AN EVALUATION OF THE ETHICAL CONCERNS RAISED BY A LIBERIAN RESEARCH ETHICS COMMITTEE USING THE PRINCIPLES AND BENCHMARKS PROPOSED BY EMANUEL ET AL. (2008)

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DECLARATION

I, Sienneh Zezay Tamba, declare that:

1. The research reported in this thesis, except where otherwise indicated, is my original research.
2. This thesis has not been submitted for any degree or examination at any other university.
3. This thesis does not contain other persons' data, pictures, graphs, or other information unless specifically acknowledged as being sourced from other persons.
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Sienneh Zezay Tamba
Candidate
Date: 30 November 2023

I hereby declare that I did supervise the student in conducting the study contained herein and confirm that the student has my unreserved permission to submit it for assessment.

Dr. Heidi Matisonn
Supervisor
Date: 1 December 2023

DEDICATION

This work is dedicated to the cherished memories of my late parents, Mr. Joseph Flomo Zezay and Mrs. Alicia Akoi Zezay, and the entire Tamba family. Special recognition is given to my husband, Mr. John Alcorolson Tamba, and our beloved children Anslem, Immaculate, and Charlotte.

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the opinions and views expressed in this dissertation are those of the author and do not necessarily reflect the official stance of the National Institute of Health.

ABSTRACT

BACKGROUND

The 2014 Ebola outbreak in Liberia attracted researchers from the Global North and organizations to undertake research involving human participants. Research projects, including collaborations between those in the global north and those in the global south, have a longstanding history of exploiting underprivileged and vulnerable populations. This increase in research activities raises a lot of ethical concerns, given the vulnerable nature (poverty, illiteracy, and weak health systems) of the majority of Liberians. There, the critical role of research ethics committees (RECs) in protecting the rights and welfare of research participants became evident. One useful approach to help understand whether RECs are effectively evaluating the ethical risks and benefits of a research protocol and ensuring that the rights of research participants are protected is through the use of the Emanuel et al. framework. The framework developed by Emanuel et al. encompasses a comprehensive set of eight ethical principles and provides a systematic approach for evaluating the ethical aspects of research at various stages, ranging from the initial planning and design through the implementation and dissemination stages. This study aims to identify the ethical concerns raised by a Liberian REC using the benchmarks proposed by the Emanuel et al. framework.

METHODOLOGY

A qualitative case study design was used to collect the data from the meeting minutes of 17 protocols reviewed by the Liberian REC from 2018 to 2019. The data was examined using content analysis and mapped onto the eight principles of the Emanuel et al. (2008) framework.

RESULTS

The findings revealed that 94% of the concerns raised by the Liberian REC could be matched to the framework. Of these, the three most frequently raised ethical concerns, ranked in descending order, were related to the principles of scientific validity, fair participant selection, and informed consent. The least raised concerns were related to social value and collaborative partnerships. The study also identified other concerns, such as inconsistency in completing the application forms and the absence of section sub-headings and references.

CONCLUSION

Overall, the selected REC is focused on ensuring that the rights and welfare of research participants are protected. Based on the findings of this research, there is a need to strengthen the capacity and performance of the REC for conducting ethical reviews of research protocols in Liberia, especially in the context of emerging infectious diseases and global health emergencies. Thus, the Emanuel et al. (2008) framework provides a valuable tool for evaluating the ethical conduct of research in Liberia. It is adaptable and takes into account the country's unique social and cultural context while at the same time emphasising the importance of informed consent. In addition, collaborative partnerships which are emphasised in the framework, need to be taken heed of, particularly in Liberia, where many people have limited experience in research. It also helps identify potential gaps in the review process and promotes sustainability in capacity building for researchers and REC members to protect the rights and welfare of research participants and infrastructure in the research setting.

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CHAPTER 1

INTRODUCTION

This chapter provides an overview of the study's specific problem, which involves the evaluation of the ethical concerns raised by a Liberian Research Ethics Committee (REC). This evaluation is conducted by applying the principles and benchmarks proposed by Emanuel et al. (2008). The chapter also includes the study's problem statement, the research questions, objectives, the definition of keywords, and an illustration of the study's scope.

1.1 Background

Health research has played a significant role in advancing scientific knowledge and improving the quality of life of humankind (Nass et al., 2009). At the same time, however, it is important to acknowledge that some scientific advancements have been linked to the mistreatment and exploitation of human participants involved in this research.

The issue of including individuals in health research is complicated by the potential conflict of interest that arises between the researcher's scientific inquisitiveness and the participants' fundamental human rights (Katz et al., 1972). This conflict arises due to the varying degrees of willingness among researchers to understand the disease trend while ensuring participants' safety and dignity.

Several international guidelines and codes have been formulated to govern the ethical practices of health research involving human participants. The primary objective of these regulations is to prevent the repetition of unethical actions by researchers and to establish a harmonious equilibrium between the advantages and potential risks associated with participation in research projects. One of the provisions included in many of these guidelines is an important requirement for the inclusion of an autonomous entity to conduct an ethical review of all research protocols (CIOMS, 2016; OHRP, 2009; World Medical Association, 2000). In the context of the United States, the entities responsible for overseeing research ethics are often known as Institutional Review Boards (IRBs), but in other regions, they are commonly referred to as Research Ethics Committees (RECs) (Kass et al., 2007).

In accordance with this directive, RECs have been created globally to oversee the ethical implementation of health-related studies involving human participants. Nevertheless, despite the considerable efforts made in recent decades to enhance and boost the capabilities of RECS in LMIC countries, certain countries still face challenges in this area. This is particularly evident in the growing number of collaborative research initiatives between high- and low-and-middle-income countries, specifically emphasising biomedical research (Igoumenidis & Zyga, 2011; Nuffield Council on Bioethics, 2014). According to Ashcroft and Pfeffer (2001), the primary purpose of RECs is threefold. Firstly, RECs aim to safeguard the rights of research participants by ensuring that they are adequately informed about the research, possess the ability to recognize and address potential risks and provide their voluntary consent. Secondly, RECs strive to ensure that the research outcomes will benefit the community in which it is conducted. Lastly, RECs serve as a public platform to hold researchers accountable for their actions.

Despite the existence of national and international guidelines that delineate the roles of RECs in safeguarding the rights and well-being of research participants and preventing potential harm and exploitation (Zielinski et al., 2014), there are still concerns regarding the unethical practices and scientific misconduct in research (Igoumenidis & Zyga, 2011). One argument is that these international guidelines are predominately rooted in the concepts and philosophies of the global North. Consequently, the interpretation and application of these guidelines provide a substantial obstacle to RECs in different regions worldwide (Emanuel et al., 2004). In light of this observation that RECs play a critical role in protecting the rights and welfare of research participants, and with the intention to assist RECs in their responsibilities, Ezekiel J. Emanuel, David Wendler, and Christine Grady (2000) developed a framework, which analyzed prominent international ethical guidelines, for ethical research (Emanuel et al., 2004). The framework consists of eight (8) principles and benchmarks designed to be comprehensive and applicable to all types of research involving human participants in various contexts, including low- and middle-income countries. The Emanuel et al. framework has received praise for its comprehensive nature, leading to its adoption by RECs in several countries globally (Tsoka-Gwegweni & Wassenaar, 2014).

Tsoka-Gwegweni and Wassenaar (2014) observed that there are relatively few empirical studies about the framework's applicability to the ethical review of research protocols by the RECs in low- and middle-income countries. This observation implies that further research is required to determine how the framework can be adapted to the specific ethical and cultural

research challenges in these settings. One suggested approach to doing such a study is to undertake a comprehensive review and evaluation of the ethical concerns RECs raise in these settings. This review could identify the framework principles frequently highlighted as concerns by RECs, those that provide the most challenges in practical implementation, and those that are most likely to conflict with others. This data could be used to formulate application recommendations for the framework in low- and middle-income countries.

In light of this, Tsoka-Gwegweni and Wassenaar (2014) conducted the first study to analyze biomedical REC meeting minutes in South Africa using content analysis. They used the framework developed by Emanuel et al. (2004) to assess and categorise the RECs' ethical concerns. According to the study's findings, informed consent, scientific validity, fair participant selection, and ongoing respect for participants were the most commonly raised concerns.

The objective of this study was to repeat the studies conducted by Tsoka-Gwegweni and Wassenaar (2014) and Silaigwana and Wassenaar (2019) and employing the same analytical methodologies to provide an analysis of the ethical concerns raised by a REC in Liberia during the review of research protocols, in order to justify a particular decision (approved, requiring change, or disapproved). The selected REC meeting minutes were analysed and evaluated using the framework proposed by Emanuel et al. (2008) to assess its applicability to the Liberian context.

1.2 Study Rationale

The primary responsibility of RECs is to evaluate and oversee the ethical implementation of a research protocol, aiming to minimise harm or risk and maximise the benefits for participants (CIOMS, 2016; World Medical Association, 2000). While there exists a substantial body of literature on RECs discussing the ethical review activities of RECs in general (Abbott & Grady, 2011; Angell et al., 2008; Angell & Dixon-Woods, 2018; Kennedy et al., 2022; Martín-Arribas et al., 2012; Silaigwana & Wassenaar, 2015; Tsoka-Gwegweni & Wassenaar, 2014), limited attention has been given to the ethical concerns raised specifically by RECs in Liberia.

The ethical concerns raised by RECs in Liberia when reviewing research protocols following the post-2014 Ebola outbreak remain unclear despite the increased presence of overseas researchers, primarily from Western countries. This phenomenon can be attributed to the fact

that external researchers may have brought different ethical perspectives to Liberia, potentially lacking familiarity with the cultural context of Liberia. Consequently, this may have contributed to an increase in the number and complexity of research protocols being reviewed by Liberia RECs. Research projects, including partnerships across regions in the northern and southern parts of the world, have a longstanding history of exploiting underprivileged and vulnerable populations (Ahmad, 2001; Bishop, 1995; Parker & Kingori, 2016; Washington, 2007). This reality gives rise to substantial ethical and legal considerations of utmost importance, particularly within countries in the southern part of the world (Franklin, 2021). The efficacy of RECs in effectively fulfilling their primary obligations to protect the rights and well-being of research participants is contingent upon various factors, including their composition, training, and capacity to discern the significant ethical considerations within research protocols submitted for review.

Understanding the ethical concerns raised by RECs during the review of research protocols in Liberia is of utmost importance, given the pivotal role they play in safeguarding the well-being of study participants. Currently, there is a lack of published empirical studies specifically outlining the ethical concerns RECs address in Liberia. In order to gain a comprehensive understanding of the practical activities undertaken by REC, it is imperative to address this gap. The primary objective of this study was to identify and evaluate the ethical concerns raised by a REC in Liberia during the review of research protocols.

1.3 Research Questions

The study seeks to answer the following question(s):

- What ethical concerns are raised by the selected Liberian REC during the review of research protocols?
- Is there an observable pattern to the ethical concerns raised by the REC? If so, what is the pattern?
- Are the concerns raised consistent with the Emanuel et al. (2008) framework?
- Does any Emanuel et al. (2008) framework feature dominate the REC's concerns? If so, which one?

1.4 Aims and Objectives

Using the principles and benchmarks of the ethical review of research protocols proposed by Emanuel et al. (2008), the study sought to identify, categorise, and evaluate the ethical concerns frequently raised by a Liberian REC during the review of research protocols.

1.5 Specific Objectives

The specific objectives were to:

i. Review the archived meeting minutes [2018 and 2019] of the selected Liberian REC to identify and describe the ethical concerns raised during the committee's review of research protocols.
ii. Analyze the ethical concerns raised by the selected Liberian REC to determine if there is an observable pattern.
iii. Evaluate and rank the ethical concerns the selected Liberian REC raised using the principles and benchmark proposed by Emanuel et al. (2008) to assess its applicability.
iv. Determine if any Emanuel et al. (2008) framework features are more prominent in the ethical concerns of the selected Liberian REC.

1.6 Scope of the Study

The scope of this study was restricted to evaluating the ethical concerns raised by one Liberian REC during the review of research protocols. The study aimed to identify any pattern in these concerns and determine their consistency with the principles and benchmarks proposed by Emanuel et al. (2008). The primary data source for the analysis consisted of the archived meeting minutes of the selected REC for the years 2018 and 2019.

This time frame was selected for several reasons, including the availability of a suitable sample size and the challenges encountered in obtaining access to meeting minutes. The recovery of meeting minutes, particularly for older meetings, can pose difficulties.

1.7 Key Words and Abbreviations

Below is a list of some keywords and abbreviations used in this study:

ACRE IRB: Atlantic Center for Research and Evaluation Institutional Review Broad

Emanuel et al. Framework: The eight (8) principles proposed for the ethical conduct of research in low-resource settings.

Ethical: Relating to beliefs and actions about right and wrong.

Ethical Concerns: Situations that occur when a given decision, scenario or activity creates a conflict with a society's or individual's moral principles.

Liberia: The West African country at the centre of this study

LMHRA: Liberia Medicines and Health Products Regulatory Authority

MoH: The Liberian Ministry of Health

NREB: National Research Ethics Board

REC: Research Ethics Committee

CHAPTER 2

LITERATURE REVIEW

This chapter provides an overview of the existing literature on research ethics within the global context. It examines the progression of ethical issues within health research, beginning with the inception of biomedical experiments and culminating with the establishment of comprehensive ethical standards and regulations. The analysis examines significant events and pivotal landmarks that have played a crucial role in shaping the field of research ethics. These include the Nuremberg Code, the Tuskegee Syphilis Study, and the Belmont Report. This chapter underscores the increasing recognition of the imperative for ethical norms and the establishment of ethical review mechanisms to safeguard the well-being of individuals involved in research. Furthermore, it offers a discussion of the theoretical framework employed in the study.

