Saturation was reached at eight interviews where no new data was developed (Abdul et al., 2018). Participants were essentially saying the same thing. A ninth interview was conducted to verify the data, and subsequently, interviews stopped with nine participants (Abdul et al., 2018).

3.8. Limitations, positionality, and feasibility

3.8.1. Limitations

A limitation of the study is that it was limited to two universities in the Gauteng region. Therefore, it is possible that the study's findings cannot be applied to all South African universities that have registered to review non-medical research studies. However, the findings might guide further research in ethics committee oversight. Another limitation of this study was that one organisation that the researcher believed could benefit from the results did not grant permission. A further limitation of the study is that interviews are often long and labour-intensive and require the skills of an experienced researcher (Adams, 2015). In a bid to address this limitation, the researcher did an ethics training course and conducted a pilot interview to gain confidence in conducting the interviews. The sample size was small, which was a result of the time frame of the study and obtaining permission letters took about three months to obtain. However, saturation was reached. Future research on this topic might benefit from a larger sample size and a longer time span.

3.8.2. Positionality

In terms of positionality, the researcher is employed as a research ethics administrative officer at one of the universities, and this information was disclosed to participants in the participant information sheet (PIS) for transparency before the interview was conducted. The researcher conducted all data collection processes in her capacity as a student. The researcher's student email address was used to send the request for participation. Although the researcher works within the non-medical ethics domain, she was completely objective in the research process, whereby all findings were written up on merit with no influence from the researcher.

In this study, the researchers' positionality is viewed as a strength since it made access possible and because of her contextual understanding of the research issue, which made it possible to interact with the topic in greater detail. The goal of the research is to improve the ethics committee domain's current processes, so contextual knowledge is viewed as a strength. Participants invited to participate in the research practised their autonomy in that they decided whether to participate in the research or not. Participants were not forced or influenced by the researcher in any way to participate in the research. The researcher did not offer any incentive to participate in the research, which was fully explained. Some participants are known to the researcher; all data collection processes were conducted professionally and ethically. It was envisaged that the results of the study would inform current monitoring practices used by non-medical ethics committees and that the researcher's bias did not influence the research process.

Participants completed a consent form outlining all the terms of consent they consented to, as part of a sound formal consent strategy designed to prevent bias and coercion. Participation

was completely voluntary, and participants had the freedom to withdraw from the study at any time without any adverse consequences (Longhurst, 2003). Participants were notified that they could have a summary of the results upon request if they so wished. Participants were also informed that the results would be used for research purposes.

3.8.3. Feasibility

Feasibility refers to the degree to which people who conduct a study, or an intervention may do so practically in a location that has been selected as being authentic (Gagnon & Barber, 2018). Given that every participant is a resident of the Gauteng region, the researcher had equitable access to participants in terms of feasibility. Both the participants and the researcher saved money on travel expenses because the interviews could be done online at a time that worked for them.

3.9. Ethical Considerations

Ethical clearance was applied for and granted before any data collection commenced for this study at the institution where the researcher is a student. During the interview process, the participants were safeguarded and protected. Participants were provided with a participant information sheet (PIS) inviting participation in the study. The researcher assured participants that the interview was anonymous, and that confidentiality was maintained throughout the data collection process, as well as in the reporting of the results. In terms of anonymity, the participants were made aware that anonymity will be maintained in the reporting of the results. Participants were also made aware that, anonymity will not be maintained throughout the data collection process as the researcher knew who she was interviewing. The researcher assured participants that participation in the study was entirely voluntary, and participants had the option of withdrawing from the study at any time. Participants were told that the interview should not take longer than one hour. On average the interviews lasted between 20 – 35 minutes. All aspects, like what participation involved, any risk involved in the study and who to contact if there are any ethical breaches, were explained to participants. The study was innocuous, which did not necessitate the need for a distress protocol. Participants did not experience any stress or trauma, and the interview did not have to be stopped at any point.

It was crucial that participants understood the nature of the study and were provided with adequate information. Most ethical guidelines state that informed consent cannot take place unless people freely choose to participate. This decision must be made after carefully considering the study's design, the benefits and drawbacks of taking part, and their legal rights

as participants (Hill et al., 2008). When participants agreed to participate in the interview, informed consent was obtained whereby participants signed the consent form and sent the form back to the researcher via email. The formal consent form outlined exactly how participants' data will be managed and what, if any, confidentiality measures the researcher is providing (Ahlin, 2019). A formal consent strategy was used because it allowed participants to tick off on the form exactly what they were agreeing to. Participants were also made aware that data will be protected and stored on a password-protected computer only accessible by the researcher and supervisor.

3.10. Validity and reliability

The data for this qualitative study was gained from the participants' firsthand experiences and perspectives, therefore, it yielded a high level of validity. Validity is premised on the truthfulness of the inferences that stem from the research (Bryman, 2016). The researcher was able to obtain first-hand accounts of participants' experiences, perceptions, and behaviours, the use of semi-structured interviews provided for excellent validity (Ahlin, 2019). To further enhance validity, the researcher made a concerted effort to maintain consistency throughout the interviews by posing the same questions to each respondent and allowing for data-rich diversions (Ahlin, 2019). However, follow-up questions were asked from some participants to gage more in-depth knowledge on certain aspects. Reliability in a study was related to information being consistent and the ability of the data to be generalised to other models (Ahlin, 2019). In terms of the nature of qualitative research, reliability may not be as elevated as validity because semi-structured interviews open paths to explore certain avenues within the research that may not be asked through straightforward questioning (Ahlin, 2019).

To increase reliability, the researcher used the model recommended by (Ahlin, 2019), who recommends that the first interview conducted advise the other interviews yet to be conducted as areas of significance to the topic may surface from the initial interview that was not necessarily included on the interview guide. A pilot interview was conducted to determine the validity, accuracy, and reliability of the interview questions as well as to establish a more accurate timeframe for the interview. This process informed the semi-structured interview schedule.

3.11. Conclusion

To better comprehend the research topic and provide answers to the research questions, this chapter described the methodology that was employed for the study. The researcher was able to collect the opinions, insights, and ideas from ethics experts who are knowledgeable in the field of non-medical ethics by using the qualitative technique in this study. The efficiency of monitoring techniques for non-medical research and their potential to guarantee ethical compliance in research projects were among the topics covered by the qualitative approach.

4. CHAPTER 4: DATA PRESENTATION AND FINDINGS

4.1. Background

This chapter aims to discuss the findings that emanated from the semi-structured interviews conducted on the non-medical monitoring approaches that are used by university non-medical ethics committees, as well as their effectiveness. This qualitative study comprised semi-structured interviews conducted with nine participants. The participants comprised of non-medical ethics committee chairs, co-chairs, members, and experts, who are responsible for the function of monitoring non-medical research they approve. Data was gathered from participants, and themes were devised and assessed to ascertain current monitoring approaches utilisation by non-medical ethics committees and how effective these are in relation to participant protection, non-medical nuances, limited capacity, resources, training, new research methodologies, and current guidelines.

The themes will be introduced with support from italicized interview snippets from the interviews conducted. Data was analysed using thematic analysis. Thematic analysis offers simple, organised methods for extracting codes and themes from qualitative data that has been collected (Clarke et al., 2015). This chapter will briefly introduce each theme that emanated from the semi-structured interviews. The results are divided into categories, with alignment to the research questions and conceptual framework.

The participants interviewed have significant involvement in monitoring non-medical research that a registered non-medical university committee approved. Typically, non-medical research involves research conducted with human participants (interviews, focus groups, surveys, ethnographic research, etc.) that does not involve medical testing or conducted in hospitals. There was consensus that non-medical university ethics committees should monitor studies that are approved by their committee, especially for compliance purposes. However, it was evident that participants were not certain about the most appropriate way of monitoring social science studies that ensure participant protection.

Registered students, staff members, and external people submit applications to the non-medical university ethics committees for review and approval. In addition to review and approval, monitoring is conducted to ascertain how data collection went, if ethical problems occurred, and how these were mitigated. The need for monitoring and being ethical is undisputed. The nature of non-medical university ethics committee monitoring tends to be passive as opposed to active monitoring.

4.2. Overview of findings

All participants participated in reviewing, approving, and monitoring (to some degree) non-medical research approved through a registered ethics committee at a Gauteng university. The types of ethics applications reviewed, approved, and monitored by participants are all nestled within the non-medical sphere.

The first finding of the study revealed that monitoring is predominately passive because it is viewed as the most practical and feasible form of monitoring to conform to the guidelines. Passive monitoring is used because non-medical ethics committees do not have the resources (time, financial, human) that would enable them to conduct active monitoring. Passive monitoring is perceived as adhering to statutory requirements. The findings revealed that only certain individuals within the committee conduct the monitoring for the committee. These reports are not seen or ratified by the rest of the committee. The findings suggest that not all members participate in monitoring. The findings revealed that monitoring reports should be ratified at a quorate meeting, which is not the case based on the findings.

The second finding of the study revealed that monitoring can facilitate ethical behaviour and compliance if researchers are conscientious and carefully consider the ethics of their studies. Alternatively, the findings also revealed that monitoring is seen as a tick-box exercise and is done for compliance without careful ethics consideration, which does not facilitate ethical behaviour.

The third finding of the study revealed that resources are an issue for ethics committees, and it certainly affects how monitoring is conducted. Ethics committees' resort to passive monitoring, which they are not able to control because they do not have the time, human resources, funding, and specified monitoring training to conduct active monitoring effectively.

The fourth finding of the study revealed that the monitoring may assist in detecting deviations from approved studies. However, this is reliant on the researcher reporting the deviation through the amendments process. The interviews revealed that ethics committees currently have no control over whether deviations are reported. The findings suggest that the use of signed consent forms as a means of monitoring would only ascertain if the correct form was used as approved and if participants understood and consented to participate. However, the review of the signed consent form will not reveal any deviations or compromised participant protection during data collection, as this form is supposed to be signed before data collection commences.

The fifth finding of the study revealed that the current monitoring guidelines are not geared towards non-medical studies. The monitoring guidelines are premised on medical research. This leaves non-medical ethics committees in a vulnerable position of having to conform to guidelines that do not specifically speak to their needs as a committee. The need for adaptation to the monitoring guidelines was undisputed among the participants interviewed.

The following five themes emerged from the interview findings:

4.2.1. Monitoring approaches used and the responsibility of monitoring at South African universities

Monitoring is conducted for compliance in terms of adhering to the DOH (2015) guidelines and further conducted in the most feasible way that is believed to be fit for purpose for non-medical research. It was revealed through the interviews that monitoring is conducted as a statutory requirement. The interviews further revealed that the passive monitoring approach is used because it proved to be the most practical way of monitoring approved non-medical studies. Passive monitoring consists of the submission of annual reports/progress reports and the submission of any amendments to the approved protocols. This form of monitoring seemed to be the most practical approach, taking available resources and time into consideration. This form of monitoring is reliant on the integrity of the researcher, reliant on the researcher to be honest, as well as the researcher submitting and submitting said reports on time.

