STRUCTURAL AND FUNCTIONAL CHARACTERISTICS OF TWO INSTITUTIONAL RESEARCH ETHICS COMMITTEES IN ESWATINI

BY

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A THESIS SUBMITTED TO THE SCHOOL OF MEDICINE IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER'S DEGREE IN INTERNATIONAL HEALTH RESEARCH ETHICS

MOI UNIVERSITY

2021

DECLARATION

Declaration by the candidate

I hereby declare that the work for this thesis is my original work and has not been presented for a degree in any other University. No part of this thesis may be produced without the permission of the author or university.

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DEDICATION

This work is dedicated to the following: my beloved parents Mr M.M. Dlamini and my ever loving and caring mother Mrs Siphelile Nothando Dlamini for being an inspiration, to my supportive, encouraging and loving husband Nsimbi Sibusiso Shongwe and children (Sinakekelwe Tandzile Shongwe, my angel and Mncobi Mnakekeli Shongwe, my shining armour).

ABSTRACT

Background

Institutional Research Ethics Committees (lRECs) are in their infancy in Eswatini (formerly Swaziland). Currently, there are delays in submission of ethics review minutes for approval of institutional research protocols from local IRECs to the Eswatini Health and Human Research Review Board (EHHRRB) formerly the National Health Research Review Board (NHRRB). This puts into question the resource and functional capacity of these IRECs in performing their oversight role of protecting human participants in biomedical research within their institutions. Understanding how these IRECs function is critical in improving the ethical and scientific quality of biomedical research in the country.

Objectives

This study sought to describe the resource needs and operational challenges of the University of Eswatini-Faculty of Health Sciences Research Ethics Committee (UNESWA-FHSREC) and the Southern Africa Nazarene University-Faculty of Health Sciences Research Ethics Committee (SANU-FHSREC) in Eswatini.

Methods

A cross-sectional, descriptive survey was conducted in October-December 2017 with the only two university IRECs in Eswatini at the time. A purposive sampling strategy was employed and data were collected among all the committee members of the two institutions (N=15 from UNESWA-FHSREC and N=5 from SANU-SHSREC) using the Research Ethics Committee (REC) Quality Assurance Self-Assessment Tool. Descriptive statistics were used to describe the characteristics of each IREC in each of the following domains of the tool: organizational aspects (54 possible points), membership and education training (30 possible points), communication of decisions (5 possible points), review of specific items in protocols (43 possible points) and committee resources (16 possible points), among other domains.

Results

Both IRECs did not attain the maximum achievable points of 200 in the assessment. The UNESWA-FHSREC's overall score was 104 (52%) and 86 (43%), for the SANU-FHSREC. For the profile and distribution of the IRECs, the results showed that a majority of the IREC members were males (n = 13, 65%) with master's degrees (75% n = 15). In terms of the structural aspects, both IRECs had a number of gaps; they scored less than 50% in almost all the domains. The functional characteristics have a possible overall score of 100, UNESWA-FHSREC scored 72 (72%) whilst the SANU-FHSREC scored 48 (48%); generally, both IRECs did better in this part of the assessment.

Conclusion

Notwithstanding that the two institutions had IRECs in place, the study showed a number of gaps in their profile & distribution, structural and functional characteristics. The study showed that both IRECs have limited resource and functional capacity which may compromise their ability to perform their oversight role in protecting human participants in biomedical research within their institutions.

Recommendation

There is need for capacity building, resource mobilization and enactment of policies within the two IRECs in order to strengthen their structural and functional characteristics. The findings call for the Government of Eswatini, the University authorities and the national board to assist the IRECs with resource mobilization, protocol review mentorship to improve their capacity.

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ABBREVIATIONS AND ACRONYMS

CIOMS	Council for international organizations of Medical Sciences
COI	Conflict of Interest
DHHS	Department of Health and Human Services
FDA	Food and Drug Administration
FWA	Federal Wide Approval
FHS	Faculty of Health Sciences
GCP	Good Clinical Practice
ICMR	Indian Council of Medical Research
IND	Investigational New Drug
IREC	Institutional Research Ethics Committee
IQR	Interquartile Range
IRB-RAT	Institutional Review Board Researchers' Assessment
LMIC	Lower and Middle-Income countries
MERETI	Middle East Research Training Initiative
MOH	Ministry of Health
MTRH/MOI IREC	MOI Teaching and Referral Hospital/MOI University Institutional Research Ethics Committee
NBAC	National Bioethics Advisory Committee
NIH	National Institute of Health