2.1 Significance of Health Research Ethics

The active involvement of humans in research has substantially impacted the advancement of knowledge and understanding of various diseases and health conditions. This has resulted in the improvement of human safety and well-being across many sectors and disciplines. The advancements in medical science have resulted in significant achievements, including identifying antibiotics, developing organ transplantation techniques, and establishing psychotherapy as an effective treatment modality. Additionally, various other medical advances, as documented by Das and Sil (2017) and Rodrigues and Plotkin (2020), have played a crucial role in saving countless lives and enhancing the overall well-being of the global population. Health research has facilitated the comprehension of risk factors, diagnosis, treatment, and preventative strategies for several diseases and ailments, including cancer, diabetes, HIV/AIDS, and mental disorders. The achievement of smallpox eradication would not have been feasible without the dedicated pursuit of reducing morbidity and mortality (Rodrigues & Plotkin, 2020). The recent endeavour to mitigate the worldwide COVID-19 pandemic by means of vaccine development to impede disease transmission (Hanney et al., 2020; Rodrigues & Plotkin, 2020) demonstrates how research can be employed to tackle health-related obstacles. Health research has played a crucial role in informing the development and assessment of health policies and initiatives to promote fairness and social justice for all individuals (Resnik, 2020).

Nevertheless, doing health research entails many ethical issues and dilemmas that necessitate thorough consideration and resolution by researchers and other parties. The practice of ethical research entails the protection of participants' rights, interests, and overall well-being. This statement suggests that researchers must strive for the equitable and courteous treatment of participants, as well as safeguard their privacy and maintain confidentiality. Researchers must also ensure their research is conducted to prioritise safety and ethics while guaranteeing the accuracy and reliability of their findings. Ethical research practices are regulated and enforced by establishing and implementing ethical principles and standards of conduct as outlined in various national and international codes, guidelines, regulations, and laws (Taquette & Souza, 2022). These principles and standards serve the purpose of ensuring ethical conduct in research and safeguarding the rights of participants.

According to Beauchamp and Childress (2013), ethics refers to the moral principles and values regulating human conduct. Within the research realm, ethics plays a significant role in guiding the execution of health-related studies. Health research involves the dynamic engagement between researchers and participants, necessitating safeguarding the rights and welfare of the individuals involved. Some primary ethical problems in health research include the potential for physical or emotional harm to participants, the risk of privacy and confidentiality breaches, and the possibility of participant exploitation. Researchers must mitigate these dangers and safeguard the well-being of study participants. The achievement of this objective can be realized by the observance of ethical principles and norms, as well as the acquisition of informed consent from participants before their engagement in research activities.

2.2 Research Ethics Review in Africa

The high disease burden in Africa, coupled with an increase in the emergence of new diseases and an effort to address the 10/90 gap in the Millennium Development Goal, has resulted in a significant increase in the number of health-related research activities that pose more complex ethical concerns across the continent (Nyika et al., 2009; Silaigwana & Wassenaar, 2015). Therefore, a critical review of research protocols is required to safeguard the rights and welfare of research participants. In addition, the ethical applicability of these research protocols cannot be overstated, as Milford et al. (2006) explain that collaborative research is typically conducted within the regulatory framework of Western countries.

The University of Witwatersrand in Johannesburg, South Africa, founded the first documented

REC in the region in 1966 (Cleaton-Jones & Wassenaar, 2010), followed by Zimbabwe in 1974 (Ndebele et al., 2014). Since then, many institutional RECs have been established in research, academic, and healthcare institutions (Dixon-Woods et al., 2007). According to Ikingura et al. (2007), the increase in collaborative research projects, the requirement by scientific journals for ethics committee approval from the researchers, and the complexities of new biomedical technologies were the driving forces behind the establishment of RECs in many countries. Despite an increase in the establishment of RECs in many countries, this has not necessarily been accompanied by an increase in the oversight capacity of RECs, leaving the continent's populations vulnerable to potential exploitation by the West (Ndebele et al., 2014). In addition, Milford et al. (2006) noted that the possibility of potential exploitation is largely associated with collaborative research, which is conducted using the international ethical guidelines of Western approaches when, in reality, the country's socio-economic and cultural norms are not taken into account.

2.3 Health Research in Liberia

2.3.1 Institutions Governing Health Research in Liberia

The governance of health research in Liberia is under the Ministry of Health's (MoH) jurisdiction. The functions of the Liberian MoH, as outlined in section 39.3 of the Act establishing the ministry (Ministry of Foreign Affairs, 2016), encompass the formulation, implementation, monitoring and evaluation of health policies, plans and standards. According to Section 39.4 (c) of the Act, the MoH is obligated to "coordinate and promote the conduct of health and health-related research." The MOH established the Research Unit (RuMoH) in 2011 to fulfil its mandate (Ministry of Health, 2018). According to the Ministry of Health (2018), the RuMoH manages, coordinates, and regulates health research in Liberia. The entity in question performs administrative reviews and grants approvals for research protocols. The institution guides researchers regarding the appropriate institutions or line ministries that need to be contacted to obtain gatekeeper permissions. Additionally, it outlines the ethics or regulatory institutions that require approvals, as stated by the Ministry of Health (2018).

The MOH does not directly engage in the process of reviewing, approving, and monitoring research activities. However, the National Public Health Institute of Liberia (NPHIL) has assumed the responsibility of fulfilling this job. The primary objective for establishing NPHIL was to

engage in medical and public research projects that would provide valuable insights to shape the public health policies of Liberia (Ministry of Foreign Affairs, 2016). The authority of the institution encompasses the ability to collaborate with the MoH and other relevant sectoral agencies to enforce environmental and public health laws, policies, and regulations (Part 2 section 2.4 (a)(x)). Additionally, the institution is empowered to "set up Institutional Review Boards on public health and medical research" (Part 2 section 2.4 (a)(xix)).

Furthermore, the institution is responsible to "coordinate activities relevant to national specimen bank" (Part 2 section 2.4 (a)(xx)).

The institutions governing health research in Franklin's (2021) study are classified into two main categories. The first category consists of regulatory or legal institutions, including the Research Unit of the Ministry of Health (RuMoH), the National Public Health Institute of Liberia (NPHIL) (discussed above), and the Liberia Medicines and Health Products Regulatory Authority (LMHRA). The second category comprises ethics institutions, namely the National Research and Ethics Board (NREB) and Atlantic Center for Research and Evaluation Institutional Review Broad (ACRE IRB), formerly known as the University of Liberia-Pacific Institute of Research and Evaluation (UL-PIRE).

The LMHRA assumes the responsibility for reviewing, approving, and monitoring clinical trials and registering or licensure drugs and medical devices in Liberia (LMHRA, 2014). The LMHRA was established on September 30, 2010, by an Act of the National Legislature (Ministry of Foreign Affairs, 2010). According to Section 1.1 of Part 4 of the LMHRA Act, the Authority is an autonomous body that reports directly to the President of Liberia. It is required to submit an annual report of its activities to the Legislature.

In 2014, during the peak of the Ebola outbreak, the MoH established the National Research Ethics Board (NREB). The NREB is a multidisciplinary committee consisting of scientists, non-science specialists, and individuals from the community. Their primary responsibility is to review and approve research protocols. The Ministry incorporated the previously existing Liberia Institute of Biomedical Research (LIBR) Ethics Committee into its structure, including individuals from additional institutions as members. and added members from other institutions. The Ministry of Health Policy report proposes the establishment of a central national body (Ministry of Health,2018). This new entity would be responsible for developing standardized guidelines for ethics committees throughout Liberia.

The ACRE IRB, also known as the Atlantic Center for Research and Evaluation Institutional Review Broad, was established in 2005 as a collaborative initiative between the University of Liberia, a premier government-owned University, and the Pacific Institute for Research and Evaluation, a research institution in the United States (S. B. Kennedy et al., 2006). The ACRE IRB provides services to individuals and institutions in Liberia interested in medical or social science research involving human subjects (UL-PIRE IRB, 2008). According to stakeholders, these ethics institutions have an unwritten understanding that the NREB is specifically responsible for biomedical research (Franklin, 2021). This local institutional structure in Liberia is similar to that in Kenya, Botswana, Malawi, and South Africa (Office for Human Research Protections (OHRP), 2018); Franklin (2021). *Table 1* summarises the key institutions involved in health research in Liberia and their respective roles.

Table 1: Key Institutions and their Roles

ROLES	REGULATORY			ETHICS	
	LMHRA	R_uMoH	NPHIL	UL-PIRE	NREB
OVERSIGHT	X*	X	X	X	X
REVIEW	X*	X		X	X
APPROVE	X*			X	X
MONITOR	X*			X	X

Key
LMHRA=Liberian Medicines and Health Products Regulatory Authority; R_uMoH=Research Unit of Ministry of Health; NPHIL=National Public Health Institute of Liberia; NREB=National Research Ethics Board

*Clinical trials only

Adapted from Franklin (2021)

As seen in Table 1, among the five institutions overseeing health research in Liberia, only two (ACRE and NREB) are actively engaged in conducting ethical reviews, granting approval, and regulating human research within the country. On the other hand, the MoH carries out an "administrative review" process to authorize research activities in Liberia.

2.3.2 Ethical and Regulatory Documents Governing Health Research in Liberia

According to Franklin (2021), the governance of health research is currently categorized into five major documents. The documents are classified into two categories: 1) regulatory or legal documents (Public Health Law (PHL), National Research for Health Policy (RHP), and the

Clinical Trial Guidelines (CTG); and 2) ethics documents (National Research Ethics Board documents and ACRE IRB, Policies and Procedures Handbook), which refer to the guidance documents from local ethics committees or institutional review boards.

2.3.3 Research Ethics Review in Liberia

Liberia has two functional RECs: the National Research Ethics Board (NREB) and the Atlantic Center for Research and Evaluation Institutional Review Broad (ACRE IRB). However, it is worth noting that Liberia does not have a national ethics committee, as indicated by the Ministry of Health (2018) and Sombié et al. (2017). In recent years, Liberia has emerged as an important country for conducting collaborative health-related research, including partnerships with international pharmaceutical companies. This development has been particularly notable following the unprecedented Ebola Virus Disease (EVD) epidemic in 2014. Nevertheless, there is a lack of coordination in the oversight of ethical review for research protocols. The lack of coordination may suggest the absence of a clearly established procedure to ensure comprehensive ethical considerations in any research involving human participants.

As a result, some research protocols may not undergo scrutiny from a REC. In contrast, others may be reviewed by a REC who lacks the requisite expertise to adequately review the research protocol under consideration. The aforementioned practice can potentially contribute to the unethical conduct of research, exposing participants to potential risks. Liberia has established a framework comprising policy documents, regulations, processes, and structures to govern human research activities within its jurisdiction. However, what seems to be an existing governance framework appears to be poorly coordinated (Franklin, 2021). This prevailing situation has been characterized by the "lack of governance, coordination, and management, as outlined in section 1.1 of the 2018 Research for Health Policy (RHP) (Ministry of Health, 2018). According to a study conducted by Sombié et al. (2017) and supported by the RHP, it has been asserted that the country lacks a specific budgetary allocation in the Ministry of Health budget for funding health research. This lack can potentially impact the establishment and implementation of governance structures and procedures within the health research field. According to Franklin (2021), the absence of an audit record of existing regulatory and ethical guidelines raises questions about the alignment between existing regulatory and ethical requirements and the internally approved mandate of REC. There has been a lack of evaluation of the governance framework in soliciting input from stakeholders regarding the incorporation

or omission of protective provisions, such as the inclusion of ethics reviews, the requirements for informed consent and forvorable risk-benefit ratio, the need for collaborative partnership, within the existing local guidelines. Moreover, researchers are faced with uncertainty regarding identifying the appropriate REC for conducting ethical reviews, given the various research types, such as social science, clinical trials, health system, implementation, and epidemiological studies. The background information about Liberia's accredited protocol review institutions is included in Table 2.

Table 2: Key information of the Ethics and Regulatory Approval Institutions

Parameters		Ethics		Regulatory
		UL-PIRE IRB	NREB	LMHRA
Year of Establishment		2005	2014	2010
Members	Scientist	2	19	9
	Non-scientist	5	2	1
	Comm. Rep.	0	1	1
	Total #	7	22	11
Type of Review	Scientific	YES	YES	YES
	Ethics	YES	YES	YES*
Review Template?		NO	NO	NO
Website	Present?	YES	NO	YES
	Address	http://www.ul-pireafrica.org/the-irb-policy-handbook/	____	www.lmhra.org
Registered?	Local	NO	NO	____
	Entity	___	____	
	Int'l	YES	YES	
	Entity	OHRP	OHRP	
SOP	Present?	YES	YES	YES
	Year of Publication	2008	2014**	2014

*Perform ethics review, but only as part of their evaluation process; **Document actually originally published in 2011

Adapted from Franklin (2021)

Table 2 presents pertinent details on the establishment year, composition, and type of review conducted by the accredited approval institutions in Liberia. According to the data presented in the table, it can be observed that, as of the data collection period in 2021, none of the institutions possessed a standardized template to streamline the review process. Furthermore, there was a lack of a national institution regulatory body responsible for registering these institutions and overseeing their operations, particularly in the case of RECs.