This implies that a huge responsibility is placed on the researcher to adhere to the requirements of ethics approval. This further implies that researchers should be knowledgeable about ethical standards, ethically reporting, and conduct themselves accordingly during the research process.

For passive monitoring to be successful, it requires that researchers submit regular updates in the form of annual reports, amendments, protocol deviations, and SAE on their studies. This is to ensure that participants were protected and that in the event any ethical issues occurred, the researcher followed appropriate steps in mitigating them. Relying on the researcher's integrity to submit and reflect honesty in the submitted reports is paramount to the success of passive monitoring. Insight from the interviews revealed that researchers may not always submit these reports, therefore leaving the ethics committee uncertain about whether participants were protected during the research process. Tsan and & Nguyen (2019) advance that the continual review process has the potential to protect participants, but non-compliance by researchers in this regard continues to be challenging. This creates a situation where university ethics committees do not have oversight after the approval stage, which could leave participants vulnerable. This is indicative of ethics committees not having complete jurisdiction over

participant protection. However, at the same time, universities and ethics committees have the responsibility of producing ethical research that requires minimal oversight.

> *"So, therefore really our only fullback position is passive monitoring, and this, is really done through annual monitoring reports. It's not maybe the best way to undertake this in totality, because it relies upon the willingness of the researcher to give us information, so if they don't give us information, even if we ask for it, I mean there's not a huge amount that we can do."*
>
> ***Participant 3***

> *"An annual report and they're supposed to do that at least once a year. And if it's a medium or high-risk study, they have to do it twice a year. It's done on a basis where you know we don't have the capacity to follow up and to chase people."*
>
> ***Participant 2***

Interviews revealed that passive monitoring may not be the most effective way of monitoring, but in the climate of limited resources, it seems feasible. The annual report allows researchers to state if they had any ethical issues during data collection and how it was managed. This further allows the committee to understand what ethical issues could arise and if researchers are able to identify ethical issues and deal with them appropriately. This form of reporting allows committees to engage with researchers and establish if any ethical issues that arose were dealt with appropriately and if any further action may be required.

> *"I am the one who signs most of these reports and most of them, the few that we actually receive. Occasionally, there's an issue where like there was one query the other day where they had decided that they were having difficulty with finding participants in a particular organization. And then they're just decided to kind of informally chat to people. And then I jumped in, and I said, well, you know, OK, did they actually get consent and permissions and what was going on there? So, I think it depends on honesty of the researcher."*
>
> ***Participant 2***

As a DoH (2015) monitoring requirement, registered ethics committees are required to conduct both passive and active monitoring (i.e. site visits); participants expressed that non-medical university ethics committees had to strike a balance in terms of the monitoring requirements and the committee's capability to fulfil these requirements fully.

> *"So, it has the danger of changing the dynamics, of the research site being surveilled, it's not always appropriate. We know that these regulations were made for animal and medical research. I don't really see it working in a socially situated context. Especially, some of this research doesn't even occur in Johannesburg. If you do apply the sort of rule of site visits (active monitoring), how do you apply equitably for studies?"*
>
> ***Participant 4***

The responsibility of monitoring

According to the DOH (2015) guidelines, ethics committees are responsible for monitoring, but the findings of the interviews suggest that only a select few conduct the monitoring and not the committee in its entirety. The interviews revealed that the chair and the administrator of the committee usually perform this function. This is indicative that the entire committee may not be involved in monitoring research that they approve, as these reports are not ratified at ethics meetings. This finding suggests that ethics committee members are not involved in all aspects of their responsibility as members of the ethics committee. This finding further suggests that members may not be trained in monitoring studies that are approved. It further suggests that committee members do not have the resources (time and financial) and expertise to monitor approved studies.

> *"Monitoring tends to be an end user process. It's quite an administrative process, so it's not seen by the whole committee, but by, a few members of the committee. The reason why I say it's quite administrative is that it doesn't come back to the committee. It relies very much on the researcher to report, and then whoever's reviewing it to take it at face value."*
>
> ***Participant 4***

> *"OK, so there are no specific guidelines in terms of who will do the review (monitoring). So, it could be a select two individuals with no conflict of interest, but eventually it would be maybe an expedited process and the approval can then of course be done in between meetings. But all approvals need to be ratified as a minimum and at the next upcoming Ethics Committee meeting because it ultimately it remains the responsibility of the Ethics Committee and not of an individual or a few members."*
>
> ***Participant 7***

As monitoring is done as a compliance requirement, this suggests that monitoring is not conducted with the careful consideration required for participant protection and as stipulated by the guidelines. It appears that monitoring may be conducted in its most minimalist form to conform to requirements. The danger of this kind of minimalist approach could result in participant protection being compromised and committees failing to deal appropriately with ethical concerns that may be revealed through monitoring.

> *"Which I guess really reflects a balance between some kind of a statutory requirement as put forward by the NHREC and the capacity of the institution to fulfil those statutory requirements."*
>
> ***Participant 3***

According to the participants, they felt that the function of monitoring should not just be limited to the university non-medical ethics committee. The responsibility should extend to supervisors of the researchers, who are closer to the research. Supervisors monitoring their students would be best placed to ensure participant protection as they would have access to the documentation, and this process would not break any confidentiality and anonymity breaches.

> *"Supervisors should also be accountable for monitoring their students during the data collection phase."*
>
> ***Participant 5***

> *"So, in a sense, sort of active monitoring might be something that supervisors might better do because they are closer to the research subjects and closer to the researchers themselves than we are."*
>
> ***Participant 3***

This alludes to role players within the universities (Supervisors, Faculties, Research Office) being part of monitoring research as opposed to just the ethics committee having to monitor research. Kombe et al. (2014) concurred and stipulated that the entire university community has a responsibility with regard to ethical research by preventing or reporting unethical behaviour. This speaks to creating a culture of research ethics and promoting that researchers behave ethically when conducting research.

4.2.2. The role of monitoring in ethical behaviour and compliance

The interviews revealed that there are varying opinions with regard to the role of monitoring in ethical behaviour and compliance. Some respondents felt that if researchers are serious about being ethical, then the annual report system could facilitate some form of reflection on ethical issues and could assist in researchers being more compliant.

> *"If a researcher is conscientious and actually does go through the annual report process. Then I would imagine that the format of our reports would facilitate some sort of reflection and help them to think about have there been ethical issues? Is there something that they need to consider? If you've got researchers and we see a lot of researchers who are quite naive or just don't understand the process or you know they can't be bothered with this kind of a monitoring process. Then there may well be things that are slipping through the cracks that we don't know about."*
>
> ***Participant 2***

Mehta et al. (2023) stated that the primary goals of monitoring by ethics committees are to provide continual protection of research participants, protection of the institution, and advance

research. Therefore, the purpose of the annual report is to ensure that participants are protected, and if anything, unethical occurred the proper channels were followed to mitigate any form of risk to research participants and the institution. However, based on participant feedback, this form of monitoring may or may not facilitate that researchers present ethical behaviour and compliance. It becomes apparent that there are researchers not understanding the purpose of ethics monitoring which negatively affects the process.

> *"I am more concerned with instilling in people a sense of what they should be doing from an ethical perspective in terms of their research rather than policing people; you know, I do not feel that it is the ethics committee's responsibility to police people, even though we do have the responsibility of oversight for some of these projects."*
>
> ***Participant 2***

Of the respondents who viewed monitoring as aiding in ethical behaviour and compliance agreed that the passive monitoring approach allowed researchers to engage with the ethics committee when things did not go as planned and allowed for engagement in terms of dealing with any issues ethically.

> *"I think researchers are ethical in their reporting, and I think we have built such a good relationship with our students and researchers or supervisors, I think we've got to learn to trust them and what information they put into the progress report is as true as it can be, when they actually collecting this data and look we cannot be on the field with them monitoring them 24 hours but we use the progress report. We use the progress report is a pretty good indication that ethical standards are being upheld."*
>
> ***Participant 5***

By contrast, some respondents felt that the annual report monitoring approach is seen as a tick-box exercise, and researchers may not even submit these reports. It is seen as an added burden which solely relies on the researcher's integrity. Researchers may not even complete these forms with the necessary ethical considerations and perform this function for the completion of the process.

> *"From my perspective, one of the trickiest things about monitoring is when there is noncompliance with monitoring; what are the implications for researchers?"*
>
> ***Participant 9***

4.2.3. Factors Influencing Monitoring

There was an overwhelming consensus that factors such as limited capacity, appropriate guidelines, limited resources (human and time), and training specific to monitoring influence how monitoring is conducted at university non-medical ethics committees.

Guidelines

Participants indicated that the passive monitoring approach is used because they do not have enough resources and time to conduct efficient monitoring as prescribed by guidelines.

Guidelines are a crucial factor when implementing monitoring effectively because they guide committees to monitor in a way that speaks to the types of research they review. Medical ethics predominately monitor studies that are conducted within a hospital setting or clinical trials. Non-medical studies involve social science-type studies, which may involve vulnerable participants as well as people's opinions of a certain phenomenon. The interviews revealed that the current guidelines do not speak to the types of research that non-medical ethics committees deal with.

> *"But they (guidelines) don't really talk much about vulnerable participants. For me that's more important, going into a vulnerable community or with a vulnerable group. They (guidelines) don't really consider the types of studies that we engage with on the non-medical committees. So, I would say no, it's not fit for purpose. You know, they're pushing even in the reports and things that we had to fill in for the audit and the annual reports, all that they really interested in is active monitoring, which is something that we always end up having to defend. Why we're not doing it?"*
>
> ***Participant 2***

> *"It does impact on how one does monitor because it gives you an outline of what has to happen active and passive monitoring has to happen. But as mentioned that capacity and funding is a huge problem. So, it's all fair and well to put stuff like that and in the guidelines and say you have to do certain stuff, but you can't because you don't have the funding. The guidelines are very heavily medically inclined. So, it's very difficult to catch that balance between what should be done and shouldn't be done in the realm of non-medical social sciences."*
>
> ***Participant 1***

Resources (Human and Time)

Effective monitoring requires ethics committee members and administrative staff to set aside time to ensure the adequate workforce and the required funding to conduct effective monitoring are in place. Ethics committees are made up of chairs, members (usually academic staff as part of academic citizenship) and administrative staff that meets once or twice a month to deliberate on ethics applications. Ethics committee chairs and members are required to set time aside time over and above their busy schedules to attend ethics meetings and attend the review of applications. This is indicative of ethics committees being overburdened with ethics requirements as a committee but not having the required resources to fulfil these requirements.