NHS	National Health Service
NHSSP	National Health Strategic Plan
NHRRB	National Health Research Review Board
OHRP	Office for Human Research Protections
P.S.	Principal Secretary
REC	Research Ethics Committee
SANU	Southern African Nazarene University
SEC	Scientific Ethics Committee
SIDCER	Strategic Initiative for Developing Capacity in Ethical review
SSA	Sub Saharan Africa
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNISWA	University of Swaziland
U.S. A	Unites States of America
TDR	Training in Tropical Research

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to the following;

To God the Almighty for His unconditional love and grace to see me through this project for two years. To my supervisors; Professor Ann Mwangi and Professor David Ayuku for providing technical support, guidance and encouragement during the writing of this thesis. Thank you for letting me follow my dream, I will forever be indebted to you. May the almighty God continue to Guide and bless you as Always.

To my loving, caring and supportive husband, Nsimbi Sibusiso Shongwe for holding the fort at home and taking care of our children Sinakekelwe Tandzile Shongwe and Mncobi Mnakekeli Shongwe while I was away.

The Department of Behavioural Sciences team; Dr. J. Baliddawa, Dr. I.J Chesire, Mr. Alfred Kirui, Ms. Joyce Mitei and Ms. Dorice Kinyanjui thank –you so much for being there for me and your friendship during my course of study and my entire stay in Kenya.

To the two Universities; University of Swaziland-Faculty of Health Sciences and Southern African Nazarene University –Faculty of Health Sciences for allowing that their facilities be part of the study. Special thanks to the Institutional Research Ethics Committee Members in both Universities for being part of the study participants. Without your input, this study would not have been a success.

To Mduduzi C. Shongwe for being my source of inspiration, encouragement during trying times and for his technical guidance, review and proof-reading this work. In addition, to the entire Shongwe and Dlamini families, thank you for your continued support and patience.

Lastly, my most and sincerest appreciation goes to my principals; Ms Rejoice Nkambule, Deputy Director Public Health and Dr. Simon Zwane, Principal Secretary for their unwavering support and encouragement.

CHAPTER ONE

1.1 Introduction

The last few decades have seen an increase in the volume of research carried out in developing countries, including Sub-Saharan Africa (SSA) (Sleem, El-Kamary, Silverman, et al., 2010). According to the World Bank and Elsevier, research output doubled in SSA between 2003 and 2012, increasing its global research share from 0.44% to 0.72% (World Bank, 2014). The volume of research in Low and Middle Income Countries (LMIC) has similarly increased significantly during the last two decades (Abbott & Grady, 2011).

In Eswatini, research involving human subjects has increased exponentially in the last decade in response to health, development and economic challenges. In relation to health research, outputs have been (and still are) used to help the country develop evidence informed policies in public health and clinical programmes. The increase in health research has necessitated putting structures in place including Institutional Research Ethics Committees (IRECs) as well as developing policy guidelines at national and institutional level to guide their functioning ("Guideline for researchers – Ministry of Health, Swaziland," n.d.).

A Research Ethics Committee is a formally constituted group of suitably qualified persons who have a mandated authority (institutional or national) to review (primarily from an ethics perspective) and approve research involving human participants (Marian Kruger, Paul Ndebele, and Lyn Horn, 2014). An IREC is further described as a group of individuals appointed to protect the interests of research participants and address moral issues pertaining to health research (Kass et al., 2007). The IREC is an administrative body established to protect the rights and welfare of human research

subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. Researchers planning to conduct studies among or with human participants are expected to submit their research protocols to the IREC for vetting, and an independent and competent ethical review (Kass et al., 2007).

To carry out their mandate, IRECs rely on tools such as a research policy, research guidelines, operational standards or procedures, as well as a knowledgeable and competent membership. These key structural characteristics are crucial for the functioning of IRECs. This study sought to assess and describe the structural and functional characteristics of institutional research ethics committees in Swaziland with a view of identifying the necessary guidance and participants ("SIDCER Network and IRB Recognition Programme," n.d.), strengthening required by the Ministry of Health and the relevant Universities.