2.4 Theoretical Framework

2.4.1 Emanuel et al. Framework

Ezekiel J. Emanuel, David Wendler, and Christine Grady (2008) proposed a conceptual framework to assist RECs and researchers in the ethical evaluation of research protocols (Emanuel et al., 2000, 2004, 2008). This framework synthesizes international ethical codes and guidelines to establish a comprehensive and systematic structure for conducting and evaluating health research (Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014). According to Molyneux and Geissler (2008), the framework offers ethical justifications and specifics for implementing each principle in particular political, sociocultural, and economic contexts and settings. The framework proposed by Emanuel et al. was first developed in 2000 and consisted of seven principles. Notably, the collaborative partnerships principle was not included in the initial version of the framework (Emanuel et al., 2000). The document was revised by the authors in 2008 to allow the RECs to verify that the proposed research incorporates a collaborative partnership with key stakeholders, in addition to adhering to the protection of research participants based on international ethical guidelines (Emanuel et al., 2008). The existing framework has a set of eight essential ethical principles and their accompanying benchmarks that must be followed during all stages of a research project. The eight principles of the framework are collaborative partnerships, social value, scientific validity, fair selection of participants, favourable risk-benefit ratio, independent review, informed consent, and respect for recruited research participants and communities (Emanuel et al., 2008). The framework was initially developed for clinical research in developing countries. However, Wassenaar and Mamotte (2012) adapted the framework for use in social science. Their adaptation showcased the universal applicability of the framework's principles to social scientists globally, thereby advocating for its extensive implementation. Below is a brief description of the ethical principles.

Collaborative partnership: According to Emanuel et al. (2004), a collaborative partnership is a relationship or liaison between the researcher, sponsors, policymaker, and communities in developing countries to reduce the likelihood of exploitation by ensuring that developing countries can evaluate the significance of the research to their community. Ideally, research should be driven by the community's expressed needs. It should be based on respect for the

community's values, circumstances, culture, and social practices so that community representatives can make substantial inputs to the research to ensure the fair distribution of benefits (Emanuel et al., 2004). This principle requires the inclusion of community representatives in the planning and implementation of the research and the dissemination and application of research findings to improve the community's health.

Social Value: This principle aims to ensure that the research conducted in a community has the potential to generate information or address questions that could lead to improvements in health and well-being or directly influence the formulation of policy and practice without wasting time and resources (Emanuel et al., 2004). The research protocol should clearly define the beneficiaries of the research and how they will benefit directly or indirectly.

Scientific Validity: This principle ensures that the research design, methodology, and data analysis techniques are ethical and scientifically valid (Emanuel et al., 2004). The method and design should provide valid and reliable answers to the research questions. In addition, it requires that previous studies and current knowledge justify the research and that only scientifically qualified researchers (in terms of education and ability to care for participants) conduct the study.

Fair Participant Selection: According to Emanuel et al. (2004), inclusion criteria and the selection of study populations should not be based on the availability and vulnerability of the participants but rather on ethical justifications. This principle seeks to ensure that the selection of the study population is consistent with the scientific goal of the research and not dependent on convenience (Emanuel et al., 2004). The process should minimize risk, maximize benefits, and safeguard the rights and dignity of the research participants to ensure that the research conforms to scientific norms and generates valid and reliable data. The selection of research participants should consider other ethical principles that contribute to the conduct of research in an ethical manner. For instance, the social value of research is likely to be realized when the collaborative partnership principle is taken seriously (Emanuel et al., 2004).

Favourable Risk-Benefit Ratio: According to Emanuel et al. (2004), clinical research should provide participants with a favourable risk-benefit ratio. This principle can be subdivided into risks, benefits, and assessments. The research risks must be justified because the risk to the participants is outweighed by the anticipated benefits to them and the expected benefits to society. The assessment of various risks (physical, psychological, social, or legal) must be delineated, and the probability and magnitude of such risks must be quantified as much as possible.

Independent Review: This principle aims to ensure that there are no conflicts of interest in the protocols and that an independent research ethics committee is publicly accountable; the ethical assessment of the research protocols is free from the influence of the sponsor and investigator while adhering to the laws and regulations of the host country (Emanuel et al., 2004). Before implementation, the sponsor/investigator must submit all research protocols to a REC for evaluation and ethical approval. Emanuel et al. (2004) state that the REC must be independent and sufficiently knowledgeable to examine the scientific merit of a research protocol's study design and safety provisions.

Informed consent: Emanuel et al. (2004) acknowledged informed consent as the basis of health research. The principle aims to ensure that the research participants have control over their participation in accordance with their interests, preferences, and values and that they are not viewed as a means to an end (Emanuel et al., 2004). The principle requires working with the local community to establish recruitment strategies and incentives for the participants consistent with the cultural, political, and social norms (Emanuel et al., 2004).

Respect for recruited participants and study communities: According to Emanuel et al. (2004), the principle of respect for recruited participants and study communities seeks to ensure that the researchers' obligations to the participants do not end when informed consent is obtained. According to Emanuel et al. (2004), there are five key ongoing researchers' obligations to the participants: (i) develop and implement procedures to maintain the confidentiality of information collected in the research as a way to respect the privacy of the participants; (ii) inform the participants of their right to withdraw from research without repercussions; (iii)

provide new research-related information (including newly identified risks) to the participants and host communities; (iv) monitor the participants (for worsening of conditions, side effects etc.) and ensure access to local health services or alternatives that meet national care guidelines during their participation in the research; and (v) develop clear procedures to disseminate research findings to the participants and host communities, as they participated in the research and assumed the risks and its implications for health-related policies (Emanuel et al., 2004). Table 3 provides a summary of the eight principles and their corresponding benchmarks.

Table 3: Emanuel et al. (2008) Ethical principles and benchmarks for clinical research

Principles	Benchmarks
Collaborative partnership	• Develop partnerships with researchers, makers of health policies, and the community. • Involve partners in sharing responsibilities for determining the importance of health problems, assessing the value of research, planning, conducting, overseeing research, and integrating research into the healthcare system. • Respect the community's values, culture, traditions, and social practices. • Develop the capacity for researchers, makers of health policies, and the community to become full and equal partners in the research enterprise. • Ensure that recruited participants and communities benefit from the research's conduct and results. • Share financial and other rewards of the research fairly.
Social value	• Specify the beneficiaries of the research. • Assess the importance of the health problems being investigated and the prospective value of the research for each beneficiary. • Enhance the research value for each beneficiary by disseminating knowledge, product development, long-term research collaboration, and/or health system improvements. • Prevent supplanting the extant health system infrastructure and services.
Scientific validity	• Ensure that the scientific design of the research realizes social value for the primary beneficiaries of the research. • Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the healthcare interventions they are entitled to. • Ensure the research study is feasible within the social, political, and cultural context or with sustainable local healthcare and physical infrastructure improvements.
Fair selection of study population	• Select the study population to ensure the scientific validity of the research.

	• Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership, and social value. • Identify and protect vulnerable populations.
Favourable risk-benefit ratio	• Assess the potential risks and benefits of the research to the study population in the context of its health risks. • Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits of collaborative partnership, social value, and respect for study populations.
Independent review	• Ensure public accountability through reviews mandated by laws and regulations. • Ensure public accountability through transparency and reviews by other international and non-governmental bodies, as appropriate. • Ensure independence and competence of the reviews.
Informed consent	• Involve the community in establishing recruitment procedures and incentives. • Disclose information in culturally and linguistically appropriate formats. • Implement supplementary community and familial consent procedures that were culturally appropriate. • Obtain consent in culturally and linguistically appropriate formats. • Ensure the freedom to refuse or withdraw.
Respect for recruited Participants	• Develop and implement procedures to protect the confidentiality of recruited and enrolled participants. • Ensure that participants know they can withdraw without penalty. • Provide enrolled participants with information that arises in the course of the research study. • Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participants, at least as good as existing local norms. • Inform participants and the study community of the results of the research.

Source: Emanuel et al. (2008) Framework

CHAPTER 3

RESEARCH METHODOLOGY

This chapter describes the methods and procedures used to achieve the project's stated aims and objectives. It describes the study's paradigmatic positioning, study design, inclusion processes, data collection and analysis. In addition, the ethical ramifications of conducting the study and their resolution are highlighted.

3.1 Research Paradigm

The interpretivist paradigm guided the present study, which was firmly grounded on analysing data generated from the review of the meeting minutes of the selected REC. This paradigm was selected to facilitate a comprehensive understanding and interpretation of the textual content within the targeted documents. According to Kivunja and Kuyini (2017), the researcher must understand and attribute significance to the texts under analysis without introducing personal views.

3.2 Study Design and Rationale

The present study employed a case study methodology to identify and assess the ethical concerns frequently raised by a REC in Liberia. According to Yin (2018), a case study is an empirical design employed to address the "how" or "why" questions about a particular issue or phenomenon. Examining a specific scenario in depth is a practical approach to understanding a case. In this instance, the research employed a case study methodology to concentrate on a single case, namely the selected Liberian REC, to understand the ethical concerns frequently raised while reviewing research protocols. It is important to note that this research was conducted as a study with low risk, utilizing a desk review of archived meeting minutes. This research method does not entail any direct interaction with participants and does not pose any physical or psychological risks.

The study utilised the framework proposed by Emanuel et al. (2008) to identify, categorise, and evaluate the ethical concerns frequently raised by a REC in Liberia while reviewing research protocols. The study focused on the meetings held for two years, specifically in 2018

and 2019. This time frame was selected for several reasons, including the availability of a sufficient sample size and challenges encountered in obtaining access to meeting minutes. Retrieving meeting minutes, particularly for older meetings, can pose difficulties. By prioritizing 2018 and 2019, the researcher effectively enhanced the probability of acquiring the requisite meeting minutes for the investigation. Furthermore, the reason for the determination of this period could be linked to the confidential nature of the minutes and the manner in which they were held, resulting in limited accessibility. Notwithstanding these factors, it is imperative to acknowledge that the sample size of two years may not be adequate to encompass all of the ethical concerns that the RECs have reported in Liberia. The primary objective of the current study was to do a retrospective analysis of meeting minutes to identify and assess the ethical issues highlighted during the approval of research protocols.

While the primary emphasis of this study was on qualitative research, a mixed-method approach was employed. This methodology enabled the researcher to understand further the ethical concerns that the Liberian REC raised. This approach involved utilising both qualitative and quantitative methods for the data analysis. The research methodology employed was content analysis, a method for analyzing textual content or other forms of communication to identify relevant patterns and themes within the data. Specifically, this approach was applied to the archived written meeting minutes of the selected Liberian REC. This facilitates an in-depth understanding of the ethical concerns raised in the meeting minutes. It is important to note that the quality of the content analysis depends on the researcher's ability to identify the various ethical concerns. The researcher used a method developed by Mayring (2014) to identify the communication categories. This entails developing a coding framework that includes a list of the ethical concerns that the REC could raise. Subsequently, the researcher used the coded framework to analyze the meeting minutes. The quantitative approach entailed frequency analysis, a process that counted the number of times each ethical concern was raised. The researcher believed this approach represented the best way to understand the specific concerns frequently raised by the selected REC while reviewing research protocols.

The study utilised the analytical framework proposed by Emanuel et al. (2008) as the basis for the analysis. The framework proposed by Emanuel et al. encompasses a collection of ethical principles that serve as a guiding tool for the ethical evaluation of research protocols. The framework was employed by the researcher to identify the different ethical concerns that were

raised in the meeting minutes and to determine whether or not these concerns aligned with the framework.

3.3 Study Location

This study was conducted in Liberia, a country located on the coast of West Africa near the Gulf of Guinea, which shares its border with Sierra Leone, Guinea, and the Ivory Coast. Liberia has a population of 5,249,689 (Worldometer, May 15, 2022), with 16 indigenous ethnic groups (tribal groups) that account for 95% of the population and other nationalities accounting for the rest (World Population Review, May 15, 2022). One of the world's poorest and most under-developed countries, the country is ranked 175 out of 189 globally, with a Human Development Index (HDI) of 0.480 (UNDP, May 15, 2020).

Figure 1: Map of Liberia (world atlas/maps/Liberia)

3.4 Sampling Strategy

To include relevant data in this study, a purposive sampling methodology was utilized to select the meeting minutes from initial protocol applications that the full committee members reviewed. According to Babbie (1995), purposive sampling is characterized by deliberately selecting samples with features that best represent the research issue. The non-random approach employed in this context does not necessitate the utilization of a fundamental theory or a specific number of participants. Instead, the researcher identifies the requisite information and actively seeks out individuals who possess the requisite knowledge or experience and are willing to contribute it. This approach enables a targeted and deliberate selection process, guaranteeing the incorporation of individuals who have the potential to provide significant and valuable perspectives to the research (Babbie, 1995).

According to the ACRE Policies and Procedures Handbook (2022), the selected REC convenes up to 12 scheduled meetings annually, each dedicated to reviewing a single protocol. Therefore, the cumulative count of records over the designated review time is 24. The retention of all archived meeting minutes is independent of the study type (biomedical, social, or behavioural) and is contingent upon the protocols being submitted for full review by the REC.

Throughout the two years, the selected REC reviewed 17 research protocol applications. Among these, nine were discussed during the meetings held in 2018, while eight were reviewed in the meetings conducted in 2019. The current study used a similar methodology to that of Silaigwana and Wassenaar (2019) and Tsoka-Gwegweni and Wassenaar (2014). This allowed for a consistent approach to the review process and ensured that the study's findings were comparable to those of other studies in the project.