"It has a huge impact I believe, from the training to capacity to the funding, if you don't have the funding, you can't get capacity to be able to do the monitoring to the full extent. This is something that we're raised with the NHREC numerous times at numerous audits and meetings."

Participant 1

"I think ethics committees always feel that they under resourced relative to the work that they have to do and so this does effect monitoring as well."

Participant 9

Training

The interviews revealed that committee members are not specifically trained in monitoring studies approved by the ethics committee. Members are not clear on what is required for effective monitoring and what to look for when monitoring to ensure that the study was conducted ethically and that participants were protected. The guidelines in this respect are not helpful. This is indicative of ethics committee members implementing monitoring as they see feasible, taking limited training and unclear guidelines into consideration. This finding speaks to a need to implement a requirement for specific monitoring training for members of committees.

"So here it's actually quite frustrating regarding monitoring because the NHREC says yes, you need to monitor. It's really important to monitor, but they don't actually give us any information about how to monitor. So, it's actually very frustrating because the NHREC consistently tells us, as a committee and I suspect you know, it isn't just us, it's everyone. They say to everyone you must monitor, but they don't actually tell us how we should monitor or what they're actually looking for. It's actually very difficult to know what we're doing is conforming to those standards or expectations of monitoring because they don't actually tell us what those expectations are."

Participant 3

Universities are becoming more research-intensive, resulting in more Master's PhD studies and staff projects, which results in more ethical clearance application submissions. University non-medical ethics committees are required to review, approve, and monitor all applications that are submitted. Limited capacity, resources and training play an important role in the ethics committee's ability to monitor projects successfully. This creates a situation where ethics committees fulfil their responsibility of monitoring minimally because they do not have the necessary resources available.

"I think limited capacity and resources and training does affect the monitoring process and if we talk about resources I think about human resources. But I also think about human resources that are, mindful, and that can comprehend what everything is all

about, and also understanding processes. How does it work? Where does it go? I think training is very, very important. I think extra human resources would be helpful and a clear demarcation of the roles of the people that are doing this".

Participant 6

Literature supports this finding, as scholars often state that resources (human and time), specific monitoring training and financial backing are barriers to effective, more detailed monitoring being conducted by ethics committees (Dhai, 2005), (Davies, 2020) and (Karunaratne et al., 2006).

4.2.4. The role of monitoring in detecting deviations and the use of consent forms

According to the literature, ethics committee monitoring should facilitate some form of detecting deviations from approved protocols. The literature describes protocol deviation as being detected during active monitoring and not during passive monitoring (Davis, 2018; Douglass et al., 1998). However, the interviews conducted in this study, revealed that deviations are usually detected through the amendments process implemented by the ethics committee.

"However, sometimes when there are changes, students usually notify us, and we make an addendum to the original application". ***Participant 5***

"You know if they follow the guidelines and they know if they want to amend something they need to write the letter and ask for the amendment and if there are changes in terms of methods of data collection, they need to notify the committee. So, I think those are ways that we can monitor it, and research supervisors should be much more informed about this."

Participant 6

The amendments are submitted to the ethics committee for approval. Once approval of these amendments is granted, the researcher can continue with the study. However, the detection of deviations is reliant on the researcher contacting the ethics committee to request approval of amendments in the first place. The findings revealed that this may not always be the case, where researchers report deviations. This places the ethics committee in a vulnerable position where participant protection is concerned.

"A deviation from the approved study might be something like adding another question to the questionnaire. So, you know kind of like officially that is a deviation from the approved study. So, you know those kinds of things aren't necessarily problematic, but certainly in reporting substantial deviations, you know we have an amendment system in place. Which is kind of how any researcher should make changes to the approved

study. Again, you know that's kind of dependent upon the researcher actually contacting us in the first place."

Participant 3

In the case of using signed consent forms as a measure of monitoring, the literature notes that this function provides ethics committees with a measure of ascertaining that proper and full consent was obtained. Literature supports that reviewing signed consent forms discloses to committees that the proper consent form was used as approved and could disclose if faulty consent forms were used (Weijer et al., 1995). The findings of this study related to the use of reviewing signed consent forms varied. Some respondents deemed that reviewing signed consent forms could be beneficial as it could give the committee an indication that participants understood what the study was about, and they agreed to their participation in the study. This process could reveal whether the proper consent form was, in fact, signed or not.

"So, the thing is that I think asking for sign consents randomly is a very good idea, because then you could ensure that it is being done in a written sense because that is where our preference is that there's written consent. I mean, obviously there's projects where verbal consent is the way to go."

Participant 8

In contrast to the above some respondents believed reviewing signed consent forms as a measure of monitoring breaches confidentiality and anonymity. Participants sign consent forms before data collection commences, so the signed consent form does not indicate that participants were protected during the data collection phase. Furthermore, it breaches anonymity because people monitoring the study are aware of who participated in the study.

"I can sort of see the merit of asking for it (signed consent forms), but I don't actually know that it will tell us anything. But the other thing as well, of course, is that you know with respect to a consent form, a consent form is signed before the interview or before the activity. And often and if anything, unethical takes place, it actually takes place during the interaction, not before the interaction. The fact that we have a signed consent form doesn't actually tell us what took place during that, hour of the interview or the two hours of the focus group or whatever it is."

Participant 3

4.2.5. Monitoring guidelines, its influence and need for adaptation for university non-medical ethics committees

The monitoring guidelines play an important role in how university ethics committees monitor research they approve, and this was evident from the interviews conducted. The guidelines provide ethics committees with a guide on what is required in terms of monitoring. However, the interviews revealed that the guidelines are premised on medical research ethics and do not consider monitoring social science research. The interviews revealed that this is not helpful when monitoring non-medical research. Non-medical ethics committees primarily review social science research, and the need for appropriate guidelines for monitoring these types of research was evident from the participant responses.

> *"I have found it surprising that we can be audited, but we won't be asked for input on constructing guidelines for Social Research. So, it's that the medical and animal guidelines have been adapted to socially situated research. It's very hierarchical and how it's applied and as far as I know there has not been an effort by NHREC to come to ethics committees around the country and have a forum, where people from the non-medical committees give input into how these guidelines should be written".*
>
> ***Participant 4***

There was consensus from the participants that there is a need to adapt or change monitoring guidelines for non-medical research. Non-medical research varies substantially from medical research, and therefore, the way monitoring is conducted for these different categories should vary as well.

> *"It's not one size fits all, medical doesn't necessarily just fit non-medical. We need to look at that very carefully and maybe there should be a section in the NHREC guidelines that specifically speaks to medical and non-medical."*
>
> ***Participant 6***

> *"So, I think, the guidelines try to sort of set one standard and I think that it would be helpful if they could differentiate and say, you know, based on risk level, these are the expectations for monitoring."*
>
> ***Participant 9***

Respondents were of the view that if the monitoring guidelines were determined per committee and research type reviewed, it would result in clear guidelines of how each committee should monitor and the most appropriate questions to ask for monitoring purposes. There was consensus that adaptations to the guidelines are required around the types of monitoring required per risk level for non-medical research. A higher-risk study will require a more rigorous monitoring approach. Respondents suggested that aspects such as new research

methodologies and vulnerable participants should be considered when drafting the monitoring guidelines to make it more suited to non-medical research. A more nuanced and suited monitoring approach for non-medical research to ensure participant protection and adherence to ethical standards is therefore required for university non-medical ethics committees.

> *"It is difficult to make provisions for that in the DOH 2015 because the NHREC Council does not have authority, but examples to contextualize would be helpful and better training and understanding of the ethics principles could also assist in that regard, but I think it is unfortunately, it's a gap because there's no other act or body who actually mandates authority over non-medical ethics committees or non-health committees".*
>
> ***Participant 7***

The interviews further revealed that university non-medical committees require a suitable framework for monitoring non-medical research. Through the interviews, it was suggested that the oversight body (NHREC) should provide information to ethics committees on how to monitor, what to look out for, and how monitoring should be conducted per risk associated with a study. What kinds of studies require a higher level of monitoring, and what form of monitoring it should take. The respondents expressed that a suitable monitoring framework will enable university ethics committees to be more compliant.

> *"I think it is fair, I just think there could be a bit more detail in the guidelines and maybe stratified according to risk of the research".*
>
> ***Participant 9***

4.3. Conclusion

This chapter outlined the key findings that emanated from the study. Passive monitoring is practices by non-medical ethics committees because it is considered feasible in the context of limited capacity, funding, and the nuances of non-medical research. However, this function is conducted by a select few within the committee. The study further revealed that monitoring could facilitate ethical behaviour, but this is mainly dependent on the researcher and their perception on monitoring. The findings reveal that resources continue to be problematic for ethics committees in relation to monitoring and this is also substantiated in the literature. Monitoring could assist in the detection of deviations, but again this is reliant on the researcher to report such deviations. Furthermore, the study found that the governing guidelines for monitoring are paramount in guiding and assisting ethics committees to monitor appropriately for their committee, and if guidelines are ineffective, it impacts monitoring.

5. CHAPTER 5: ANALYSIS OF FINDINGS

5.1. Introduction

The study aimed to investigate monitoring approaches used by non-medical university ethics committees and their effectiveness. The study further aimed to ascertain how aspects such as guidelines and limited capacity and resources affect monitoring for non-medical research. To evaluate the effectiveness of non-medical monitoring approaches, the study sought to answer the below main research question and sub-questions.

5.2. Main Research Question

How effective are university non-medical monitoring approaches and how do the current guidelines for non-medical research aided in ensuring ethical standards are adhered to during the data collection process?

5.2.1. Sub-questions

- How effective are the South African guidelines with regard to monitoring non-medical research in the context of limited resources and capacity?
- How can South African monitoring guidelines be adjusted to fit the non-medical research ethics space to ensure effective ethics compliance throughout the data collection process?

This chapter is dedicated to analysing the findings from the interviews conducted with nine participants who monitor non-medical research in their capacity as chairs, co-chairs, members, and experts. This chapter will also draw on findings from previous literature on this topic.

The following codes and themes were devised from the interviews conducted. Each theme will be discussed in this chapter with the use of anonymous quotes from the interviews for reference. To maintain anonymity, the participants were coded as set out below.