According to WHO Standards and Operational Guidance for Ethics Review of Health-related Research with humans; structural and functional characteristics of an ethics committee involve its organization, operations, physical structures, purpose and efficiency. The WHO guidelines further highlight that functional and structural characteristics include the constitution of IRECs, membership structure, establishment of offices, quorum requirements, record keeping and archiving, consultation with external experts, training of members, meeting requirements, and elements of review. Functional and structural characteristics of IRECs are further described as composition of the ethics committee, physical offices, human and equipment resources and training (Conformity & Committees, 2017). Roles and responsibilities of an IREC include providing leadership in research and development through setting

out research policy, providing research guidelines, developing and maintaining an institutional research data base, providing training on research proposal writing and critical appraisal of scientific literature and monitoring of implementation of approved protocols (Bergel, 2015). The committee further, provides independent evaluations of proposed research to determine if they are ethically acceptable, checking clinical investigators' potential biases, and evaluating compliance with regulations and laws designed to protect human subjects (Sleem, El-Kamary, & Silverman, 2010).

1.2. Study Background

A review of research history gives a clear account of reasons why it has been necessary to establish a culture of ethical practice in research. The history of research is without any doubt littered with abuse of research participants. It is evident that prior to requirement of ethical practice in research, many research participants lost their lives or suffered medical and psychosocial complications as a result of participating in research without knowing or without being given a choice on whether to or not participate (Kim & Scialli, 2011). The evolution of research ethics has a long history which extends from development of the Nuremberg Code in the 1940s to enactment of the National Research Act of 1974 and birth of the Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States of America.

While much effort has been made to put in place research ethics guidelines, the most prominent is the Nuremberg Code which was issued by the Nuremberg Military Tribunal in 1947. The code introduced the concept of informed consent as first principle and the right of participants of research to withdraw from studies as the

ninth principle (Shuster, 1997). The code focuses on human rights (Shuster, 1997) and forms a cornerstone of research that involves human participants. The Nuremberg code is not legally binding but has been instrumental in informing development of human rights laws (Greek, Pippus, & Hansen, 2012). It is a guideline that was put in place before there were any international research standards. There is no doubt that prior to their existence, the absence of such standards subjected human research participants to harm.

A well-documented case of bad ethical practices in research is the case of German military physicians who conducted medical experiments in concentration camps on prisoners without seeking their consent. These experiments resulted in deaths, physical disfigurements and possibly psychological harms. A criminal case against the German physicians initiated in December 1946 in the famous Nuremberg trial found 23 individuals guilty and were given sentences ranging between death, life sentence and lesser prison terms (Shuster, 1997).

In another scenario, pregnant women in Europe were subjected to thalidomide, a sedative, which resulted in foetal deformities. Many of these women involved were not aware they were taking the drug on trial because they had not been asked to give consent. Events around thalidomide promoted a need to ensure effectiveness and safety of drugs before release for use. This led to passage of legislations which require drug manufactures to get approval from drug regulators such as the Food and Drug Administration (FDA), in United State of America, before they can market their products (Kim & Scialli, 2011).

Arising from the principles of the Nuremberg code, the Helsinki declaration was borne with its main focus being on responsibilities of the researcher. Just like the

Nuremberg code, the Helsinki declaration is not legally binding but has informed legislation and regulations in many jurisdictions in western countries (Coleman et al., 2008). The declaration mostly addresses clinical research and is founded on the principle that a physicians shall act in the patient's best interest when providing medical care (Adopted, Assembly, & Helsinki, 1964). The Declaration has been revised nine times with the latest being 2013 during the 64th General Assembly of the World Medical Association held in Fortaleza, Brazil. It establishes the concept of Good Clinical Practice (GCP) which dictates that research with humans should be based on the results from laboratory and animal experimentation and that research protocols should be reviewed by an independent committee prior to initiation of research. It also states the necessity of informed consent by research participants and research should be conducted by medically and or scientifically qualified individuals.

Researchers in a syphilis study on African Americans, known as the Tuskegee syphilis study, stopped in 1973 after forty years of follow up, wanted to study the natural history of syphilis. As a result, participants in the study were subjected to medical examination but were never informed about the diagnosis or given treatment even though treatment (penicillin) had been available for decades from the 1950's. Some of the participants died directly from the untreated syphilis lesions (Brandt, 1978).The government of the United States enacted the National Research Act in 1974 in response to the fallout from the Tuskegee Syphilis Study. The National Research Act gave rise to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research and guidelines for the ethics of human research subjects in the United States.