3.5 Recruitment

The leadership (Chair and administrator) of the selected REC was contacted by email and informed about the nature and significance of the study. Furthermore, a formal correspondence was sent to the chairperson of the selected REC to solicit a gatekeeper's permission to access their committee's archived records of meeting minutes from 2018 through 2019. Upon receiving the gatekeeper's permission, the administrator responsible for the REC proceeded to obtain and disseminate the records to the researcher.

3.6 Unit of Analysis

The term “unit of analysis” pertains to a specific entity or element subjected to content analysis. Two distinct types of analysis units exist: recording units and context units. The recording unit refers to a particular segment of text that is quantified and classified, such as a phrase or paragraph (Prasad, 2008). On the other hand, the concept of the context unit refers to a large body of information associated with the recording unit (Prasad, 2008).

The recording units utilized in this study consist of the minute records obtained from the selected REC. This study used frequency analysis to record the occurrences of a particular phrase in each category (Prasad, 2008). This approach of quantifying data in content analysis encompasses a range of procedures, including the measurement of the space and time that a category appears, the determination of the presence of a specific category within the recording unit, and the evaluation of the frequency of category occurrence within the context unit (Prasad, 2008).

Selecting the appropriate quantification procedure depends on the research questions to be answered. Frequency measurement is commonly used as it assumes the frequency of a word or category is a valid indicator of importance, value, or intensity. Further, every individual count is presumed to carry equal significance in the analysis (Singleton et al., 1993).

3.7 Context Categories Development

According to Mayring (2014), content analysis primarily involves developing communication categories. The quality of the analysis relies on clearly identifying these categories (Mayring, 2014). The analysis of the minutes for 17 protocol review meetings used categories derived from the eight principles and associated benchmarks outlined in the Emanuel et al. framework. Below are the eight principles of the framework:

- Collaborative partnership
- Social value
- Scientific validity
- Fair subject selection

- Favourable risk-benefit ratio
- Independent ethics review
- Informed consent
- Respect for participants and study communities

A brief description of these principles was provided in Section 2 to foster a clear understanding of their ethical significance. The description above operationalizes the content categories and establishes an understanding of the analyzed data. These categories are considered to be mutually exclusive as they address various aspects of research ethics. This division aids in linking the content categories with the communication in the minutes. The categorization adopted from the framework proposed by Emanuel et al. (2008) has been simplified and presented in Table 4.

Table 4: Coding Framework

Principles	Categories Utilized
Collaborative Partnership	Community involvement and synergic interaction
	Research fairness (north-south partnership)
	Capacity building
	Respect for and adherence to local values and laws
	Fair sharing of benefits of research with participants
Social Value	Prioritize and address local health needs
	Results publication/dissemination and utilization to strengthen local systems (policy)
	Impact on health system
Scientific Validity	Appropriate design and methods
	Methodological designs achieve outcomes
	Study feasibility
	Availability of qualified (academically and ethically) researchers?
	Prior knowledge
Fair participant selection	Fair and equitable selection
	Vulnerability
	Suitable study population
	Protections for vulnerable populations
Favourable risk-benefit ratio	Risk identification and minimization
	Type and magnitude of benefits
	Risk-benefit ratio
Independent review	Ethics and regulatory compliance
	Transparent review
	Conflicts of interests
	Ethics shopping
	Reconciliation of multiple reviews
	Recruitment and incentives applicability to the local context

Informed consent	Respect for autonomy
	Appropriate disclosure documents and process
	Presentation and accuracy of information
	Consent/assent for those with limited agency
	Gatekeeper permission
	Local languages, where necessary
Respect for participants	Confidentiality and privacy
	Reporting obligations
	Refusal withdrawal with no penalty
	Periodic updates on studies
	Post-trial access to final products
	Ancillary care
	Treatment or insurance for trial-related injuries
	Resolving contentious findings

Adaptation of the Emanuel et al. (2004) framework

Categorizing the content into specific activities ensures that the content categories are distinct and do not overlap. The utilization of this categorization allows for the easy classification of words, phrases, sentences, or paragraphs into the appropriate categories (Mayring, 2014). According to Prasad (2008), the quality of content analysis depends on well-formulated and comprehensive categories. This suggests that all communication analyzed should fit into one of the identified categories.

3.8 Methods

3.8.1 Data Collection/ Desk Review

In January 2023, the University of KwaZulu-Natal (UKZN) Biomedical Research Ethics Committee (BREC) granted full ethics approval for the study, with reference number BREC/00004860/2022. The selected REC for this study granted the research full ethics approval in February 2023. A Gatekeeper permission was received from the chairperson of the selected REC to access and evaluate the minutes of the REC. This permission is documented in the gatekeeper permission, provided in Appendix 3, which is withheld to ensure confidentiality. See Appendices 1 - 2 for the documents pertaining to the ethics approvals.

The minutes were accessed via email after signing a confidentiality agreement (to ensure that the data obtained from the REC is saved in a secured location and disposed of appropriately) with the selected REC. The minutes were coded using the eight principles and benchmarks of the framework developed by Emanuel et al. (2008) to document the observable pattern in the

ethical concerns raised while reviewing research protocols.

3.9 Data Analysis

The research methodology involved implementing a systematic data analysis procedure comprising many key steps. These steps included the determination of the unit of analysis, the identification of relevant categories or themes, the application of coding techniques, and the subsequent analysis and reporting of the findings. The following section outlines the steps involved in the analysis process.

- The first step involved identifying the unit mentioned in the text, which was then quantified and placed into various categories. The categories were defined using the framework proposed by Emanuel et al.
- The second step entailed the identification of coding categories/themes utilizing the pre-established framework (Appendix 4).
- The third step was to pilot the coded framework using one of the meeting minutes. The completed form was shared with a colleague to confirm the consistency of interpretation and approach.
- The fourth step was to code all the minutes.
- The fifth step was to capture the information from the coded minutes on a standardized data capture sheet (Appendix 5) to determine the frequency counts of each ethical concern raised in the minutes. A provision to capture "other" categories of concerns not covered by the Emanuel et al. (2008) framework was provided. The data was captured using Microsoft Excel and shared with two independent expert coders to ensure methodological compliance and confirm interpretation and quality control consistency. The analysis was done using simple descriptive analysis, and the results are presented graphically.
- The sixth and final step entailed recording noticeable features and frequencies of coded categories and making interpretations.

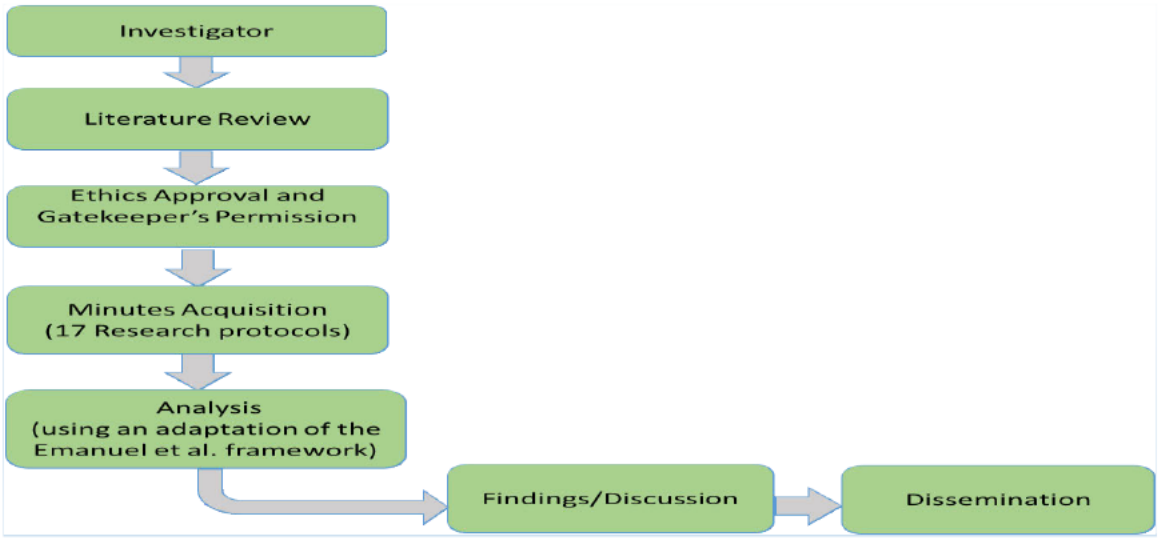


Figure 2: Flow of Research Activities

3.10 Reliability, Validity and Rigor

Reliability in content analysis refers to the degree of consistency or agreement among researchers in coding or categorizing data and ensuring that text classification adheres to established standards (Busch et al., 1994). To enhance the reliability of this study, a strategy was employed wherein a portion of the encoded data, namely the minutes, was shared with a fellow researcher to confirm the coding methodology used.

The study's validity is contingent upon its ability to derive generalizable inferences from the findings. Specific coding rules were established to ensure a systematic coding process. Busch et al. (1994-2012) argue that the generalizability of results depends on the reliability of the developed categories and their accurate measurement of the studied data. Hence, the authors emphasize the crucial role of coding rules in facilitating conceptual analysis. As a result, the coding rules formulated for this study effectively addressed the concerns surrounding the generalizability of the results.

The assessment of the quality of qualitative research involves the consideration of four criteria: credibility, transferability, confirmability, and dependability. Anney (2014) asserts that the conventional criteria commonly employed to evaluate research credibility, including internal and external validity, reliability, and objectivity, may not always apply to qualitative studies. Researchers Korstjens and Moser (2018) employed trustworthiness to assess the credibility and dependability of their research findings.

The credibility criterion addresses the internal validity considerations inherent in qualitative research, which aim to ensure that the study successfully achieves its objectives (Shenton, 2004). The credibility of the research findings is achieved through three distinct stages. The methods outlined in this paper 1) provide a comprehensive description, facilitating another researcher's replication of the study. 2) The sampling method used in selecting the meeting minutes indicates that the researcher exerted minimum influence over the types of minutes to be selected. 3) Replicating two previous studies utilizing similar research methodology: Silaigwana and Wassenaar, 2019 and Tsoka-Gwegweni and Wassenaar, 2014.

Two further approaches were employed to enhance the trustworthiness of the data and the resulting conclusions. Two key concepts discussed by Korstjens and Moser (2018) are "prolonged engagement" and "persistent observation." In the context of this study, the term "prolonged engagement" pertains to the duration of examining the selected REC meeting minutes. The concept of "persistent observation" is informed by establishing codes and utilizing a core category to examine data features. Almost four months were dedicated to thoroughly reviewing the meeting minutes to understand the ethical considerations. This extensive examination significantly facilitated the subsequent tasks of coding and thematic categorization.

Dependability relates to the extent to which a research study can produce the same results when repeated (Shenton, 2004). This study achieved dependability by rigorously coding and analysing the data from the minutes, ensuring high consistency and uniformity. A method is implemented to provide dependability and confirmability, which involves the provision of an audit trail. This audit trail includes components such as raw data, analysis notes, coding notes, process notes, and reports as deemed appropriate in the given context.

3.11 Ethical Considerations

The Emanuel et al. framework served as the basis for this study's ethical considerations, which govern the ethical conduct of research involving human participants. By applying this framework, the study guaranteed that ethical concerns were appropriately addressed. Below is a discussion of the specific ethical considerations relevant to this study.

3.11.1 Collaborative Partnership

Given the purpose and scope of this study, a traditional collaborative partnership was deemed unnecessary as the primary focus entailed the review of archived REC minutes. Nevertheless, gatekeeper permission was acquired in order to access the records of the selected REC. This research will contribute to a better understanding of the ethical concerns raised by African RECs.

3.11.2 Social Value

The Emanuel et al. framework emphasises the principle of "social value," underscoring the critical need to clarify the societal benefits of research within the local community in which it is done effectively. The importance of this research holds immense value within the context of the literature review, as it examines ethics and research experiences in African countries. The research findings will provide insight into the ethical issues the selected REC considered during the research protocol review. Furthermore, this research endeavour will advance knowledge regarding the practical use of Liberia's Emanuel et al. framework. The research findings will additionally be shared with the selected REC and published to make a valuable contribution to the broader academic community.

3.11.3 Scientific Validity

The study's research design demonstrated scientific rigor and reliability by relying on previously published studies that had undergone peer review. The thorough review of relevant literature provided a robust basis for analyzing the ethical concerns discussed by the selected REC during their meetings. The principle of scientific validity entails the researcher's competence and capability to conduct the study effectively. In this context, the RECs evaluated the researcher's qualifications and competence to ascertain their research suitability. Additionally, the researcher presented documentation of their participation in the South African Research Ethics Training Initiative (SARETI) program, indicating their commitment to ethics training. Furthermore, the researcher reassured the REC with their dedication to overseeing the research and assuring the proper implementation of the study.

3.11.4 Fair Participant Selection

The research approach involved carefully considering how the researcher selected the REC, sampled the minutes, and collected the data, including the selection procedure for the minutes and the criteria for including or excluding specific elements. It is important to mention that this study did not involve human participants.