Table 3: Codes

Participant	**Designation**
Participant 1	Research Ethics Expert
Participant 2	Chair of a Non-Medical Ethics Committee
Participant 3	Co-Chair of an Ethics Non-medical Committee

Participant 4	Non-Medical Ethics Committee member
Participant 5	Non-Medical Ethics Committee member
Participant 6	Co-Chair of an Ethics Non-medical Committee
Participant 7	Research Ethics Expert
Participant 8	Co-chair of an Ethics Non-Medical Committee
Participant 9	Chair of an Ethics Non-Medical Committee

The following themes emanated from the interviews conducted, and these are interconnected. Five themes were prominent from the interviews: 1) Monitoring approaches utilised and the responsibility of monitoring at South African universities, 2) The role of monitoring in ethical behaviour and compliance**,** 3) Factors influencing monitoring, 4) The role of monitoring in detecting deviations and the use of consent forms**,** and 5) Monitoring guidelines, its influence and need for adaptation for university non-medical ethics committees. The interview results were analysed using thematic analysis and the use of previous literature.

5.3. Thematic Analysis

5.3.1. Theme 1: Monitoring approaches used and the responsibility of monitoring at South African universities

The review and approval processes practised by South African university non-medical ethics committees are rigorous. However, the post-approval monitoring process lacks in comparison. According to Blunt et al. (1998), ethics committees must review large volumes of research projects which vary greatly in nature and, at the same time, have the challenging task of maintaining a consistent approach that affects their ability to monitor with the same rigour. Halwai and Vaswani (2023) purport that ethics committees are often thorough for the initial review; they are also responsible for post-approval monitoring of the research they approve. Although great effort is made in the pre-approval process, there is a serious lack of surveillance and oversight after approval (Halwai & Vaswani, 2023). This is due to various factors that influence the committee's ability to monitor. In many instances, monitoring is kept to a minimum. Ethics committees are accountable for monitoring research that gained approval

through their committee for the primary purposes of ensuring participants are protected, and ethical conduct of research (Pandiya, 2011).

The two forms of monitoring exist: passive monitoring and active monitoring. According to Shetty et al. (2014) and Thatte and Marathe (2017), passive monitoring consist of the assessment of documents submitted by researchers as updates on their studies, whereas active monitoring means visiting study sites to ascertain that studies are being conducted ethically. The interview findings suggest that university non-medical ethics committees tend to conduct passive monitoring (the submission of documents by researchers), and this is based on risk level. All participants who were interviewed mentioned that only passive monitoring is conducted through their non-medical ethics committee.

Passive monitoring is used as opposed to active monitoring due to various reasons such as limited resources, time, funding, expertise for active monitoring, committee workload, location of study, and the volume of applications received for review. Many non-medical ethics committees find it challenging to conduct active monitoring as required by the guidelines due to a lack of human resources, inadequate communication, and restricted access to study sites (Kruger et al., 2014). The findings of the interviews concurred with scholars in the field, expressing that ethics committees are challenged in relation to what is required/expected of them versus their ability to meet these expectations.

According to Ndebele et al. (2014), several factors affect an ethics committee's capacity to review and oversee research studies, including ineffectively managed committees, inadequate funding, overworked committee members, outdated laws, and low or non-existent awareness of guidelines. Although there are established guidelines (framework) for monitoring by the NHREC, the capacity is limited, resources are scarce, members are overworked, and therefore, ethics committees cannot meet these requirements. This is indicative of the monitoring guidelines (framework) as stipulated not yielding the anticipated results because non-medical committees are not fully able to meet the requirements for monitoring. This concurs with the literature, as many ethics committees in Africa expressed that their functions are hindered by challenges related to a scarcity of resources and insufficient training of ethics committee members (Nyika et al., 2009).

There was a correlation between the literature and the findings from the interviews in terms of why a passive approach is adopted as opposed to an active approach. Mostly, ethics committees do passive monitoring, which includes evaluating data at predetermined regular intervals, per

the SOPs, such as serious adverse event (SAE) reports, evaluations of protocol deviations or violations, progress reports, or any protocol amendments, etc. (Shetty et al., 2014). Davis (2018) describes that for university non-medical ethics committees to monitor as stipulated by oversight boards (passive and active) it requires active monitoring expertise, time, and capacity, which university non-medical ethics committees do not have. Therefore, university non-medical ethics committees often try to find a balance between the requirements for monitoring and the ability to monitor with the available resources of the committees for compliance and to meet NHREC requirements.

The passive monitoring approach alludes to certain complexities regarding its success. It assumes researchers are always responsible when adhering to ethical standards, and it assumes that ethics committees are fully capacitated and trained to perform the monitoring function successfully. The interviews highlighted that this is not always the case; challenges in this regard exist. Ochieng et al. (2013) contend that researchers do commit ethical violations and that ethics committees should not solely rely on annual reports as a true reflection of participant protection during the research process. Additionally, as universities become more research-intensive, the workload increases with minimal capacity at hand to perform all required responsibilities. This is further exacerbated by the fact that DOH (2015) guidelines require both active and passive monitoring for all registered ethics committees, irrespective of the type of research they review and approve. Although passive monitoring is permitted, interview findings and literature support that passive monitoring does not sufficiently meet the requirement of participant protection after ethics approval.

The responsibility of monitoring

Non-medical university ethics committees comprise chairs, co-chairs, members, and administrative staff who are as a committee ultimately responsible for monitoring research the committee approves. Monitoring is fundamentally the responsibility of the registered non-medical committee, as described by the DoH (2015) guidelines that stipulate that ethics committees have the responsibility to monitor the research they approve. The guidelines do not explicitly state who exactly should monitor, but ultimately, the university non-medical ethics committee is collectively responsible. Monitoring non-medical studies is ideally done for compliance purposes to conform to statutory requirements and is not conducted by the entire ethics committee. Literature stipulates that ethics committees should be multidisciplinary, knowledgeable, and capacitated to conduct all duties required by ethics committees, which includes continued monitoring (Kaur et al., 2017) and (Davies, 2020). The interview findings

are further supported by Guillemin et al. (2012), who quoted De Vries and Forsberg (2002) and stated that more knowledgeable capacity is required to enable committees to perform their duties adequately and sufficiently as ethics committees.

According to Kaur et al. (2017) and Davies (2020), the makeup of ethics committees, particularly those at universities, should be multidisciplinary, appropriately established, and capacitated. This allows for the pooling of knowledge across the disciplines and areas deemed necessary for comprehension to provide a comprehensive assessment of any moral dilemmas that may arise during the research project. The guidelines are clear that the ethics committee should monitor. However, the guidelines do not clearly state how the ethics committee should take on the responsibility of monitoring that is all-inclusive of all members, ensuring capacity and monitoring knowledge and expertise for ethics committee members. Currently, monitoring is conducted by chairs who are willing and to be compliant. This leaves a gap in terms of ethics committee members not having expertise or being knowledgeable on monitoring and, therefore, not fulfilling their complete role on the committee.

It could be argued that to strengthen the function of monitoring and to strengthen the committee, build capacity, and share the committee workload, members should also be involved and capacitated in monitoring non-medical research. However, the guidelines do not have specific requirements about who should conduct the monitoring. There is a gap in the guidelines that should be addressed through detailed guidelines with regard to the responsibility of the entire committee for monitoring.

5.3.2. Theme 2: The role of monitoring in ethical behaviour and compliance

Kombe et al. (2014) argue that there is a need to promote research integrity, ethical behaviour, and compliance among researchers, and monitoring has been identified as an avenue to do so. It is envisaged that monitoring should not be viewed as a process that is cumbersome and merely conducted for compliance. Once all parties involved in the monitoring process view monitoring as supportive as opposed to a hindrance, it could lead to progressed ethical behaviour and full compliance. The role of monitoring in aiding ethical behaviour and compliance varies in literature and is either seen as aiding in ethical behaviour and compliance or seen as interfering and questioning the researcher's integrity. As noted in the literature, some schools of thought regard monitoring as aiding in ethical behaviour because it allows researchers to detect where they went wrong, enabling timely corrective action, and allows for educational support (Shafiq et al., 2021; Cox et al., 2023). Whereas some scholars believe monitoring may be a form of policing research and may not aid in researchers being ethical

and compliant (Makhoul et al., 2014). This was corroborated through the interviews as well. The interviews revealed that there were varying opinions in terms of monitoring as a tool for aiding ethical behaviour and compliance.

Kombe et al. (2014) further argued that research integrity could be promoted through training, proper regulatory frameworks, and scrutinising current research policies for weaknesses. In terms of literature and the interviews conducted, there is no consensus with regard to whether monitoring aids in ethically conducting research or whether researchers are ethically compliant. The interviews did, however, concur that researchers should be trusted and trained so that they are equipped to conduct research ethically.

Within the university setting, most applicants who apply for ethics through non-medical ethics committees are students studying towards a degree. Their focus is on obtaining ethics clearance to start with data collection. The submission of the annual report requirement is therefore not always followed through by students which questions their ethical behaviour and compliance behaviour. According to Kruger et al. (2014), researchers need to be reminded to submit their annual reports because they do not always do it on their own. Non-compliance is difficult within a university setting because someone could have been compliant all through their Master' and PhD journey but slips up right at the end close to completion, and withdrawing ethics at this stage could result in massive repercussions for both the university and the student.

There is no definitive answer regarding whether monitoring does make researchers more compliant and makes researchers conduct research ethically. There are other factors, such as instilling a research culture and more support from the university community, which may be more effective in creating more compliant and ethical researchers. An array of mechanisms to ensure compliance and ethical behaviour should be explored to ensure ethical research. This is a duty that should be the responsibility of the entire university community and not just the ethics committee, especially as universities within South Africa become more research-intensive.

Monitoring as a tool for ethical behaviour is viewed differently among researchers, scholars, and individuals applying for ethical clearance. This speaks to the need for changed perceptions around ethics committee monitoring. The perceptions should be geared towards how monitoring creates a more ethical society, and that participant protection is at the heart of ethics monitoring.

5.3.3. Theme 3: Factors influencing monitoring

Guidelines

Research ethics committees have a tremendous amount of obligation due to the global expansion of research (Dhai, 2005). South Africa is a country that is conducive to favourable growth in research, yet sadly still has many vulnerable and poor populations (Dhai, 2005). To this end, the provisions within the guidelines ensure that the ethical conduct of research in South Africa is a legal duty (Dhai, 2005). Research ethics committees that review, approve, and monitor research should abide by these guidelines that are stipulated within the DOH (2015) guidelines. These guidelines are in place to ensure research ethics committees are ensuring participant protection for research that is conducted. Monitoring guidelines are stipulated for ethics committees to abide by and implement. In the non-medical ethics committee context, implementing these guidelines to ensure participant protection presents challenges for non-medical ethics committees regarding fulfilling the statutory requirements and the committee's ability to fulfil them. Hence, the guidelines stipulated for monitoring non-medical research do have an impact on how university non-medical ethics committees monitor research.