The national Commission for the Protection of Human Subjects of Biomedical and Behavioural Research subsequently produced the Belmont Report which summarised research ethics into three principles namely: Respect for persons, Beneficence and Justice (Mandal, Acharya, & Parija, 2011). The need for regulation of research involving human participants thus became imperative.

Globally, IRECs are an attempt by governments to streamline a variety of processes to ensure the protection of human subjects involved in research (Hyder et al., 2013). One of their key responsibilities is to ensure that risks to study participants are minimized and that they are reasonable in relation to anticipated benefits and to the importance of the knowledge to be generated (U.S. department of Health & Human Services, 2009). In the US, formation of IRECs was an idea of James Shannon, Director of NIH, after recognizing that impartial review might mitigate conflicting differences in the ethical responsibilities of physician-investigators to research subjects from those of physicians to their patients in `an effort to protect the rights and welfare of research subjects. This was further approved by the US Public Health Service policy in 1966, where it recommended that ethical review should be expanded to all Departments of Health Education and Welfare (DHHS predecessor). It was not well enforced until 1971 when the regulations for the protection of human subjects for DHHS, were published in 1974 (45CFR.46), that included a requirement for group ethics review and the term "institutional review board (IRB)" was introduced. The World Medical Association also introduced a review by an independent committee for over-sight of science and ethics into the 1975 revision of the Declaration of Helsinki (Coleman *et al*., 2008). Most IRECs were formed in response to global pressure for the protection of human subjects during research. For example, at the 2004 Ministerial Summit on Health Research in Mexico City, health officials from 58 countries called for national

governments to adopt regulations providing for the "ethical oversight" of health research.

The past few decades have witnessed significant growth in health research in Africa in response to the serious health challenges in the continent. Developed countries have funded a significant proportion of these researches. This has increased the volume of research in Africa, but has not necessarily been accompanied by improvements in health research oversight systems, including ethical review committees' performance. This leaves the continent vulnerable to potential exploitative research funded by resource-rich countries (Kruger, Ndebele, & Horn, 2014). In response to the growth in research in Africa that were being conducted through various initiatives, efforts to build capacity for stronger systems for human research protection also improved (Abbot & Grady, 2011, Ndebele et al., 2014; Networking for Ethics on Biomedical Research in Africa, 2006).

Africa has also not been spared from being victim of research conducted without approval of a research ethics committee. For example, in Nigeria, in 2001, 30 families sued the Pfizer pharmaceutical company over trials of trovafloxacin (Trovan), an antibiotic that was intended to treat meningitis. The new drug was tested on nearly 200 children during a meningitis outbreak. The trial compared Trovan with the recommended drug Ceftriaxone. Unfortunately, children in the control arm allegedly received Ceftriaxone at an inadequate dose. Eleven children died, while some survivors suffered permanent brain damage and paralysis. During investigations, it was found that the clinical trial had not been approved by a local research ethics committee, and that the families concerned were not adequately informed that their

children were research participants in a study employing the use of Trovan (Okonta, 2014).

Another example of research conducted without either research ethics approval or individual informed consent is the study conducted by Dr. Bezwoda, testing the efficacy of breast cancer chemotherapy in South African women (Rodenhuis, Huitema, van Dam, de Vries, & Beijnen, 2000). The above-mentioned examples made governments of the African countries to put their ethics committees in place.

In sub-Saharan Africa, several countries have put in place RECs, with South Africa being the first one. South Africa established her first ethics committee through the University of Witwatersrand in 1966 (Department of Health South Africa, 2004). The South African Department of Health requires that all health research undertaken in the country be reviewed and approved by a research ethics committee registered with the National Health Research Ethics Council of South Africa. Zimbabwe followed and enacted an REC in 1974 (Mariana Kruger, Paul Ndebele, 2014)

Eswatini, on the other hand, had no research ethics committee until 2006, when her first REC was established by the Ministry of Health with assistance from the World Health Organisation ("Guideline for researchers – Ministry of Health, Swaziland," 2014). Before the existence of the then Swaziland Research Ethics Committee, research protocols were submitted with a letter requesting to conduct research in Swaziland to the Ministry of Health, Principal Secretary 's (P.S.) office who would then instruct a few officials from the Ministry to convene as a special committee to review the protocols. After the review, the special committee would report back to the Principal Secretary's office which in turn responded to the researcher. Like many low

and middle-income countries in the SSA, Eswatini has just initiated the idea of developing local RECs at institutional level.