3.11.5 Favourable risk-benefit ratio

The study employed a research methodology that utilized content analysis as an unobtrusive method, avoiding direct involvement of individuals. As a result, the study is considered to have minimal risk, with the primary ethical concern revolving around the potential breach of confidentiality. The documents analyzed in this study were highly confidential. Therefore, preventing the release of sensitive information into the public domain is crucial, as doing so can adversely impact the institution's reputation and pose potential risks to research participants. In order to safeguard the identity of the data (applicants), the research protocols were coded anonymously through numerical codes, and stringent precautions were taken to ensure confidentiality. The collated textual data underwent analysis and was afterwards presented in a format that provided anonymity, aggregation, and removal of any identifying information. The data obtained from this study would hold considerable importance in identifying and recommending addressing ethical and legal concerns related to protecting human participants in biomedical research conducted in Liberia.

3.11.6 Independent Ethics Review

While human participants were not directly involved in this study, the utilization of pre-existing data underwent a thorough ethical review process conducted by a duly constituted ethics committee. The utilization of existing data in this study has been approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC) in South Africa (reference #: BREC/00004860/2022; Appendix 1) and the Atlantic Center for Research and Evaluation Institutional Review Board (ACRE IRB) in Liberia (reference #: 23-02-358; Appendix 2) following an expedited review. Obtaining ethical approval from these committees supports

adherence to ethical norms and signifies a dedication to preserving the fundamental principles of research ethics.

3.11.7 Informed Consent

Although the selected REC provided a gatekeeper's permission, the specific letter is being withheld to ensure confidentiality; it can be accessed to conduct an audit. In addition, a confidentiality agreement was established between the leadership of the REC, wherein all received material would be treated as confidential. Furthermore, the collected data underwent an analysis process and subsequent reporting in a manner that guarantees anonymity. This approach ensures no specific individuals, institutions, or processes are identified or disclosed. The protocols addressed in the minutes were allocated distinct numerical identifiers to preserve the parties' confidentiality. Precautionary measures were implemented to ensure the security of the papers, encompassing the utilization of computer password protection and the storage of hard copies in locked cabinets. The data will be subject to destruction after five years to enhance the preservation of confidentiality. These processes follow the principles of health research ethics and safeguard the privacy and confidentiality of research participants and their data.

3.11.8 Respect for Participants and Study Communities

In this study, utmost care was taken to protect confidentiality. This was achieved by de-identifying research projects in the minutes and substituting names and protocol titles with unique codes. The minutes were stored securely in a lockable cupboard within a residential setting, and a password was used to access the computer for data analysis.

CHAPTER 4

RESULTS

This chapter presents the study's findings. These findings include the number of protocols reviewed annually, the number of ethical concerns raised, and the results regarding the applicability of the Emanuel et al. framework to the reviewed protocols' ethical concerns. Tables, graphs, and analyses present the most significant findings, while the analyses provide a more comprehensive and detailed understanding.

4.1 Description of the Data Evaluated

The majority of the protocols, precisely 15 out of the total, exclusively engaged human participants, accounting for approximately 88% of the total. One protocol involved human and animal participants, constituting 6% of the total, while another exclusively featured animal participants, accounting for 6%. All protocols were observational, indicating that the investigator(s) did not intervene or manipulate the variables. The protocols had a national scope, meaning they were conducted within the country's borders. The majority of the protocols (12, 70%) were related to health. The remaining protocols were in the fields of social science (3, 18%), public administration (1, 6%), and education and nutrition (1, 6%). 16 protocols collected data from primary sources, whilst one protocol relied on secondary sources for data collection (Table 5).

Table 5: Types of Protocols reviewed by the selected REC

Principles	Number of Protocols	Percentage
Health Related	12	70%
Social Science	3	18%
Public Administration	1	6%
Education and Nutrition	1	6%

4.2 What Concerns were Frequently Raised by the Selected REC during the review of research protocols?

This study aimed to identify, categorize, and evaluate the ethical concerns the selected Liberian REC raised while reviewing research protocols. The analysis of the REC's minutes revealed that 124 concerns were raised during the review of protocols. Out of the total sample, a

significant majority (117, 94%) aligned with the eight principles of the Emanuel et al. (2008) framework. The remaining concerns (7, 6%) could not be categorized under the Emanuel et al. framework. These concerns were categorized as "other-administrative" in the coding process. The types of concerns raised by the REC are presented in *Figure 3*.

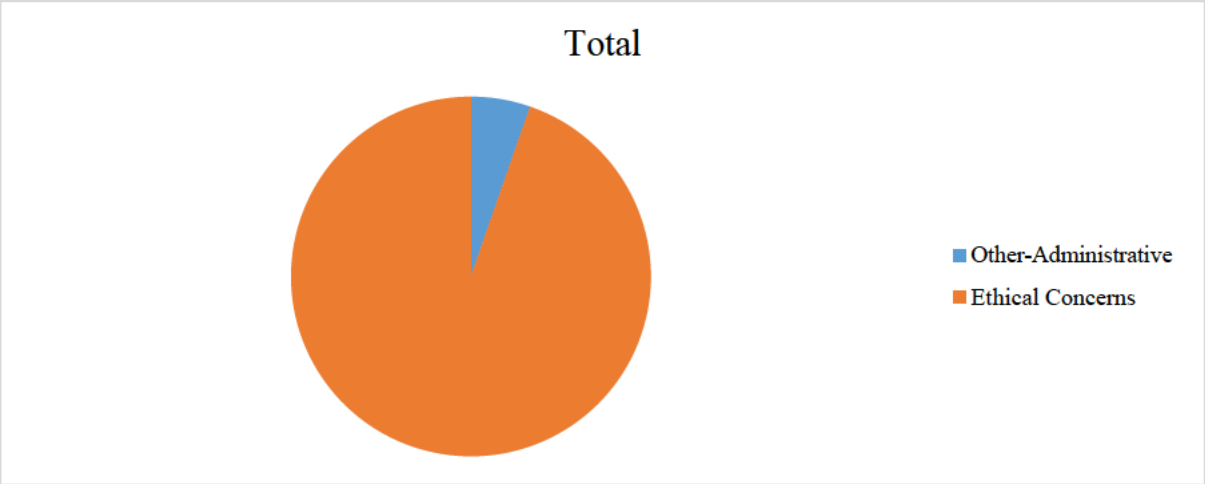
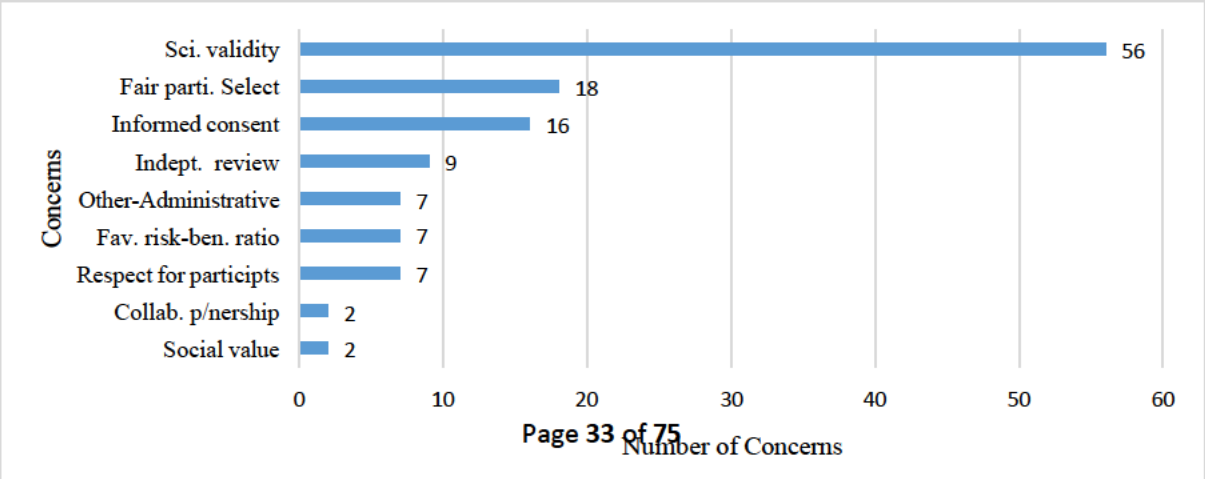


Figure 3: Type of concerns raised by the selected REC during the review

4.3 What are the Most Frequently Raised Concerns by the Selected REC during the Review of Research Protocols?

One of the objectives of this study was to identify the REC's most frequently raised concerns during the review of research protocols. The results indicate that the most frequent concern raised was the protocols' scientific validity, with a frequency of (56, 45%). This was followed by fair participant selection (18, 15%), informed consent (16, 13%), independent ethical review (9, 7%) and "other-administrative" concerns (7, 6%). Concerns regarding favourable risk-benefit ratio, respect for participants and study communities, collaborative partnership, and social value were relatively low, with (7, 6%), (7, 6%), (2, 2%), and (2, 2%), respectively. *Figure 4* depicts the distribution of the concerns raised by principles.

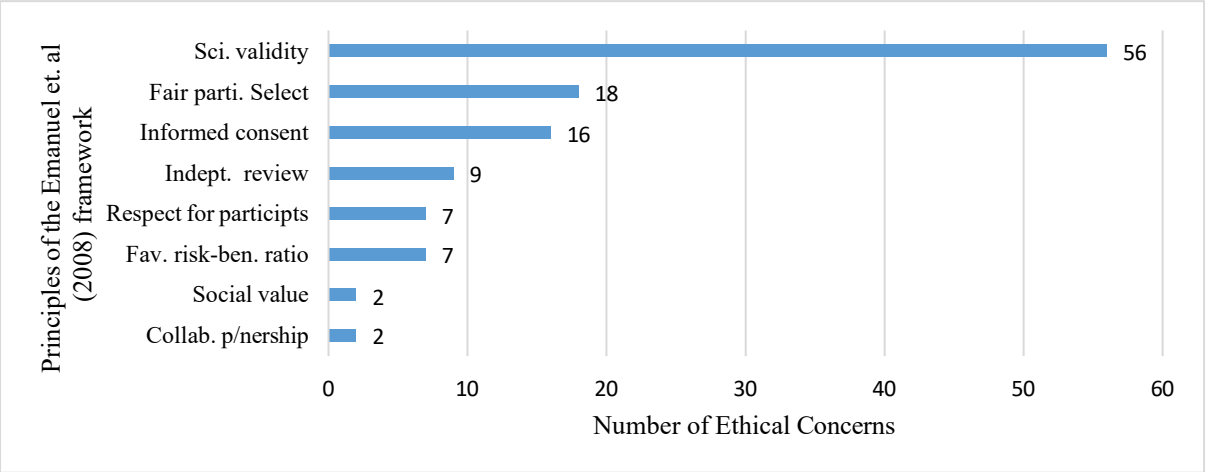


Key: *Sci. validity=Scientific validity, Fair parti. Select.=Fair participant selection, Informed consent=Informed consent, Indept. Review=Independent ethics review, Fav. Risk-ben. Ratio= Favorable risk-benefit ratio, Respect for participts=Respect for participants, Collab. p/nership=Collaborative partnership, and Socialvalue= Social value*

Figure 4: Concerns raised by the selected REC categorized per the principles of the Emanuel et al. (2008) framework

4.4 Prioritization of Some Ethical Concerns over Others

Another study objective was to determine whether the selected REC prioritized or ranked any particular ethical concern higher over others. The results showed that the REC prioritised some ethical concerns over others. Figures *5 to 7* below completely categorise the 117 ethical concerns arranged according to their respective principles and accompanying benchmarks.



Key: *Sci. validity=Scientific validity, Fair parti. Select =Fair participant selection, Informed consent=Informed consent, Indept. Review=Independent ethics review, Fav. Risk-ben. Ratio=Favorable risk-benefit ratio, Respect for participts=Respect for participants, Collab. p/nership=Collaborative partnership, and Social value= Social value*

Figure 5: Frequencies of the prioritization of ethical concerns raised by the selected REC (2018-2019)

4.4.1 Scientific Validity

The three ethical concerns that received the most attention from the REC under the Emanuel et al. benchmarks of scientific validity are depicted in Figure 6: the appropriateness of the research design to achieve the desired outcomes (42, 75%), the availability of qualified researchers (academically and ethically) (7, 12.5%), and prior knowledge of the research topic (7, 12.5%).

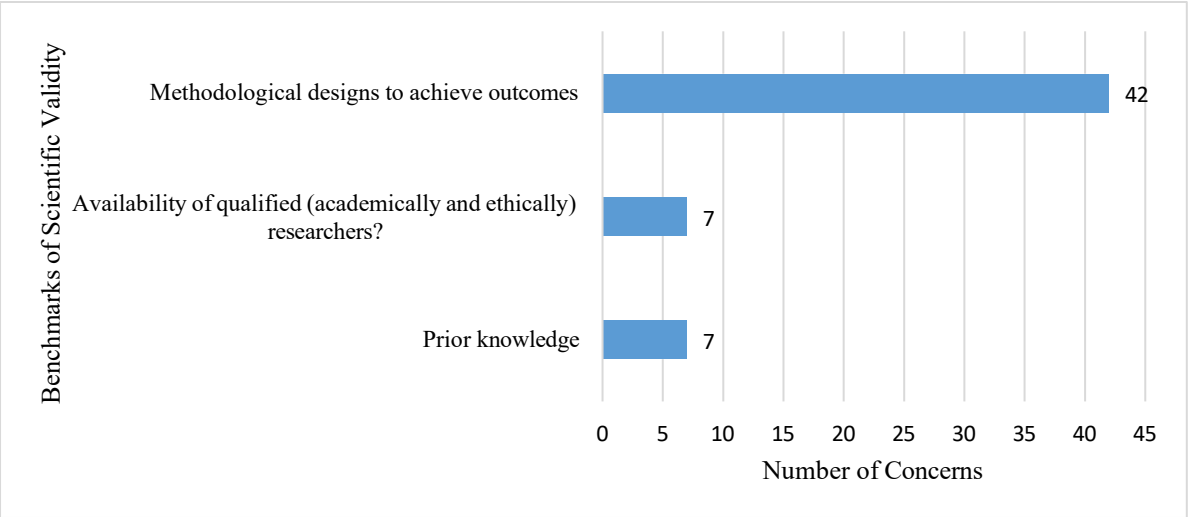


Figure 6: Ethical Benchmarks: Scientific Validity

4.4.2 Fair Participant Selection

One of the ethical concerns that emerged frequently under the Emanuel et al. principle of fair participant selection was ensuring the research participants were selected fairly and equitably. This concern was raised in 18 out of the 18 for fair participant selection, resulting in a 100% occurrence rate.