Guidelines for monitoring as interpreted by non-medical university committees were implemented to be compliant but within the bounds of what the university non-medical committees could fulfil. As substantiated by the interviews conducted, the monitoring function is performed, however, within the capability of the committees and the resources available. The guidelines are premised on health research. However, they apply to all ethics committees that are registered, which include non-medical and animal ethics committees. There are clear distinctions between ethics committees and the type of research they approve. This requires more nuanced monitoring guidelines per type of committee that can protect participants taking part in research studies.

Many studies within the non-medical realm look at studies that are not conducted within health settings or clinical trials. Non-medical studies often involve innocuous studies, studies involving vulnerable participants, and studies encompassing new research methodologies. Irrespective of whether research is medically inclined or not, participants must be protected. Monitoring requirements and guidelines to ascertain participant protection should vary based on the research being evaluated. It is argued in the literature that monitoring guidelines should be geared towards the types of research being evaluated for participants partaking in research.

Literature supports the stance that guidelines should be appropriate for what is being monitored. Milford et al. (2006) and Ndebele et al. (2014) promote that there is a serious need for suitable local ethical guidelines and standards to support the training of ethics committee members, to encourage the independence and diversity of the committee's membership, and to ensure that authorized research ethics protocols are being monitored appropriately. Knight (2019) argues that as research methodologies changed over the years with the inclusion of technological advancements, which altered interactions with participants, calls for a need to relook at guidelines that are fit for purpose. The literature and the interviews conducted support the need for appropriate guidelines for monitoring non-medical research that fits the scope thereof. The guidelines should guide, aid, and explain how monitoring should be conducted. However, this is not currently the case. Committees are devising their strategies for monitoring based on the type of research involved. This may not meet the monitoring requirements envisaged by the NHREC.

The monitoring guidelines are non-specific because they cater to various disciplines and various research being evaluated by ethics committees. This is understandable. However, these generic guidelines do impact monitoring because they create a situation where non-medical university ethics committees may not monitor as required for the type of research. It is clear from the literature and the interview findings that monitoring guidelines for university non-medical ethics committees should be adapted to cater to all ethics committees, considering the different types of research each committee reviews and approves. This creates a better system of monitoring, which then translates into better protection of human participants and better functioning of the committee. It further creates a situation where ethics committees are clear in terms of what should be monitored, why and how.

The research question in this study was, How effective are university non-medical monitoring approaches and how do the current guidelines for non-medical research aided in ensuring ethical standards are adhered to during the data collection process?

The findings of the research affirm that the guidelines do not aid specifically in ensuring ethical standards are adhered to during data the data collection process for university non-medical ethics committees. This is because the current guidelines are not suited for non-medical research, and neglect to take the type of research being evaluated into consideration. Non-medical research cannot be monitored in the same way medical research is monitored. Therefore, for the guidelines to be effective with regards to ensuring participant protection,

they should be tailored to fit the scope of research being evaluated, as well as available resources of the ethics committee. Therefore, there is a gap in the monitoring guidelines that caters for detailed appropriate guidelines per committee per type of research they consider and review, and their available resources.

Resources (Human and Time)

The function of monitoring approved studies has clear advantages but obstacles as well. These obstacles include inadequate legislative support, a lack of resources (financial, time and human), and organizational structures (Cox et al., 2023). Often a lack of resources, and training are often cited as hindrances to adequate monitoring by non-medical ethics committees (Karunaratne et al., 2006) and (Davies, 2020). Within a university setting, individuals who form part of the committee are experts in various multidisciplinary fields. The study conducted by Kaur et al. (2017) on ethics committees in India revealed that the composition of ethics committees should comprise active members who represent a diverse range of ethical, cultural, legal professional, educational, and community interests, as well as experts from multiple disciplines who are crucial for properly judging a research project.

Only a few individuals are willing to serve on ethics committees because of the time commitment attached to serving on the committee. Members are not compensated to serve on the committee, which essentially means that they are volunteering to serve on the committee. Volunteering for a function that requires a large time commitment, over and above their day jobs. Universities are becoming more research-intensive, resulting in more submissions for ethical clearance. Some responsibilities are often minimally conducted because of time and capacity. Participants cited capacity as a major issue experienced by ethics committees. Ethics committees are often overburdened because there is not enough capacity for all the responsibilities required by ethics committees. Kadam and Karandikar (2012) provide support for this, stating that untrained staff, an overwhelming workload, space limitations for ethics committee work, a lack of administrative capacity, and inadequate compensation for committee members are just a few of the problems that ethics committees must deal with.

Often, only one administrator is provided for ethics committees. However, the responsibility they carry is huge, and often, certain responsibilities fall through the cracks (monitoring) because there is not enough capacity to complete these tasks with the required dedication adequately. As capacity, time and funding are issues for committees, it results in a situation

where there are requirements for monitoring, but ethics committees are constrained and unable to fulfil this requirement effectively. There is a clear gap between what is required in terms of the guidelines and the committee's ability to fulfil these requirements. The governing authorities do not consider the realities faced at universities when drafting these guidelines. Clear guidelines on capacity requirements should be stated in the guidelines that would enable all the requirements for ethics committees to be met. The sub-research question in this study was, 'How effective are the South African guidelines with regards to monitoring non-medical research in a context of limited resources and capacity?.' It is clear from the findings that when the guidelines were drafted, resources for non-medical ethics committees were not considered because ethics committee staff were not able to meet the expectations of the guidelines with the resources available. There is a clear link between the committee's ability to monitor effectively and the resources available. This is indicative of current guidelines not being effective for monitoring in a resource-constrained environment.

Training

Ethics training will assist in creating a culture of research integrity among staff, students, and ethics committee members that will assist in ethical behaviour required when data collection commences. Training specific to monitoring is required because it will assist those assigned for monitoring to know what to look for and simultaneously ascertain that ethical standards were upheld, and participants were protected. Therefore, the development of appropriate monitoring training is required. Although the guidelines mention that monitoring should be conducted and certain types of monitoring are mentioned, the guidelines fail to mention what exactly is required for monitoring, how to monitor per type of committee, who exactly should conduct the monitoring, and what is required when monitoring. The guidelines do not state what kind of training and training level is required for monitoring.

There is consensus in the literature and the interviews that training would assist in ensuring that monitoring is conducted with more careful consideration and understanding. University ethics committees are accountable for monitoring participant safety in the absence of an infrastructure that would make it possible for them to do so (DeMets et al., 2006). There is a disconnect between what is required in terms of monitoring and the training to do what is required by the guidelines. Working within a capacity-limited environment restricts ethics committees when it comes to monitoring studies and following up with researchers to submit

their annual reports. Active and passive monitoring are required, however, there are no specific monitoring training guidelines provided to committees to do this function. There is a gap in the guidelines that speaks to specific monitoring training for ethics committees that will enable ethics committees to perform the monitoring function that is done more effectively.

5.3.4. Theme 4: The role of monitoring in detecting deviations and the use of consent forms

Protocol deviations occur when there is a detour from what was initially approved by the ethics committee. Some deviations are necessary because research evolves, and a deviation may result in more insightful findings. However, researchers should immediately report any deviations to the ethics committee and follow the proper procedures in having the deviation approved before any further data collection can commence. This further relies on the researcher's integrity to report these deviations, to avoid any unethical behaviour. Literature advances that the monitoring function of ethics committees should be strengthened to detect deviations and a host of other research misconduct (Gajbhiye et al., 2020) (Cox et al., 2023). The interviews revealed that the best way to report deviations is through following an amendment process. The problem with this process is that it is reliant on the researcher to do this. The researcher may not always report deviations, which could result in participant protection being compromised. According to Cox et al. (2023), to identify protocol deviations and a variety of other ethical misconduct, such as faulty consent, unapproved recruitment procedures, and elements of non-compliance, ethics committees should monitor approved studies more closely. Kruger et al. (2014) advance this sentiment by expressing that the expansion of the ethics committee's responsibility to include random monitoring of research they approve could help prevent, identify, and lessen research ethical irregularities in cases when investigators do not always follow the approved protocol. These violations can frequently result in serious harm to participants as well as have an impact on the study's findings (Cox et al., 2023).

The participants emphasised that amendment processes are in place within the university non-medical ethics committees, and information on the process is readily available. However, there is no control over researchers after they receive their ethical approval. Ethics committees do not have systems in place, which prompts researchers to submit annual reports by the due date. Although all ethics information is available, there is no guarantee that researchers will read the information. All information pertaining to researchers being compliant and knowledgeable regarding any ethical issue is available. However, there is no mechanism available to ensure that researchers are fully aware of what is required when they need to deviate from what was

approved. This finding reveals that more awareness is required around protocol deviations, the seriousness of reporting it and how it affects participants. Literature expresses that monitoring could be conducted with more careful consideration, resulting in the detection of deviations. The structure of the monitoring report could be relooked and revised to ask questions that prompt more careful ethical consideration on the researcher's part.

Consent forms

The DOH (2015) guidelines recommend that post-approval monitoring mechanisms can extend to reviewing signed consent forms (DOH, 2015). Literature expresses that reviewing signed consent forms aids in participant protection and avoids conflict of interest, and this process can assist ethics committees in detecting issues that may have been missed through the submission of annual reports (Apau Bediako & Kaposy, 2020) and (Sugarman et al., 2005). This suggests that reviewing informed consent as a measure of monitoring is a strong tool for ascertaining whether participants were protected. Literature also contends that informed consent is pivotal because participants should be fully informed about the research and what they are either agreeing to or not agreeing to (Borovecki et al., 2018). Kruger et al. (2014) contend that monitoring can also be thought of as a form of quality control, in which the non-medical ethics committee watches the consenting procedure to determine first-hand whether the entire procedure is adequate. However, in the case of non-medical studies, study sites are located across the country and even abroad.

The literature makes a strong case for the use of consent forms as a monitoring mechanism for participant protection to be used by ethics committees. In contrast to the literature, the interviewees believed that viewing signed consent forms only establishes if correct consent was obtained and what participants agreed to. However, there is no consensus regarding reviewing consent forms is an effective approach for monitoring. It does not disclose if anything unethical took place during the interaction with participants. For effective monitoring to be obtained, it should ensure that participants are protected throughout the process. Taking the views of scholars within the ethics monitoring field and the participants interviewed reviewing signed consent forms is only a small part of effective monitoring. Effective and full monitoring requires more strategies to be implemented, along with reviewing signed consent to be effective. Although the DOH (2015) guidelines mention the use of reviewing signed consent forms as a means of monitoring, it cannot be used in isolations; a thorough monitoring strategy should be devised to accompany this method of monitoring to be effective. A gap identified with the use of reviewing signed consent forms is that it allows for a breach of

confidentiality and anonymity, and participants may not even be aware that someone other than the researcher or supervisor is aware that they participated in the study.