In 2006, the then Scientific and Ethics Committee (SEC) was established to review and approve all health research studies conducted in the country. The National Health Sector Strategic Plan (NHSSP) identified research as a key component for strengthening policy, planning, monitoring and evaluation of systems in the health sector. The re-establishment of the Health Research Unit in 2009 was in line with the aspiration of the NHSSP to develop research capacity in the country. To safeguard the dignity, rights, safety and wellbeing of research participants, several tools were put in place including the National Health Research Policy, Health Research Guidelines and National Health Research Agenda.

The National Health Research Policy 2014-2023 dictates the establishment of the semi-autonomous Eswatini Health and Human Research Review Board (EHHRRB) as the final authority for approval of health research conducted in the country. The EHHRRB replaces the then MOH's Scientific and Ethics Committee and NHRRB. The EHHRRB is appointed by the Minister of Health based on merit and after expression of interest. Its membership consists of 9 members comprising the chairperson, vice chairperson, secretary, and additional six members, who should include a statistician, an epidemiologist, a research specialist, legal/human rights specialist, public health specialists, and a physician ("Guideline for researchers – Ministry of Health, Swaziland," 2014).

The Eswatini Health and Human Research Review Board meets quarterly to discuss operational issues and protocols sent online monthly for review. Its other functions are to receive, review and adjudicate on research protocols submitted, provide advice

on scientific and ethical issues to the research community; monitor the implementation of approved protocols including spot checks; management of databases and transfer of specimens and research materials; take action on research that has breached approved protocol or because of adverse events, study close-out reports for studies; encourage proper management and dissemination of research findings; oversee the two institutional research ethics committee's and take decision on protocols that have exceeded their duration as well as renewal of Federal Wide Approval (FWA) .

In response to the increase in the number of research protocol submission, the NHRRB has assisted in the establishment of two IRECs in 2013 and 2014, respectively. These two IRECs were established under two Universities in Eswatini; University of Eswatini, Faculty of Health of Health Sciences (UNISWA, FHS) and Swaziland Southern African Nazarene University (SANU). The UNESWA, FHS IREC was established in 2014. At the time of data collection, The University of Eswatini, Faculty of Health of Health Sciences has a capacity of slightly over 500 students each year who pursue Degrees courses and may require submitting their proposals to UNESWA, FHS IREC for ethical clearance. On the other hand, the Southern African Nazarene University IREC was established in 2015 and has a capacity of serving over 800 students.

Both institutional research ethics committees have training hospitals which serve as the practicum and research areas for their students. The cadres trained in these institutions include nurses, laboratory technicians, pharmacy technicians and environmental health officers. The two IRECs review study protocols mostly from the students, mainly dominated by the nursing cadre, pursuing studies at Degree

levels. However, staff proposals are reviewed by NHRRB which also issues clearance letters for students' studies after being cleared by their institutional research ethics committee.

Noteworthy though is that, there has been insufficient attention to assessing whether these committees are actually improving the protection of human research participants. Without a system for evaluating research ethics committee's actual impact, the rationale for having them is weak, and opportunities to remedy their correctable problems are likely to be missed.

In many African countries, Eswatini included, governments have enacted, and some are in the process of enacting, legislation requiring research ethics committees review of research involving human participants ("Guideline for researchers – Ministry of Health, Swaziland," 2014). Even without a governmental mandate, many research institutions in resource-poor countries have created RECs on their own initiative, sometimes in collaboration with other countries or with non-governmental organizations (Coleman and Bouësseau, 2008). This arose because most research is carried out in collaboration with international partners and in a few cases because of the recognized need for ethics reviews (Kass *et al*., 2007).

Research sponsors believe that research ethics committees review is time consuming, leading to delays that can significantly increase the costs of research. For instance, in a structured search in PubMed 43 empirical studies evaluating U.S. research ethics committees were found, with studies included if they reported an empirical investigation of the structure, process, outcomes, effectiveness, or variation of U.S. research ethics committees. Each study was reviewed to extract information about study objectives, sample and methods, study results, and conclusions. The findings

showed that for review of a wide range of types of research, U.S. research ethics committees differ in their application of the Federal regulations, in the time they take to review studies, and in the decisions made. The findings also revealed an existing variation in multicenter review, inconsistent or ambiguous interpretation of the Federal regulations, and inefficiencies in review (Abbott & Grady, 2011).