4.4.3 Informed Consent

Figure 7 shows that the REC frequently identified three ethical concerns based on the Emanuel et al. principle of informed consent. These concerns included the availability of the appropriate disclosure documents and processes (11, 69%), the provision of gatekeeper permission (3, 18.5%), and respect for autonomy (2, 12.5%).

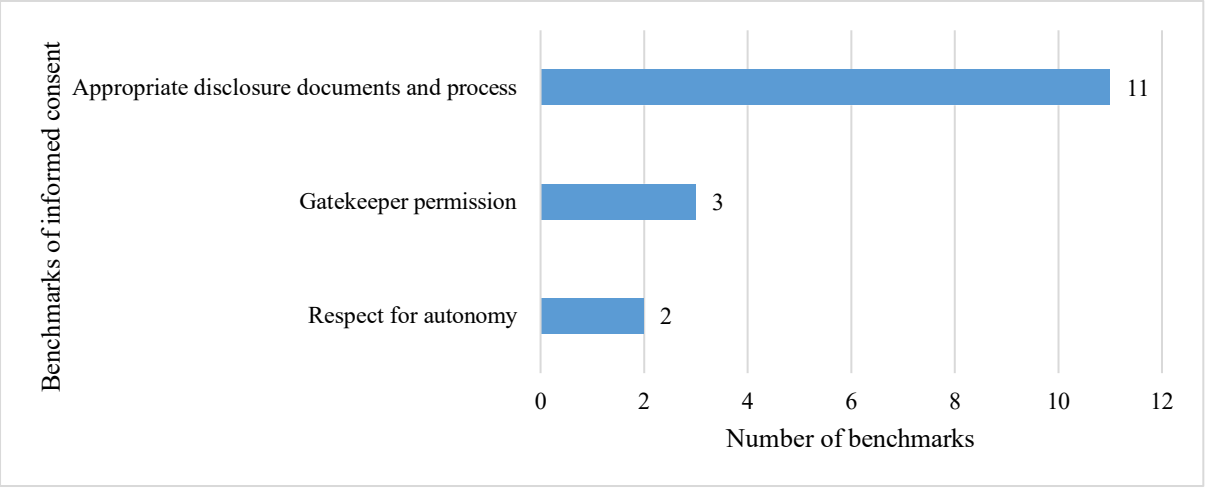


Figure 7: Ethical Benchmarks: Informed Consent

4. 5 Other Concerns Raised by the REC

In addition to the ethical concerns raised by the REC, others were identified during the review of research protocols. These concerns were categorized as "other-administrative" and amounted to seven (7). The identified concerns included inconsistency in the completion of the application forms (2), failure to submit protocol amendment (1), absence of section sub-headings and references (2), followed by a concern about incomplete application document (1), and mislabeling of the name of the REC (1).

4.6 Compatibility of the Selected REC Ethical Concerns with the Emanuel et al. Framework?

This study also aimed to determine the consistency of the ethical concerns raised by the REC with the Emanuel et al. (2008) framework. Additionally, the study intended to identify any specific aspect of the framework that dominated the REC's concerns. Based on the results, it was observed that the framework could accommodate 117 out of the 124 concerns raised by the REC. The predominant concerns raised by the REC were related to the scientific validity (56, 48%), fair participant selection (18, 15%), and informed consent (16, 14%). The least prominent concerns were related to collaborative partnerships (2, 2%) and social value (2, 2%). Table 6 presents the frequency of ethical concerns consistent with the framework proposed by Emanuel et al. (2008), arranged in descending order.

Table 6: Ethical concerns raised by the selected REC under the eight principles of the Emanuel et al. (2008) framework

Principles	Number of Ethical Concerns	Percentage
Scientific validity	56	48%
Fair participant selection	18	15%
Informed consent	16	14%
Independent ethics review	9	8%
Favourable risk-benefit ratio	7	6%
Ongoing respect for participants and communities	7	6%
Social value	2	2%
Collaborative partnership	2	2%
Total	117	100%

CHAPTER 5

DISCUSSION

This chapter discusses the findings of the study. The study aimed to review the meeting minutes in order to identify, analyse, and describe the pattern of the ethical concerns raised by the REC during the review of research protocols. The study examined the ethical concerns using the principles and benchmarks in the framework proposed by Emanuel et al. (2008). The results of the analysis were set out in Chapter 4.

This chapter contains three (3) subsections. The initial subsection aims to identify and rank the most dominant ethical concerns in a hierarchical order. Additionally, this subsection undertakes a comparative analysis with the outcome of other studies, such as those conducted by Tsoka-Gwegweni and Wassenaar (2014) and Silaigwana and Wassenaar (2019). The subsequent subsection examines the extent to which the cited concerns are consistent with the proposed framework. The final subsection discusses the observable pattern and the underlying factors contributing to the observed trends and explores their potential implications.

5.1 Identifying and Ranking the Most Dominant Ethical Concerns during the Review of Research Protocols

The concern that emerged most clearly in the review was scientific validity, which is consistent with the findings of other studies, such as Dixon-Wood (2008). In this study, scientific validity-related concerns accounted for nearly half of all concerns (48%), with fair participant selection following at 15% and informed consent at 14%. These findings are in contrast to other studies, such as those by Cleaton-Jones (2010), Tsoka-Gwegweni and Wassenaar (2014), Bengu (2018) and Selormey (2015) in South Africa and Ghana, which found that informed consent was the most frequently mentioned concern, albeit with differing percentages. Nevertheless, the results of this study are in partial agreement with previous studies. For instance, Frimpong's (2016) study in Ghana identified scientific validity as the primary concern (51.3%), followed by concerns related to informed consent (20.6%). Similarly, Kirimuzya's (2020) study on REC in Uganda reported scientific validity as the predominant concern (60.2%), followed by informed consent (11.45%). The results of this study are also partially consistent with the study conducted by Briers and Dempers (2017) in South Africa. Their study also identified significant results related to science and scientific validity despite employing a different approach

and design. In addition, the findings showed that the REC also raised concerns about the competence of the research team, including the recommendation for a local co-investigator and the qualifications and experience of the principal investigator(s) and research team. This is consistent with the CIOMS guidelines (2016), which recommend that RECs consider the competence of the research team when reviewing protocols. A majority of concerns in this category pertained to the utilization of appropriate designs and methods. This trend can be viewed as a strength because these factors contribute significantly to ensuring the scientific validity of a study.

The emergence of the principle of scientific validity was particularly evident during the review of the ethical concerns raised by a Liberia REC using the Emanuel et al. (2008) framework. This observation sheds insight into the ongoing discourse around the function of ethics committees in the context of scientific research. There is a debate regarding the scope of ethics committees, with one perspective advocating a narrow focus on ethical considerations and non-interference in scientific matters. Conversely, an opposing viewpoint asserts that ethics and science are interconnected, and thus, ethics committees are responsible for verifying the scientific soundness of research proposals (Angell et al., 2008). The findings of this study suggest a significant correlation between the considerations of scientific validity and the decision made by the REC about the outcome of a research application. The findings of this study suggest that RECs do not perceive the peer review of the scientific team as providing adequate reassurance regarding the scientific quality of research. However, RECs play a crucial role in offering valuable input to enhance the design and implementation of research, thereby ensuring its scientific validity and adherence to the highest ethical standards. The ultimate objective should be to achieve a balance that ensures research's ethical and scientific conduct. The development and implementation of policies and procedures that foster responsible and ethical research necessitate a collective endeavor involving scientists, ethics committees, and various other stakeholders.

Although fair participant selection and informed consent were the second and third most frequently raised concerns at (15% and 14%) respectively, the current study does not provide unambiguous evidence that the importance RECs in South Africa or Ghana placed on fair participant selection and informed consent differs significantly from Liberia's practice. In some studies, informed consent was given precedence, but scientific validity was equally important.

For instance, in Bengu's (2018) study on a South African social science REC, informed consent was 31%, and scientific validity was 21%. In contrast, in Silaigwana and Wassenaar's (2019) study, informed consent was 26%, and scientific validity was 16.7%. These findings suggest that the relative importance of these concerns may vary depending on the specific research context.

Since the selected REC mainly reviewed health-related research protocols (excluding clinical trials), a different picture of the ethical concerns raised by RECs in Liberia may emerge if another REC in the same setting is considered. For instance, other RECs may review a wider range of research protocols, including clinical trials, social science research, or research on vulnerable populations. Furthermore, it is important to note that other RECs may have different ethical priorities or interpret ethical guidelines differently. Nevertheless, Bengu (2018) conducted a study on a social science REC, suggesting that the concerns raised while reviewing social science research protocols may differ.

Furthermore, comparing the results from this study with those of Tsoka-Gwegweni and Wassenaar (2014), the three dominant concerns considered were similar but in varying percentages and weightings. In addition, social value and collaborative partnerships, as with this current study, were the minor concerns raised in the study conducted by Tsoka-Gwegweni and Wassenaar (2014), while collaborative partnerships were ranked fifth in Silaigwana's (2017) study.

Finally, the study also found that social value and collaborative partnerships were the least frequently raised concerns. This finding is consistent with the study of Tsoka-Gwegweni and Wassenaar (2014). Still, it is in contrast to the results of Silaigwana (2017), who found that the principle of collaborative partnerships was the fifth most frequently raised concern. The reason for this discrepancy is unclear, but there is a possibility that the selected REC did not review collaborative works, overlooked these issues, or felt that the researchers adequately addressed the issue.

5.2 Consistency of the Concerns with the Emanuel et al. (2008) Framework

While the existing institutional ethical review guidelines and international documents that informed the ethical reviews of research protocols by the selected RECS may not have been specifically designed to align with the Emanuel et al. (2008) framework, the results of this

study indicates a strong alignment between the findings and the principles and benchmarks outlined in the framework. Specifically, 94% of the concerns raised in the study were consistent with the framework. For instance, the concerns about the competence of the research and the need for a clearly defined study design and methodology align with the principle of scientific validity, as they ensure that the research yields the intended results. The concern of ensuring fair participant selection aligns with the principle of fair participant selection since it assures that all prospective participants are afforded an equal chance to engage in the research. The concern about the appropriateness of the study disclosure material aligns with the principle of informed consent since it ensures that participants receive comprehensive information regarding the research before providing their voluntary consent to participate.

5.3 An Observable Pattern, Reasons for the Observed trends, and their Implications

During the two-year review period, the most dominant ethical concerns raised by the REC follow a predictable pattern. The most common concern is scientific validity, followed by fair participant selection, informed consent, and independent ethical review. This pattern suggests that the REC is concerned about conducting research ethically and responsibly. There are several possible explanations for this observation.

First, there appears to be an increasing interest in the number and complexity of ethical issues associated with health research in low- and middle-income countries (LMICs), with a specific focus on Liberia. This phenomenon may be attributed to many factors, one of which is the increase in global health research, characterized by joint efforts. Consequently, several LMIC nations are actively engaging in collaborative research endeavors. These studies are often characterized by frequent ethical issues, such as balancing the benefits of the research with the risks to participants and ensuring that participants' voluntary consent is obtained. Within this particular context, there has been a notable rise in the level of acknowledgement and recognition of ethical concerns that are especially associated with research. Frequently, these studies include vulnerable groups, such as those who are experiencing poverty or have limited access to healthcare (include sources to support your suggestions). This context gives rise to additional ethical concerns, including the need to protect participants from exploitation and to promote the dissemination of study findings.

Second, it is possible that the interests and perspectives of the REC members may have changed over time, which may have reflected a dynamic understanding of the ethical considerations in

research. This change could be attributed to the exposure of new research methodologies and the emergence of ethical dilemmas. As science and technologies advance, REC members are continuously exposed to new ethical considerations, leading to a more comprehensive understanding of ethics in research. Furthermore, it is possible that the members of the REC may have been more actively involved in a variety of research initiatives spanning a wide range of topics. They may have also taken part in a variety of meetings with various stakeholders and stakeholder groups. The exposure to various research contexts could have the potential to influence or shape the REC member's perspectives on ethical concerns and prompt them to consider the unique ethical implications of each study protocol. For instance, in 2019 the REC may have received a higher volume of applications that differed in quality, type, topic, or methodology compared to those received in 2018. These differences may have promoted inquiries regarding scientific validity, fair participant selection and informed consent, or other controversial initiatives that may have necessitated greater scrutiny and consideration from the REC.