The interviews further revealed that supervisors of research projects should review consent forms because it will maintain the confidentially and anonymity of participants. Informed consent is a required process when dealing with human participants and is rigorously checked by the ethics committee before researchers are allowed to commence with data collection. Ethics committees scrutinise all the forms before data collection to ensure that participants are fully protected. However, the researcher's integrity is still relied upon to ensure the research process is ethical in every respect. It was revealed through the interviews that reviewing consent forms as a way of monitoring may not be adequate for monitoring non-medical research studies.

5.3.5. Theme 5: Monitoring guidelines, their influence and the need for adaptation for university non-medical ethics committees.

Davies (2020) and Flicker et al. (2007) state that community-based participatory research, which is primarily conducted within non-medical research, is not taken into consideration by statutory requirements, which were primarily written for research ethics committees whose work is related to biomedicine and health. The current monitoring guidelines do not consider socially situated research and make monitoring difficult to conduct for non-medical ethics committees. Although, the guidelines are drafted in a way that is general to all committees, it misses out on nuanced scenarios each ethics committee encounters based on the type of research studies they review and approve. This is a clear indication that the current guidelines are not fit for the social science type of research. The findings of the interviews and literature suggest that appropriate monitoring guidelines are required for university non-medical ethics committees. There is a requirement for a fair mechanism for judging qualitative research, and this entails an acceptable process for keeping track of ethics throughout the investigation (Ramcharan & Cutcliffe, 2001).

Applying active monitoring (as required in the guidelines) in socially situated research may make research participants uncomfortable and allow for a breach of confidentiality and anonymity. Participants may not be truthful in their responses to certain questions because they are aware that they are being watched. Kruger et al. (2014) explain that active monitoring may influence the behaviour of the participant and the researcher, whereby the researcher may make a greater effort to explain what the study is about. Alternatively, the participant puts forth more effort to appear to pass the test since they are aware that the non-medical member is monitoring

the study (Kruger et al., 2014). The need to add or adapt the current guidelines is imminent because of new methodologies that have emerged within this space, and the traditional monitoring guidelines may not take these into account. Insight into these methods may assist in devising a more appropriate way of monitoring with the end goal of protecting participants. Additionally, studies with higher risk levels require additional forms of monitoring as opposed to minimal-risk studies. Involving non-medical ethics committees when drafting the guidelines would be advisable because these committees deal with social science-type studies and are experts in these disciplines.

Guidelines for monitoring non-medical research need to be updated and adapted to the type of research non-medical ethics committees adjudicate and monitor. The current guidelines focus on monitoring medical research, which is not appropriate for non-medical research. The guidelines further do not take into consideration available resources, vulnerable participants, new research methodologies, the use of social media within research, artificial intelligence aspects, autoethnography studies, and indigenous research methods that are often used in non-medical social science research. Kass et al. (2007) stated that the absence of national rules and standard operating procedures had an impact on the calibre of the committees' work. This is further substantiated by De Wet (2010) who states that a successful ethics committee and suitable criteria in place will encourage thoughtful discussions and debates inside the non-medical ethics committee, which will eventually trickle down from approval to the monitoring phase. To make fair and accurate judgments, guidelines should be accurate and fit for purposes that will ensure participant protection (De Wet, 2010).

Although, the guidelines for monitoring by ethics committees are general in that it is established to cover all research ethics committees, it often leaves gaps within the sphere of monitoring because it is not a one-size-fits-all kind of approach. Although all ethics committees are obligated to comply with these guidelines, some gaps have been identified through the interviews. The gaps include that active monitoring may not always be appropriate in a non-medical context, and the guidelines need to clearly state in what scenario active monitoring should be applied within a non-medical context. Monitoring guidelines need to be developed per ethics committee, e.g. specific monitoring guidelines for medical ethics, specific guidelines for non-medical ethics, etc. The monitoring guidelines should be established with the help of ethics committee members within South Africa because they have insight into the kinds of studies that are submitted for review.

The second sub-question of this study was 'How can South African monitoring guidelines be adjusted to fit the non-medical research ethics space to ensure effective ethics compliance throughout the data collection process?.' It is evident from the literature and the interviews that guidelines for non-medical ethics committee monitoring should be adapted to include how to monitor with limited resources, consider venerable participants, new research methodologies, and aspects such as confidentiality and anonymity. Proposed adaptations should include a need for the creation of a strong ethics culture within universities. This culture should filter through from the start of the student journey. The ethics committee's duty to monitor should be publicised more to enable an environment where monitoring is seen as an enabling function, as opposed to a barrier to research. Depending on the severity of a study, monitoring guidelines should stipulate exactly what kind of monitoring is required based on risk level. E.g., if a study is determined as high risk, greater monitoring approaches should be incorporated, such as a covert active monitoring approach, and more frequent progress reports. As the number of high-risk studies reviewed and approved by non-medical ethics committees is few, researchers could be called in to provide a summary of how participants were protected during data collection.

As specific training for monitoring is required, as stipulated in literature and interviews, specific monitoring training guidelines should be presented in the guidelines. This will ensure that ethics committees know exactly what is required in terms of monitoring. This will further bring clarity in terms of what questions should be answered through the monitoring approach that will ensure participant protection. This will result in ethics committee members being aware of monitoring requirements in terms of meeting the expectations of the NHREC in terms of monitoring. This will build committee capacity and strengthen the committee.

Literature advances that ethics committees require a suitable framework for monitoring that will improve the function of monitoring (Silverman et al., 2015; Cox, 2023). A framework will give university ethics committees a structure in terms of how to monitor studies that are approved considering the risk level associated with the study. High-risk studies may require more rigorous monitoring as opposed to a minimal-risk study. The interviews revealed that more could be done in terms of monitoring and that a suitable framework should be established based on risk level. The framework should provide a structure of how monitoring should be conducted for each risk level (minimal, low, medium, and high risk) and training on how to monitor each level is required for non-medical ethics committees.

As a requirement, the guidelines require that ethics committees registered with the NHREC should conduct both active and passive monitoring. The type of monitoring required per study

should be determined by the ethics committee itself by the given authority. It is suggested that guidelines define which studies require active monitoring and how this monitoring should transpire. This will enable committees to consider nuances tailored to their committee and apply appropriate active monitoring approaches that take confidentiality, anonymity, participants, researchers, and the study results into consideration.

It is clear from the interviews and literature that monitoring is paramount and that non-medical university ethics committees should have a framework in place that is geared towards ensuring participants are protected, researchers are ethical and that the type of monitoring is fit for non-medical research. The interviews revealed the need to adapt the current approach, which would enable non-medical university ethics committees to monitor in the most appropriate way that would fulfil the statutory requirement considering the constraints, but at the same time ensure that participants are protected during the process. A hybrid system of monitoring, adapting the annual report form, and making provision for non-medical monitoring within the stipulated guidelines were mentioned as possible adaptations to the monitoring process.

5.4. Conclusion

The study aimed to answer the following research question: how effective are university non-medical monitoring approaches and how do the current guidelines for non-medical research aided in ensuring ethical standards are adhered to during the data collection process? It is clear from the findings that the current monitoring approaches are not effective, and the guidelines may not have effectively aided in ensuring ethical standards are adhered to because the guidelines are not geared towards non-medical committees. The interview findings suggest that passive monitoring is not effective because of factors such as capacity, lack of control, and inappropriate guidelines. The NHREC requires active monitoring as part of the guidelines, but this proves challenging for university non-medical ethics committees. Non-medical ethics committee faces challenges because of a lack of specific monitoring training, as well as resource constraints. Generally, the committee cannot fully fulfil the requirements of monitoring and, therefore, cannot always ensure ethical standards are upheld during data collection.

Capacity hugely impacts the function of monitoring because it would allow certain members or administrative staff to focus only on monitoring, be able to follow up on annual reports, and further be able to monitor non-medical studies as required adequately. The data collected provided evidence that current monitoring approaches used by non-medical ethics committees

(passive monitoring) are not effective. The data collected further revealed that the passive monitoring approach used does not adequately protect participants, and solely relies on researchers to submit annual report, and therefore not effective. The data collected also revealed that ethics committees do not have full control over the monitoring process, and other more effective ways of monitoring are required.

The key findings of this study are:

1) The passive monitoring approach is employed by non-medical ethics boards, which receive yearly reports from researchers. This method depends entirely on the researcher's honesty. The NHREC has set criteria (a framework) for monitoring. Nevertheless, ethics committees are unable to achieve these requirements due to insufficient ability, scarcity of resources, and overworked members. This is an indication that non-medical committees are not entirely able to meet the requirements for monitoring, which is why the specified monitoring standards (framework) are not producing the expected outcomes. While passive monitoring is permitted as a monitoring method, the literature and interview data indicate that it falls short of providing adequate participant protection following ethics approval.

   The importance of this finding is huge because ethics committees are tasked with the responsibility of ensuring that research participants are protected, and that research is reputably conducted. Research participants greatly contribute to the body of knowledge in understanding any research phenomenon. Their protection is paramount to the advancement of research. Research should not be based on data where participant protection was compromised in any form. Therefore, the monitoring should be conducted in a way that protects participants and advances research in a reputable manner. This finding revealed that passive monitoring alone does not ensure participant protection. Additional monitoring approaches, and additional resources should be investigated to ensure participant protection and full compliance.

2) The guidelines are clear that the ethics committees are responsible for monitoring. The guidelines, however, are unclear about how the ethics committee should assume the duty of monitoring, which includes ensuring that all members have the capacity, necessary skills, and knowledge. Regarding the monitoring responsibilities of the entire

committee, there is a gap in the guidelines that can be addressed through specific instructions.

This finding is important, because it suggests that most ethics committee members do not monitor studies they approved. Members are not involved in all their responsibilities as members. All members should be involved in ethics monitoring to build committee capacity, share the workload, ensure compliance, and strengthen the committee. Monitoring is pivotal to ensuring participants are protected, and that unethical behaviour did not take place.

3) The role of monitoring as a tool for ethical behaviour and compliance is discussed in the literature. Within the research community, the role of monitoring is viewed variously, with some seeing it as a support for ethical behaviour and others as a barrier to research. This illustrates the necessity of redefining attitudes toward ethics monitoring. The emphasis should be on how ethics monitoring fosters a more moral society and how participant protection is a central component.