Such audits therefore require appropriate tools to get meaningful results. One such tool is the Middle East Research Training Initiative (MERETI) self-assessment tool. This tool was initially developed by the 2009 MERETI Summer trainees and was then reviewed by researchers and REC members from the Middle East (Sleem *et. al*., 2010). The developers used elements that would measure the effectiveness of REC performance, in its mission to protect the rights and welfare of research participants.

1.3. Problem Statement

Research Ethics Committees are formed with the intention to protect rights, the dignity and welfare of research participants. Achievement of this intention is dependent on the extent of an IRECs development and effectiveness. While the majority of African countries and academic institutions have put in place research ethics committees, most of these committees are generally underdeveloped (Kruger M *et al.,* 2014) and the quality of their performance is also generally not known (Sleem H *et al.,* 2010). Data on the development status and effectiveness of research ethics committees is not readily available particularly given that their evaluation remains a challenge and institutional specific assessment tools are still being developed in many developing countries, Eswatini not excluded.

Since the establishment of the NHRRB in 2006, and the two institutional review committees in 2013 and 2015 respectively, there has been no assessment of their

structural compliance with international dictates of research standards on human subjects.

1.4. Study Justification

Since the establishment of the two IRECs in Eswatini, they have faced several challenges ("Guideline for researchers – Ministry of Health, Swaziland," (2014). It is however believed that since their formation these IRECs have evolved, it was therefore considered as proper to assess them utilizing specific and practical benchmarks to inform how they adhere to enumerated ethical principles in the performance of their duties is necessary (Emanuel, Wendler, & Grady, 2000.)

The Government of Eswatini, is currently in the process of formalizing IRECs in tertiary education institutions throughout the country as part of an effort to decentralize research ethics review. This assessment will further function as a baseline, to assist the Ministry of Health and the two Universities' authorities to ensure that the two IRECs comply with ethical and international standards. Lastly, as Sleem et al (2014) emphasized, such assessments assist to identify where the institutional research ethics committees are performing well and areas which need intervention. Lessons learnt from the two committees will inform the establishment of other university IRECs.

1.5. Significance

Protection of research participants, as intended by international research guidelines, is not likely to be achieved by inadequately developed Research Ethics Committees. The assessment by this study will assist in generating data on the functional and structural characteristics of the two pioneer IRECs for purposes of devising improvement strategies. The generated data will be used to characterise the two IRECs in Eswatini

1.6. General Objective

This study set out to assess the structural and functional characteristics of the Institutional Research Ethics Committee of the University of Eswatini, Faculty of Health Sciences and the Southern African Nazarene University Faculty of Health Sciences.

1.7 Specific Objectives

1. To describe the profile and distribution: gender, qualifications, training, affiliation to the institution and composition; for two IRECS in Eswatini
2. To assess the structural factors: organizational aspects, membership & education training and committee resources; for the two IRECS in Eswatini
3. To assess the functional factors: submission arrangements & materials, committee minutes, review procedures, review of specific items in protocol, communicating committee decisions, and continue review of approved studies; for the two IRECS in Eswatini

1.8 Research Questions

1. What is the profile and distribution of two IRECS in Eswatini?
2. What are the structural factors of two IRECS in Eswatini?
3. What are the functional factors of two IRECS in Eswatini?

CHAPTER TWO

2.0. Literature Review

In this section, the study seeks to discuss the evolution of research ethics and Research Ethics Committees, structures and functions of research ethics committees and how assessment of such committees is carried out. The practice of subjecting research study protocols for ethics review has become a norm in many countries around the world. Review of experiments has a long history that seems to have started with interest of managing experiments on radiation. It was around 1971 in the United States of America that establishment of institutional peer review mechanism was made a condition for sufficient protection of research participants. In other countries such as Sweden the requirement for research ethics committee happened earlier in the 60$^{s.}$ The requirement for independent research ethics committees was made a condition by the 29th World Medical Association General Assembly which took place in Tokyo, Japan in 1975 on paragraph 23 (Adopted et al., 1964).