Furthermore, it is possible that the REC may have developed new criteria or standards for evaluating research proposals in response to the changing landscape of research ethics. This change could have been due to the emerging ethical guidelines and regulations for research, promoting RECSs to adapt their evaluation criteria to align with these evolving standards.

Third, there may have been changes in the REC's composition and the introduction of more members with expertise in different areas, such as ethics, research methodology, and community engagement. This scenario may have led to members with different areas of expertise raising different perspectives on the ethical review process. For instance, an ethicist could have been more likely to raise concerns about informed consent and approval processes, whereas a research scientist could have been more likely to raise concerns about the design of the study. In addition, members with experience in community engagement could have more likely to raise concerns regarding the impact of the study on the community and collaborative partnership.

Fourth, this shift may have resulted from the experience of the reviewers and the skills, knowledge, and experience of the researchers who submitted their protocols to the REC. At the same time, reviewers may have gained more training and education and training in identifying and evaluating ethical concerns in research protocols. They may have become more aware of the issues and challenges that arise when conducting ethical research, especially with vulnerable populations in mind. This knowledge and experience would have allowed them to

identify a wider range of ethical concerns and to provide more specific and tailored feedback to researchers. Additionally, researchers who submitted their projects to the REC may have improved their skills, knowledge and awareness of the expected ethical principles. This may have led them to be more diligent and thorough in designing and conducting their research, particularly in ensuring the validity of their research methodologies and the fairness of participant selection. As a result, the REC may have raised fewer concerns and emphasised the research's quality and rigour.

Regardless of the rationale, this trend has several significant implications. The observed trend could suggest that the ethical review process is dynamic and responsive to the evolving demands and contexts of research, with the aim of ensuring that the research is relevant, appropriate, and considerate towards the individuals and contexts involved. This may enhance the credibility and reliability of the research and the review committee. Moreover, this observed trend may also suggest the increasing intricacy and diversity of research methods and topics, particularly in relation to marginalized communities and sensitive matters. It is imperative to ensure that the research is conducted ethically, considering the diversity and complexity of the individuals and contexts involved.

Furthermore, it is important to consider that this trend may have an impact on both the quality and quantity of research conducted and published, as well as the dissemination and utilization of research outcomes. For instance, to enhance the reliability and generalizability of research findings, it is essential to emphasise scientific validity and fair participant selection. Nevertheless, it is important to acknowledge that certain researchers or research designs may pose challenges or barriers. This may require a more rigorous and nuanced ethical evaluation and committee guidance. This approach could potentially enhance the credibility and reliability of the research and the REC.

Moreover, this observed trend could impact the ethical education and training of researchers and members of REC. Specifically, it could enhance the development of critical thinking and reasoning skills among researchers and reviewers, enabling them to analyze and evaluate ethical research effectively. Additionally, it could facilitate the articulation and formation of ethical perspectives and arguments within these individuals. By considering the implications for the ethical education and training of researchers and REC members, the ethical review committee can ensure that research is conducted to promote ethical awareness, understanding, and competency among researchers and reviewers. One potential area of improvement involves enhancing awareness and understanding of ethical concepts and fostering greater chances for

dialogue and feedback between researchers and reviewers. In this way, the trend discussed above could suggest that the REC is committed to ensuring that research is committed to ensuring that research is conducted ethically and that the rights and welfare of research participants are protected.

Concerns regarding social value and collaborative partnerships did not feature prominently in the present study, which is a cause for concern. Social value and collaborative partnerships are significant ethical issues that, if ignored, could lead to research being conducted without appropriate consultation with local communities and consideration of national health priorities and issues. Several guidelines recommend that researchers establish collaborative partnerships with host communities (CIOMS 2016; Emanuel et al. 2004). The social value of a research protocol should be evaluated, but this can be difficult for RECs to do because the value cannot be quantified. It is important to note that the possibility that these concerns were possibly not raised because they were adequately addressed in the protocol. In future research, an experienced coder will examine the protocols in greater depth and compare them with REC minutes, which will help determine why the REC did not consider social value and collaborative partnerships. Additionally, an interview with the chair or members of the REC would clarify the concerns mentioned above.

Priority should be given to research that aims to improve the well-being of the communities from which the participants are drawn. This can be encouraged by focusing on research pertinent to the communities' requirements and aspirations. However, these principles are undermined in some countries by the absence of research agendas, which should be the driving force behind the research enterprise. A country like Liberia, which lacks a harmonised research agenda and where research funding from the national budget has not yet attained a level of priority, may be incapable of implementing a drive for research tailored to its society's needs. This may not be entirely accurate; however, as of the countries addressed in the studies under consideration (namely, Cameroon, Ghana, Malawi, Nigeria, South Africa, Uganda, and Zimbabwe), Uganda, South Africa and Ghana are at various stages of development and may contribute to research in different ways. Therefore, it is necessary to investigate this issue to identify the underlying cause. It is also possible that the social value or collaborative partnerships are not emphasized during the training of members of RECs, which explains the lack of questions raised during ethical evaluations of research protocols.

The following discussion relates to the aspects the current study categorized as "other-administrative" concerns. The findings showed that "other-administrative" concerns were

ranked 5th during the review of research protocols by the REC, implying that the REC is more concerned with the procedural aspects of research than the ethical implications. Although administrative concerns are important in maintaining and streamlining an effective review process, they should not take precedence over ethical considerations during the review meeting, which is intended to determine the protocols' scientific validity and ethical precision. This finding seems problematic, as it could lead to unethical research conduct. For example, a researcher may be tempted to cut concerns or overlook ethical considerations in order to meet administrative requirements. This could put research participants at risk of being exploited or harmed. In addition, it could create a perception that ethical concerns are not as important as administrative concerns. This perception could discourage researchers from submitting ethical research protocols. If researchers know they will be judged more harshly on administrative than ethical grounds, they may be less likely to submit them. This could mean less ethical research is conducted, negatively impacting society.

Furthermore, such a finding could undermine the public's trust in research. This makes it more challenging to recruit research participants and obtain research funding. As such, it is crucial to ensure that these matters do not overwhelm the underlying ethical considerations.

5.4 Strengths and Weaknesses of the Emanuel et al. (2008) framework

The Emanuel et al. framework is a set of ethical principles and standards for evaluating biomedical research. It contains a set of benchmarks for each principle. These benchmarks are intended to provide more specific guidance on implementing the principles in practice.

In general, the Emanuel et al. framework is widely recognized for its comprehensive and flexible nature, making it a valuable resource for RECs to evaluate the ethical integrity of research protocols in diverse settings and contexts (Bengu, 2018; Kirimuhuzya, 2019; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014). One could argue that the framework is suitable for both scientific and ethical review, aligning with the two cardinal principles of review, namely scientific validity, and ethical integrity of research. This assertion is supported by the findings of this study, which emphasize that concerns regarding scientific validity, fair participant selection, and informed consent were prevailing (Table 5). Moreover, there was a high degree of agreement with the framework despite the variations in the results of various studies.

Despite the framework's usefulness, it also has a few flaws. The absence of a ranking or

prioritization system for the eight principles raises uncertainty on the appropriate balance or weigh to assign them in ethical decision-making (Silaigwana, 2017; Tsoka-Gwegweni & Wassenaar, 2014). The framework does provide a clear indication of the specific benchmarks that could be seen as fundamental factors leading to the REC's rating in the absence of substantial attention to them. The aforementioned sources (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014) provide valuable insights for individuals faced with a dilemma that require the assessment and ranking of ethical principles in various contexts, including cultural diversity, disease burden and socioeconomic and political environments. The framework lacks the capacity to offer clear guidance on addressing conflicts between principles and ethical dilemmas due to the absence of a hierarchical weighting system for the principles.

Furthermore, this study and others cited above have presented empirical support for additional ethical concerns not considered by the existing framework. These concerns include properly storing biological samples, which may require acquiring an export permit or a Material Transfer Agreement (MTA) (Silaigwana, 2017; Tsoka-Gwegweni & Wassenaar, 2014). In addition, it is worth noting that administrative matters, such as the availability of research funds and the researcher's level of experience, might potentially influence and negatively affect the principles of social value, scientific validity, and favourable risk/benefit ratio (Silaigwana, 2017; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014). The requirements mentioned are stipulated in international ethical guidelines, such as CIOMS guidelines from 2002 and the Declaration of Helsinki from 2013. Moreover, the field of bioethics is evolving, but the framework is not updated to reflect the changes in research ethics. This can cause the framework to become obsolete and no longer reflect contemporary ethical standards.

Fourth, this study was conducted using content analysis. Prasad (2008) argues that content analysis is susceptible to potential misinterpretations as a text analysis tool. This is due to the researcher's need to exercise subjective judgment in determining the appropriate categorization of the text. This study acknowledges the potential for the researcher to misread or overinterpret some of the text, perhaps resulting in inaccurate findings regarding the ethical decision-making process of the REC.

Fifth, a degree of overlap was observed across some aspects of the principles, posing challenges in categorising some ethical concerns from the minutes. Consequently, some concerns were found to pertain to multiple principles simultaneously. The concerns were assigned to the most appropriate category and included and counted once. This observation implies the possibility

of coding errors within the dataset. To enhance the reliability and generalizability of future studies, the researcher should engage several coders, strive for consensus on coding determinations, and gather and analyse data from multiple RECs in Liberia.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

This chapter presents the conclusions from the study and explains its contribution of the study to the existing body of knowledge. In addition, the chapter presents an analysis of the study's limitations, with suggestions for future research and the distribution of the study's findings. Furthermore, the chapter highlights the potential practical applications of these conclusions.

6.1 Conclusion

This study is the first known evaluation of the ethical concerns a Liberian REC raised during the research protocol reviews using the Emanuel et al. (2008) framework. The selected REC raised concerns ranging from ethical to non-ethical considerations. The study's outcome indicates that most of the protocols evaluated by the selected REC were health-related.

The ethical concerns most frequently raised were scientific validity followed by fair participant selection and informed consent. Additional ethical concerns highlighted by the REC included various considerations. These included independent ethics reviews. Furthermore, the REC emphasized ensuring a favourable risk-benefit ratio.

Additionally, the REC raised the importance of maintaining ongoing respect for study participants and study communities. The REC also recognized the need for social value. Lastly, the committee emphasised the importance of fostering collaborative partnerships. The study results showed several issues that contributed to the REC's concerns, including inconsistencies in completing the application form, failure to submit protocol amendment, mislabelling of the REC's name, and incomplete application documents.

The three ethical concerns the REC most frequently raised during the research protocol review were similar to those raised by RECs in Ghana, South Africa, and Uganda. The primary objective of RECs is to protect the rights of those participating in research by ensuring that informed consent is obtained and enhancing the welfare of participants during and after research.

The results indicate that the framework provides a valuable tool that can be used to categorise most concerns raised during meetings of the Liberian REC research ethics protocol review. The

results indicate that this framework can be used to conduct comparative studies to evaluate the concerns raised by RECs during research protocol reviews in the country. This might be achieved by employing a more extensive sample of RECs than the one utilized in the present study.

6.2 Recommendations

The following recommendations are hereby advanced, especially in an effort to proffer suggestions for policy and future research:

6.2.1 Recommendations for the Conduct of a Comparative Study

A comparative study should be conducted to evaluate the concerns of accredited RECs during the review of research protocols in Liberia, including those operating in hospitals, higher learning institutions, and at the national level. In addition, further studies considering an in-depth analysis to ascertain the perspective of reviewers and key researchers on the types of concerns raised by the RECs and the reasons for those concerns would be useful to get a broader view of the concerns raised by the RECs. This approach will help generate a more comprehensive picture that can be used to ascertain the applicability of the Emanuel et al. framework within the specific context of Liberia and the broader Africa region.

6.2.2 Need for the Assignment of Scores to Establish the Ethical Weighting of Each Principle

Assigning scores to various benchmarks could help mitigate the failure to establish an appropriate relationship between the frequency of mention and the importance of the concerns raised during review meetings. It may be necessary to conduct additional studies on "other-administrative" concerns raised by the RECs to define their contribution to the research protocol ethical review process. A systematic approach to organising these concerns is also recommended. Additional studies could examine the relationship between these findings and the compositional and training of REC members, as well as concordance (or lack thereof) with local ethical guidance.

6.2.3 Need for Research Ethics Training

While not an objective of this study, the need for ethics training should be considered as a way of supporting ethics review. That is, Liberian RECs may want to consider research ethics training for their members and health researchers. Ndebele et al. (2014) suggested that researchers and REC members require training in health research ethics in order to ensure the ongoing and competent protection of human research participants.

6.2.4 Recommendation for Future Research

Given the evolving nature of bioethics, it is important to contemplate a longitudinal study that would help document the trends of ethical concerns raised by RECs. This would be contemporary and less susceptible to personal and informational biases due to a combination of factors, including increased transparency and accountability, more diverse and inclusive review panels, greater use of standardized review criteria, and more rigorous training for reviewers. Knowledge of such trends can aid in developing ethics training and review policies and strategies. The review of health research ethics is not static; therefore, it must be adapted and readjusted over time as contexts change, feedback is provided, and histories develop.

6.3 Study Limitations

The study was subject to several limitations.

First, the study was conducted on only one of two accredited RECs in Liberia. As a result, it is challenging to generalize or draw comparisons between the outcomes of this particular REC in Liberia and others.