   The importance of this finding is significant to the body of knowledge. The success of monitoring relies greatly on how it is perceived and the role it plays. Collectively, monitoring should be perceived as an enabling tool that advances ethical research with sound research results. Monitoring should not be perceived as a mechanism to question research integrity but rather as an educational tool for better participant protection and undoubted research.

4) The study discovered that three elements - guidelines, human and time resources, and training influence how non-medical ethics committees conduct monitoring. The study concluded that the guidelines do not particularly help to ensure ethical principles are followed when gathering data for university non-medical ethics committees. Since the existing rules are inappropriate for non-medical research and fail to account for the nature of the research being assessed. As a result, there is a gap in the monitoring guidelines that addresses specific, suitable guidelines for each committee and the kinds of research they evaluate. There is a glaring discrepancy between the guideline’s requirements and the committee's capacity to meet them. When creating these

guidelines, the reality faced at universities was not considered. To ensure that all ethical committee monitoring criteria are satisfied, the guidelines should include explicit instructions on capacity needs. There is a gap in terms of specific monitoring training that ethics committees should obtain to help them carry out the monitoring responsibility more efficiently.

The importance of this finding is fundamental to the body of knowledge on ethics monitoring. Ethics monitoring requires specific training so that someone monitoring a study, is fully aware of what is required of them when monitoring. Training should ensure what to look out for, what is considered highly unethical where a study needs to stop immediately, and what is considered minor so that corrective action can be taken swiftly, without any negative consequences.

Ethics monitoring has not been adequately conducted because time and human resources are limited. People involved in ethics committee work do so in their spare time over and above their day jobs. Permanent resources and funding should be invested in the function of monitoring so that monitoring is conducted as envisaged and that any research misconduct or unethical behaviour can be dealt with properly and swiftly. Compromised participant protection and research misconduct can have damaging effects and reputational damage not just for the ethics committee but for the university as well. Therefore, proper skilled resources should be invested to avoid unnecessary consequences.

This study found that guidelines play an important role in guiding ethics committees on what is required for monitoring and how to monitor. However, the study found that the current monitoring guidelines are not adequate in a non-medical context. As a result, monitoring is conducted in the most minimalist form, resulting in reduced participant protection and a great chance of research results being affected or flawed. The role of ethics committees is to ensure participants are protected throughout the research process, and this study reveals that guidelines should be drafted in a way that enables this.

5) It has been suggested in the literature that monitoring can help identify deviations from approved studies. It is the responsibility of the researcher to notify the committee of any deviations. However, there is no system in place to guarantee that researchers understand exactly what must be done when they need to deviate from what has been approved. This result indicates that there must be a greater understanding of protocol deviations, the importance of reporting them, and the impact they have on participants. The monitoring report structure might have to be re-evaluated to ask questions that prompt more careful ethical consideration on the researcher's part.

   This finding is important because if deviations go unreported, it could have negative consequences for the study and research results. It creates a situation where the ethics committee does not have jurisdiction over the deviation as it was not approved. When a deviation is reported, and approved, the researcher can confidently continue with their study, knowing everything is ethical and above board. However, if a researcher neglects to report the deviation, they are not covered by the ethics committee, and if found out, they will have to face the consequences thereof. This could have detrimental effects on the researcher and the university.

6) The literature has identified reviewing signed consent forms as a way to keep an eye on studies that have been approved. This study found that reviewing signed consent forms is only a minor portion of efficient monitoring. In a bid to ensure monitoring is comprehensive and effective, other tactics must be put into place, in addition to checking written agreements. The DOH (2015) recommendations mention evaluating signed consent forms as a monitoring tool; however, this tool cannot be used in isolation. Rather, a comprehensive monitoring plan must be developed to go along with this monitoring approach for it to be effective. Reviewing consent forms that have been signed has been shown to have a flaw in that it permits a breach of anonymity and confidentiality, and participants are not even aware that someone other than the researcher or supervisor is aware of their participation in the study.

   The importance of this finding illustrates that reviewing signed consent forms used as a method of monitoring should be used in conjunction with another monitoring method because it is not effective on its own. Ethics committees should guard against using this

method in relation to confidentiality and anonymity. Creative ways of using this method should be explored through the assistance of supervisors who are eligible to see consent forms. This way prevents ethics committees from breaching confidentiality and anonymity concerns, and supervisors can bring anything to the committee's attention if necessary.

7) Academics who study ethical monitoring have expressed a strong desire for suitable guidelines. According to this study, the current monitoring guidelines clearly need to be modified to provide more purpose-fit monitoring that is more successful. Even though all ethics committees must abide by these rules, the interview data have revealed certain flaws. One of the shortcomings is that active monitoring might not always be suitable in a non-medical setting. It would be helpful for the guidelines to explicitly specify when situations call for the application of active monitoring in non-medical settings. According to interview data, monitoring guidelines must be created for each committee based on the research they review. Members of ethics committees should be included in the establishment of the monitoring guidelines, as they possess knowledge about the types of research that are submitted for assessment. These members are also skilled in these study fields. Guidelines for specialist monitoring training should be included, as interview data and literature indicate that special training is necessary for monitoring. Possible modifications to the monitoring process included a hybrid system of monitoring, whereby modifying the annual report form, and making provision for monitoring guidelines for non-medical studies.

   This finding illustrates that monitoring guidelines are important because they impact the way monitoring is conducted and understood by ethics committees. When guidelines speak to what exactly is required and are curtailed to the content of what is being assessed, it provides greater clarity in terms of what is expected by ethics committees. This results in a better understanding and follow-through of what is required and how to achieve the results anticipated by the guidelines. This further results in no ambiguity, and the ethics committee does not resort to minimalist monitoring approaches for the sake of compliance.

The literature and key findings argue that guidelines should be appropriate for what is being monitored. The findings that emanated from the interviews suggest that monitoring guidelines could be adapted based on risk level. Another finding suggests that a hybrid monitoring approach could be suggested within the guidelines, where more engaged interactions with ethics committees, researchers, supervisors, and faculties in terms of ethics.

6. CHAPTER 6: RECOMMENDATIONS AND CONCLUSION

6.1. Introduction

This chapter will discuss the analysis of the findings relevant to the research question and suggest recommendations for future research. The study investigated how current South African ethics monitoring guidelines for non-medical research aided in ensuring ethical standards are adhered to during the data collection process.

It is evident from the research findings that the guidelines play an important role in how monitoring is conducted within non-medical ethics committees. The guidelines essentially provide information in terms of the statutory requirements for monitoring, which includes both active and passive monitoring. As non-medical university ethics committees are registered with the National Human Research Ethics Council (NHREC), which is primarily focused on health research, they are required to conduct monitoring as prescribed for medical research. Non-medical university ethics committees do not focus on health-related research, and the scope of research they review is different.

The need for monitoring is undisputed because it plays an essential role in participant protection after the approval stage of the ethics clearance process. However, a university ethics committee must oversee approved research since ethical approval alone may not guarantee the protection and well-being of participants throughout the study (Nyika et al., 2009).

Non-medical studies vary in nature from medical studies, and therefore, a need for a monitoring system that meets the needs of non-medical ethics committees is required. Literature is sparce on an appropriate framework for monitoring non-medical research.

The guidelines for South African university ethics committees are premised on medical research, and all registered ethics committees are expected to monitor as prescribed for medical research. Additionally, monitoring non-medical studies rely on resources, which are often limited within universities. University non-medical ethics committees contend with constraints such as a lack of funding, limited human resources, and a lack of appropriate monitoring training.

6.2. Literature contributions

This study contributes to the literature in terms of university ethics non-medical committees' mandate to monitor and researchers' responsibility in aiding successful monitoring. Debate exists around whether monitoring researchers aids in ethical behaviour. This study contributes

to the body of literature on the role monitoring plays with regard to researchers being ethical and ethically conducting research.

Additionally, the study contributes to the literature in terms of the nature of non-medical research and appropriate ways to monitor it. This dynamic of monitoring non-medical research relies on researchers being involved in the process for monitoring to be successful. Additionally, the study contributes to the literature in terms of the dynamics of monitoring social science research under medically inclined guidelines. The guidelines speak predominately to monitoring medical research which requires monitoring mechanisms such as site visits, which may not be applicable to non-medical research.

The study contributes to the influence the national guidelines have on university non-medical ethics committees and the ability to monitor studies. The study expands on the relationship between ethics committees, the guidelines and the constraints experienced by university ethics non-medical committees in terms of monitoring.

The study further contributes to the literature regarding nuances specific to non-medical research and the need for suitable guidelines and frameworks for monitoring non-medical research. The study expands on literature regarding monitoring frameworks that would be more suited towards non-medical research that would contribute to greater participant protection. The study emphasises that the use of consent forms as a measure of monitoring non-medical research may not be effective, considering confidentiality and anonymity. The study advances ethical conduct is best achieved through fostering a culture of research integrity, with monitoring playing an essential role in research integrity.

6.3. Recommendations for university non-medical committees for monitoring

The study highlighted the key findings. Firstly, the passive monitoring approach is primarily practised by non-medical ethics committees and may not be the most effective method in terms of participant protection. Furthermore, passive monitoring (submission of annual reports) is often viewed as the lowest stage of the monitoring process (Kruger et al., 2014). This process is completely dependent on the researcher's integrity. The study argues that the passive approach is used because of the resources available, the nuances of non-medical research, practicality and the number of applications reviewed and approved. Kruger et al. (2014) argue that it is the responsibility of the ethics committee to find creative, more effective ways of safeguarding participant protection. However, the researcher argues that the NHREC and the universities have the same obligation in this regard.

Monitoring requires dedicated resources to be efficient and successful in achieving the goal of participant protection. Dedicated resources in terms of skilled human resources, dedicated time, and funding, should be dedicated to research ethics monitoring from the university because of the importance of monitoring. Ethics committees currently function with little assistance while still having to produce results with a high degree of efficiency. Ethics committee monitoring requires resources and a suitable framework to be effective. Institutions should play a bigger role in ensuring that monitoring is conducted effectively to ensure participants are safeguarded. A dedicated office under the scope of the research office should be established that deals directly with monitoring, which could report directly to the ethics committee (Kruger et al., 2014). This is a huge consideration for the field of ethics monitoring as this office will solely focus on monitoring and provide dedicated time and commitment to this function. This role of this office should be included in the ethics application and all the documents given to participants. Participants will thus be aware that the research activity will be monitored in some form, whether it is through a passive approach by asking the participants questions on the process, a site visit, or reviewing any forms they signed. This office should further implement a suitable framework for active monitoring that maintains the integrity of the study and that participants are aware that active monitoring could take place.