The paragraph on research ethics committees among other issues stated that a research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. The paragraph further ascribed other responsibilities to research ethics committees. A case study by Kass *et.al* of twelve African countries reveal that the research ethics in the Medical Research Council of South Africa was the oldest having been formed in 1962 (Kass *et al*., 2007). This was followed by one in Zimbabwe whose operations were intermittent until in recent times. According to the above noted case study, research ethics committees in other African countries are generally young having been formed around 2002. The Research Ethics Committee in Swaziland was established in 2006 ("Guideline for researchers – Ministry of Health, Swaziland," (2014).)

Research ethics have a longer history in developed rather than in developing countries. As a result, literature on the organization of research ethics committees in developing countries is relatively scanty. Organization of research ethics committees varies from country to country. However, research committees are generally organized at national, regional and local levels. According to the World Health Organization in its public publication on research ethics committees; basic concepts for capacity building indicates that local or institutional research ethics committee have an advantage over regional and national committees in that they are more likely to appreciate the context within which the study will take place. The publication also notes that local or institutional research ethics committee are better placed to monitor implementation of approved studies because of proximity. It observes that independence of local research ethics is likely to be compromised relative to national and regional committees (Kirigia, Wambebe, & Baba-Moussa, 2005).

The size and composition of research ethics committees also vary. There is no prescribed size of research ethics committees. A case study on research ethics committees in Africa found the size of committees to range between 9 and 31 members (Kruger et al., 2014). It would appear that committee size would be a function of the work load the respective research ethics committee manages. Composition of committee membership is also not prescribed. Enfield and Truwit, 2008, state that members can range from 5 and above and must be of different specialities; scientist, non-scientist, community representative, legal practitioner and expert in the field that will be reviewed. They further mention that these members should comprise of both sexes. The recommendation is that membership should be multidisciplinary and should be appointed in their own right as equal individuals of sound judgement, relevant experience and adequate training in research ethics

(Enfield & Truwit, 2008). While the minimum number of members is set at five, most IRECs will consist of slightly more to accommodate additional expertise and to assure that a quorum can be convened to conduct the meeting.

IRECs being a critical element in the protection of patients' and subjects 'rights with regard to their participation in research has the authority to approve, reject or stop studies or require modifications to research protocols. They may also perform other functions, such as setting policies or offering opinions on ongoing ethical issues in research (Enfield & Truwit, 2008). The ethics committees are allowed to co-opt people outside of the committee with expertise in that field, when necessary, though such members are not allowed to vote in that committee's decisions (Enfield & Truwit, 2008)

Although there is no rule that males and females be evenly distributed on institutional research committees, the female voice as a minority may be particularly problematic when reviewing protocols focused on women's issues (Yaghoobi, 2011). Indeed, both the US Department of Health and Human Services, via the Federal Wide Assurance for the Protection of Human Subjects, and the Indian Council of Medical Research uphold the importance of gender equity on ethics committees.

Thus members in a particular committee should be diverse; in backgrounds, cultural beliefs that includes consideration of racial and cultural heritage and should be sensitive to issues that include community attitudes and involvement (Enfield & Truwit, 2008). Having said this, a distinction needs to be made between lay and community representation: Lay representation often refers to individuals with no scientific or medical background and hence, could include lawyers, ethicists, priests, or theologians who have higher levels of education than individuals from the

communities being researched and hence, might not be able to assess the research from the perspective of those who actually participate in the research. Community representatives, on the other hand, would refer to non-professional, non-scientific members who belong to the community that is being researched and would more likely reflect the culture and values of the involved community (Moodley & Myer, 2007). This issue of adequate community representation, however, can often be clouded by ambiguity regarding how to define the actual community, as well as who can serve as the legitimate representatives of the communities.

Abbott and Grady further affirm that besides reviewing protocols, the RECs must provide certain administrative assurances through internal audits and record-keeping. Audits ensure that the institution's policies and procedures are upheld and allow early identification and correction of problems (Abbott & Grady, 2011). Maintenance of documentation is also crucial, including IRECs procedures, membership, all research proposals reviewed, minutes of institutional research ethics committee meetings, records of continuing review activities, all correspondence between the committees and investigators. In addition, committees must be able to assess the scientific validity of the study design to ensure that it is capable of producing reliable information (Chenneville et al., 2014b).

The World Health Organization publication on Operational guidelines for ethics committees that review biomedical research (2000) states: Countries, institutions, and communities should strive to develop ethics committees and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of

ethics committees at the national, institutional, and local levels that are independent, multi-disciplinary, multi-sectorial, and pluralistic in nature.