Second, it should be noted that the study was conducted based on the assumption that the data utilized, namely the meeting minutes, were a reliable representation of the review meeting and captured the full range of ethical concerns of the REC. Nevertheless, it is possible that some pertinent concerns that were discussed and amicably resolved may not have been documented in the minutes. This suggests the findings may not accurately reflect the ethical concerns raised during the review meetings. During review meetings, RECs often overlook positive aspects of protocols, leading to a disproportionate emphasis on identifying and highlighting what has been done incorrectly at the expense of what was done correctly, thereby giving rise to information

bias. This limitation in the study on South African RECs was acknowledged by Silaigwana and Wassenaar in 2019.

Third, the study did not use a standardized scoring mechanism to determine the ethical weighting or significance of the principles. This implies an inability to establish a correlation between the frequency of the mentioned principles and the level of importance or value assigned to the concerns raised. For example, ranking "other-administrative" as the fifth concern, following scientific validity, fair participant selection, informed consent, and independent ethics review, may suggest that these concerns were more frequently discussed in the meeting minutes rather than indicating their relative importance.

Fourth, this study was conducted using content analysis. Prasad (2008) argues that content analysis is susceptible to potential misinterpretations as a text analysis tool. This is due to the researcher's need to exercise subjective judgment in determining the appropriate categorization of the text. This study acknowledges the potential for the researcher to misread or overinterpret aspects of the text, perhaps resulting in inaccurate findings regarding the ethical decision-making process of the REC.

Fifth, a degree of overlap was observed across some aspects of the principles, posing challenges in categorising some ethical concerns from the minutes. Consequently, some concerns were found to pertain to multiple principles simultaneously. The concerns were assigned to the most appropriate category and included and counted once. This observation implies the possibility of coding errors within the dataset. To enhance the reliability and generalizability of future studies, the researcher should engage several coders, strive for consensus on coding determinations, and gather and analyse data from multiple RECs in Liberia.

6.4 Contribution of the Study

The Emanuel et al. (2008) framework is a comprehensive framework for ethical review in research. It has been applied to various contexts, including research in developed and developing countries, research with vulnerable populations, and research involving new technologies. The framework effectively identifies and addresses the ethical concerns associated with these types of research. However, the applicability or usefulness of the framework to the Liberian context has not been assessed.

Using the Emanuel et al. (2008) framework, this study assessed whether the framework applies

to the ethical concerns of selected REC in Liberia. Doing so has the potential to make the ethical review procedure transparent in Liberia, with a specific emphasis on protecting the rights and well-being of those participating in research. The study found that the framework is aligned with the ethical concerns of the selected REC in Liberia and covers the key ethical considerations in research. The framework can be used to ensure that research proposals are well-designed, that participants are selected fairly, that participants are provided with all the information they need to make an informed decision about whether or not to participate in the research, and that the potential benefits of the research outweigh the potential risks.

The study also identified some specific concerns related to the ethical review process in the selected REC in Liberia. The study provides recommendations for implementing tailored strategies to address these challenges. This information can potentially facilitate aligning the selected Liberian REC ethical review process with international norms.

6.5 Dissemination Strategy

The findings of this study will be actively shared with the target audience by tailoring the research findings through a dynamic flow of information (Davies, 2003). The approach emphasizes adapting the content, message, and communication medium to the specific audience or potential users. It involves paying attention to both the message's source and the intended audience to facilitate active discussion and engagement. Once the study is completed, the selected REC and relevant stakeholders will be informed, and a copy of the findings will be shared with them, if possible. Furthermore, an interactive and collaborative approach will disseminate the findings and recommendations (Davies, 2003).

Various methods will be employed to achieve this, including oral presentations summarizing the findings and key recommendations at regular meetings with the selected REC and through seminars and workshops for policymakers. The interactive sessions will involve REC members and key stakeholders actively working with the research to encourage self-examination and explore ways to adapt the Emanuel et al. (2008) framework to their local context. It is also anticipated that the results of this study will be published in a reputable scientific journal, providing a valuable reference for researchers and other interested parties.

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8.0 APPENDICES

8.1 Appendix 1: BREC Approval

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

24 January 2023

Mrs Sienneh Zezay Tamba (222125150)
School of Applied Human Sc
Pietermaritzburg

Dear Mrs Tamba,

Protocol reference number: BREC/00004860/2022
Project title: An Evaluation of the Ethical Concerns Raised by a Liberian Research Ethics Committee using the Principles and Benchmarks Proposed by Emanuel et al. (2008) Degree Purposes: Masters

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application.

The conditions have been met and the study is given full ethics approval and may begin as from 24 January 2023. Please ensure that any outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

This approval is valid for one year from 24 January 2023. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on RIG on the appropriate BREC form 2-3 months before the expiry date.

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

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2020) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

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

The sub-committee's decision will be noted by a full Committee at its next meeting taking place on 14 February 2023.

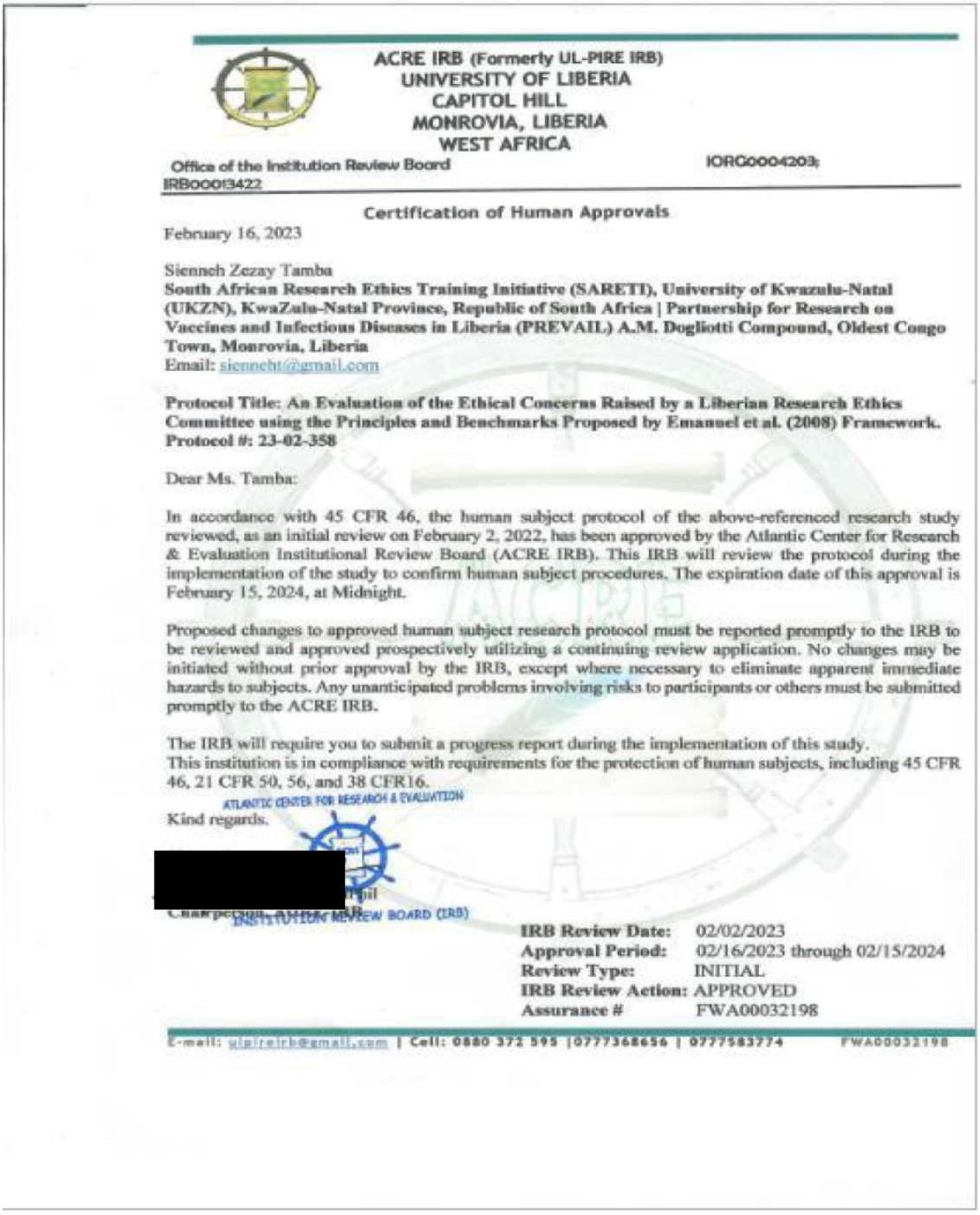
Yours sincerely,

[redacted]

Prof R Bhimma
Deputy Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
Chair: Professor D R Wassenaar
UKZN Research Ethics Office Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

8.2 Appendix 2: ACRE IRB Approval



ACRE IRB (Formerly UL-PIRE IRB)
UNIVERSITY OF LIBERIA
CAPITOL HILL
MONROVIA, LIBERIA
WEST AFRICA

Office of the Institution Review Board IORG0004203;
IRB00013422

Certification of Human Approvals

February 16, 2023

Siennch Zezay Tamba
South African Research Ethics Training Initiative (SARETI), University of Kwazulu-Natal (UKZN), KwaZulu-Natal Province, Republic of South Africa | Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL) A.M. Dogliotti Compound, Oldest Congo Town, Monrovia, Liberia
Email: siennecht@gmail.com

Protocol Title: An Evaluation of the Ethical Concerns Raised by a Liberian Research Ethics Committee using the Principles and Benchmarks Proposed by Emanuel et al. (2008) Framework.
Protocol #: 23-02-358

Dear Ms. Tamba:

In accordance with 45 CFR 46, the human subject protocol of the above-referenced research study reviewed, as an initial review on February 2, 2022, has been approved by the Atlantic Center for Research & Evaluation Institutional Review Board (ACRE IRB). This IRB will review the protocol during the implementation of the study to confirm human subject procedures. The expiration date of this approval is February 15, 2024, at Midnight.

Proposed changes to approved human subject research protocol must be reported promptly to the IRB to be reviewed and approved prospectively utilizing a continuing review application. No changes may be initiated without prior approval by the IRB, except where necessary to eliminate apparent immediate hazards to subjects. Any unanticipated problems involving risks to participants or others must be submitted promptly to the ACRE IRB.

The IRB will require you to submit a progress report during the implementation of this study.
This institution is in compliance with requirements for the protection of human subjects, including 45 CFR 46, 21 CFR 50, 56, and 38 CFR16.

ATLANTIC CENTER FOR RESEARCH & EVALUATION

Kind regards.

[redacted]

INSTITUTION REVIEW BOARD (IRB)

IRB Review Date: 02/02/2023
Approval Period: 02/16/2023 through 02/15/2024
Review Type: INITIAL
IRB Review Action: APPROVED
Assurance # FWA00032198

E-mail: ulpirerb@gmail.com | Cell: 0880 372 595 |0777368656 | 0777583774 FWA00032198

8.3 Appendix 3: Copy of the Selected REC Permission (withheld to maintain confidentiality)

8.4 Appendix 4: Data Collection Tool

Protocol Codename: _____

Date of Review: _____

Emanuel et al. Framework (modified)		No.	%
Principles	**Benchmarks**		
Collaborative Partnership	• Community involvement and synergic interaction?		
	• Research fairness (north-south partnership)		
	• Capacity building		
	• Respect for and adherence to local values and laws		
	• Fair sharing of benefits of research with participants		
Social Value	• Prioritize and address local health needs		
	• Results publication/dissemination and utilization to strengthen local systems (policy)		
	• Impact on the health system		
Scientific Validity	• Appropriate design and methods		
	• Methodological designs achieve outcomes		
	• Study feasibility		
	• Availability of qualified (academically and ethically) researchers?		
	• Prior knowledge		
Fair selection of study population	• Fair and equitable selection		
	• Vulnerability		
	• Suitable study population		
	• Protections for vulnerable populations		
Favourable risk-benefit ratio	• Risk identification and minimization		
	• Type and magnitude of benefits		
	• Risk-benefit ratio		
Independent review	• Ethics and regulatory compliance		
	• Transparent review		
	• Conflicts of interests		
	• Ethics shopping		
	• Reconciliation of multiple reviews		

Informed consent	• Recruitment and incentives applicability to the local context		
	• Respect for autonomy		
	• Appropriate disclosure documents and process		
	• Presentation and accuracy of information		
	• Consent/assent for those with limited agency		
	• Gatekeeper permission		
	• local languages, where necessary		
Respect for recruited participants and study communities	• Confidentiality and privacy		
	• Reporting obligations		
	• Refusal withdrawal with no penalty		
	• Periodic updates on studies		
	• Post-trial access to final products		
	• Ancillary care		
	• Treatment or insurance for trial-related injuries		
	• Resolving contentious findings		
Other issues not covered by the Emanuel at al. (2004) Framework			
Administrative issues			
Grammatical issues			
Procedural queries			

8.5 Appendix 5: ARCE Confidentiality Agreement

Confidentiality Agreement

This agreement is between:

[redacted]

and

[redacted]

for

[redacted]

Summary of job description/service provision:

I agree to:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Agreeing officer of the data providing institution:

Mosimma Kinge [redacted] / March 7, 2022

(Print Name) (Signature) (Date)

I agree to:

Ensure that all published data derived from the raw data will be systematically anonymised to prevent identification of the host institution, IRB members, specific protocols or investigators from being identified in public scientific presentation of the study findings.

Provide a report on this study to the data providing party.

Researcher(s):

[redacted] March 7, 2022

(Print Name) (Signature) (Date)

Research Supervisor:

[redacted]

(Print Name) (Signature) (Date)