The perceptions around monitoring and its purpose should be redefined. Monitoring should not be viewed as a policing exercise but rather a process of research integrity. The institution and the NHREC should promote this through ethics campaigns, workshops, and roadshows. Ethics committee members could arrange these activities throughout the year for researchers. The ethics committee could also implement a requirement that researchers should obtain a certificate of understanding of monitoring as part of their ethics application. This will ensure that researchers understand the purpose of monitoring and simultaneously aid researchers in behaving more ethically. In terms of considerations in the field of monitoring, there is a clear need for changed perceptions around the role of monitoring, especially on what monitoring tries to achieve and how it is used to make processes more efficient and protect society when participating in research studies.

The researcher further proposes that ethics committee members receive specialised monitoring training so that the entire committee is skilled in monitoring. Monitoring specific training should be compulsory for members and should be a requirement as a member. Members can rotate the responsibility of monitoring so that each member is skilled in this arena. This process ensures that ethics committee chairs and members know how to monitor, what to monitor and

what action is required if something unethical is discovered. This process will assist in terms of knowing exactly what is required in terms of monitoring. The institution should invest in a technological system that prompts and reminds researchers of their obligation to submit their reports. This will alleviate administrative staff having to remind researchers of this function manually and prevent things from slipping through the cracks.

Ethics committees require more administrative staff. Universities should hire skilled individuals with an ethics background so that the ethics load can be divided and equally managed. Considerations for the field of monitoring are that specialised monitoring training should be developed for ethics committees that speak to the needs of the committee. This training should give insight into when active monitoring is required or when passive monitoring will suffice. The training should include what is considered active (new creative approaches to be included) monitoring and what is passive monitoring (more than just annual report submission).

The monitoring system should ensure that deviations will be detected. If using passive monitoring, the format of the annual report form should be redefined to ask questions pertaining to deviations that make it noticeably clear to the committee whether there was a deviation or not. The guidelines should provide deeper insight into the questions that should be asked in the form of the annual report that will provide ethics committees with more valuable information from researchers. The institution should develop an effective system that deals with deviations, which should be communicated to the university community (Kruger et al., 2014). Considerations for the field of monitoring are that monitoring approaches should build mechanisms that clearly reveal deviations and include corrective action for these deviations. The forms of monitoring should work for ethics committees and not leave room for unethical behaviour to fall through the cracks.

The study found that reviewing signed consent forms only ascertains that consent was given. This form of monitoring could be implemented but not in isolation. This form of monitoring could work if accompanied by annual report submissions or quarterly report submissions. A statement should be included in the consent form stating that the ethics committee may review this consent form for monitoring purposes. This will allow that confidentiality and anonymity will not be breached. Considerations for the field of monitoring include that consent forms should be redesigned to include that monitoring forms are part of the ethics of a study. This will ensure that participants are aware of the monitoring, and they can choose whether they are amenable to being part of the monitoring process if required.

The findings suggest that the current guidelines do not aid in ensuring ethical standards are adhered to during data collection. Guidelines play an important role in how monitoring for ethics committees should be conducted. The guidelines stipulated for ethics committees should be fit for purpose and tailored to fit the needs of non-medical research. The guidelines should explicitly state levels of monitoring required per risk category. A high-risk study might require a more active monitoring approach as opposed to a minimal-risk study. What should be monitored and exactly how it should be monitored should be stipulated in the guidelines.

Non-medical ethics committee chairs and members should be involved in drafting the monitoring guidelines to include social science aspects, vulnerable participants, the use of social media, artificial intelligence (AI), new research tools and new research participants, etc. Active monitoring should be re-imagined for more than just site visits. Active monitoring could extend to meetings with researchers deemed to have medium and high-risk studies. Guidelines should build in this type of active monitoring where applicants meet with members of the monitoring office detailing their data collection journey and what had transpired. This process will ensure that any ethical issues, adverse events, or deviations are picked up quickly and that corrective action is taken timeously.

As universities are research-intensive and more people are applying for ethics, the requirement for active monitoring by way of site visits should be limited to only two studies per year. The two studies selected for active monitoring by way of site visits should be selected by the committee where an environment for site visits is conducive. Arrangements for the site visits should be communicated timely, and participants and researchers alike should be made aware of the imminent site visit. These visits should be conducted by the dedicated ethics monitoring office.

The adaptations should include monitoring principles specific to non-medical research, with scenario-type examples. The guidelines should include required specific monitoring training for every committee chair, member, and administrative staff. A forum should be formed with non-medical ethics committee experts at various South African universities. This forum should assist in drafting monitoring guidelines that are fit for non-medical research and devise guidelines for working with vulnerable participants with safeguarding them during data collection. The forum should discuss new research methodologies within social science and which appropriate monitoring approaches should be implemented. This forum should also exist as a community of practice, where members can share certain scenarios, they may have faced

and how it was managed. This forum should also share best practices where all universities can learn and implement best practices.

Considerations for the field of monitoring are that monitoring guidelines should not be drafted as a one-size-fits-all approach. Monitoring guidelines should be drafted in a manner that considers the nuances of each committee. The difference between committees should be clearly understood, and guidance from experts should be sought to ensure final monitoring guidelines are fit for purpose and take committee needs and resources into consideration. The role of active monitoring in the guidelines should be redefined not just to be reduced to site visits. Active monitoring could include one-on-one meetings with researchers or arranged meetings with participants after the research activity to ascertain if the process was ethical.

There are potential monitoring models that non-medical ethics committees could explore that could be beneficial for ethics committees monitoring. One such model is citizen monitoring. Citizen monitoring is when an institute (university) could encourage other organisations to monitor studies for them in addition to the monitoring measures already in place by the institution (university) (Buntaine et al., 2021). Buntaine et al. (2021) reported that in China when water quality was a problem, and complete oversight proved challenging, the government employed citizen monitoring. China employed citizen monitoring, whereby, non-governmental organisations would monitor the water quality, in addition to the government's measures of monitoring, to provide additional/onsite information about the water quality. In the case of non-medical ethics committees, citizen monitoring could be beneficial. Non-medical ethics committees could employ citizen monitoring by consulting with organisations where research is most conducted, e.g. local departments of education, schools, and local organisations. According to Kruger et al. (2014), ethics committees could communicate with these organisations and ask them for information about how the study is being conducted and how it is progressing. Organisations could be requested to complete a monitoring checklist or an independent report that the ethics committees could review as an additional monitoring measure (Kruger et al., 2014). Researchers could be informed of this prior to the data collection phase and inform their participants. Citizen monitoring encourages responsibility and transparency, which are characteristics of good governance, which would be beneficial to university non-medical ethics committees (Frisancho & Vasquezy, 2015). However, university ethics committees would have to consider the challenges of implementing citizen monitoring within an academic setting. These challenges include the possibility of monitoring data being bias or skew, delaying reliability (Jollymore et al., 2017). There is also a risk of understanding

how non-academics understand and operate in scientific programmes and how this affects data quality (Jollymore et al., 2017). All these factors should be considered carefully if implementing citizen monitoring within an academic ethics committee setting.

6.4. Limitations

The participants of the study were chairs and ethics committee members from two South African universities within the Gauteng region. Two experts were interviewed from the Gauteng region as well. The study could benefit from a wider sample population to include more universities within South Africa, which would provide deeper insight into the topic. Extending the research to other universities within the country could reveal other forms of monitoring that may be practised that could benefit this study. However, the selected participants were highly skilled and experienced within the ethics sphere. Hence, the depth of information provided. Another limitation of the study was the low response rate, resulting in only nine interviews conducted. The researcher did, however, manage to reach saturation with the participants interviewed.

As the study was conducted within the Gauteng region, the study may not be generalised to universities across South Africa. However, this is an opportunity for the findings to inform future studies in the sphere of non-medical ethics monitoring. The process of obtaining permission letters was time-consuming, which delayed the study. Further research studies on this topic would benefit from a larger sample size.

6.5. Future research recommendations

As universities become more research-intensive, the need for monitoring non-medical research will increase. A suitable framework for monitoring non-medical research should be explored further and be incorporated within ethics guidelines. Future research will benefit from investigating suitable specific monitoring training required for this function. A suitable structure considering capacity and resources should be explored through future research that will enable ethics committees to monitor as expected in protecting participants, but the system should also be efficient.

6.6. Summary

The research conducted involved a thorough literature review and interview process to investigate the effectiveness of monitoring approaches used by non-medical ethics committees.

The study results, findings, and literature around non-medical research found that monitoring should not be a one-size-fits-all approach. There are many factors to consider when monitoring non-medical research appropriately. Aspects like new research methodologies, the non-medical landscape, resources, and capacity should be considered. As research evolves within the social science sphere, with new research methods and new participant groups, new ethical issues are not covered by the current guidelines (Knight, 2019).

Monitoring is essential to the ethics process and should be conducted with the same rigour as the review and approval process. The need for nuanced guidelines for monitoring non-medical research is required within this sphere. Guidelines for monitoring should be suited to the committee type and the type of research being evaluated. The guidelines, with the assistance of non-medical committee chairs and members, should be drafted in a way that ensures participant protection while at the same time considering the resources available to conduct the monitoring.

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APPENDIX 1: INTERVIEW SCHEDULE FOR NON-MEDICAL CHAIRPERSONS AND MEMBERS.

1. What post-approval monitoring approaches (passive or active monitoring) are practised by the non-medical research ethics committee that you serve on?
2. To what extent are these monitoring approaches effective in ensuring that ethical standards are upheld during data collection by the researcher?
3. In what ways do these monitoring approaches allow the non-medical research ethics committee to detect deviations from approved studies?
4. In your opinion, how should monitoring be conducted for non-medical research that will ensure ethical standards are upheld during data collection?
5. How do limited capacity, resources, and training affect/impact the monitoring process of approved non-medical studies?
6. How do the DoH 2015 Guidelines stipulated by the National Health Research Ethics Council (NHREC) affect how monitoring is conducted for non-medical research?
7. In your view, what is the most appropriate monitoring framework that could be used in the non-medical space for research?

APPENDIX 2: INTERVIEW SCHEDULE FOR EXPERTS

1. What post-approval monitoring approaches (passive or active) are primarily practised by university non-medical committees?
2. To what extent are these monitoring approaches effective in ensuring that ethical standards are upheld during data collection by the researcher?
3. In what ways do these monitoring approaches allow the non-medical research ethics committee to detect deviations from approved studies?
4. How do limited capacity, resources, and training affect/impact the monitoring process of approved non-medical studies?
5. How do the DoH 2015 Guidelines stipulated by the National Health Research Ethics Council (NHREC) affect how monitoring is conducted for non-medical research?
6. Describe how these guidelines could be adjusted in order to ensure that appropriate monitoring is conducted that is suited for non-medical research.
7. In your view, what is the most appropriate monitoring framework that could be used in the non-medical space for research?