An institutional review board should always operate with some documents in place that will be guiding their operations. A number of key international documents also affirm the above statement, the Nuremburg Code, the Declaration of Helsinki and the International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences. They further state that concerns remain as to whether research proposals are adequately subjected to proper ethical review by independent committees, with appropriate structures and policies in place to ensure that the safety and human rights of research participants are protected. To affirm this statement in 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights to promote attention to research ethics in the national legislation, regulations and policies of its Member States and further affirmed that appropriate structures and policies are in place to ensure safety and protection of human rights of research participants.

A number of key international documents set out conditions for the ethical conduct of research involving human subjects and emphasise the concept of securing voluntary consent of human subjects to participating in research. In 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights to promote attention to research ethics in the national legislation, regulations and policies of its Member States. Institutional research review boards are the main mechanism of review of research proposals and

are critical to ethics governance but it is ineffective to have research ethics committees without national and regional policies (Chima, 2006)

Chris Zieliski, *et al (2014)* further agrees that a lack of standard operating procedures for research ethics committees, including mechanisms to deal with potential conflicts of interest and limited or non-existent oversight mechanisms such as accreditation of research ethics committees and monitoring of research following ethics approval could undermine the independence and objectivity of ethics review committees. Chris Zielinski, *et al, 2014* further agrees that a lack of standard operating procedures for research ethics committees, including mechanisms to deal with potential conflicts of interest and Limited or non-existent oversight mechanisms such as accreditation of research ethics committee and monitoring of research following ethics this could undermine the independence and objectivity of ethics review committees. It has been also noticed that shortage of institutional research ethics committee's assessment may put research participants at risk if those ethics committees are not capacitated enough in the protection of human subjects due to lack of information where they are lacking and where they need to be further capacitated. This can only be attainable by the assessment of these ethics committees (Silverman, Edwards, Shamoo, & Matar, 2013)

Furthermore, several scholars and advisory bodies have made recommendations to address challenges faced by institutional research ethics committees but it has proved to be a challenge since there has been scarce data of assessments, strengths and challenges done in developing countries (Kass *et al.*, 2007). Some African countries have been studied to determine the structures and function of research ethics committees and Swaziland was not included. Botswana on the other hand has further been involved in assessment of its institutional research ethics committees which still

needed to improve more work in the areas of systems of finance, target groups, and environment (Hyder *et al*., 2013). According to Silverman *et al* (2015) the self-assessment tools can also serve as quality improvement measures to help institutional research ethics committees enrich their operations.

Self-assessment of IREC's is an important aspect of determining their functionality and how it can be improved. There are several tools that are used to assess IRECs; the Octagon model originally used by the Swedish International Development Cooperation Agency comprises of eight domains in research ethics: basic values and identity; structure and organization; ability to carry out activities; relevance of activities to stated goals; capacity of staff and management; administrative, financing and accounting systems; its relations with target groups; and the national context. It is a rapid assessment instrument for the strengths and weaknesses of non-governmental organizations. The octagon offers a simple yet deliberative, and iterative tool for institutional assessment over time.

Another tool is the Office for Human Research Protections self-assessment tool which is on the Office for Human Research Protections website (Office for Human Research Protections, 2005). However, this tool is mainly based on the U.S. regulations for human subject's protection and, hence, might not be applicable to IRECs in developing countries. Another self-assessment tool is the one that was established and published by WHO/TDR which consists of two guidelines, "Operational Guidelines for Ethics Committees That Review Biomedical Research" and "Surveying and Evaluating Ethical Review Practices" (WHO/TDR, 2000, 2002). However, the operational guidelines for ethics are too detailed in some subject areas (like., "communicating a decision" and "follow-up") and it leaves out important items

relevant to REC functioning (such as resources and elements of informed consent and continuing review) whilst the review of medical research serves as an aid for conducting a process for surveying RECs, including the types of documents to be reviewed.

To add on the list is the Strategic initiative for Developing in Ethical Review (SIDCER) which is too long and includes many elements that might not be relevant to human subject's protection. Indeed, several commentators have voiced concerns that the oversight of IRECs has been characterized by increasing requirements for meticulous documentation of compliance with regulations that are unrelated to harm of research participants (Fost & Levine, 2007).

Another tool is the Institutional Review Board Researcher's Assessment (IRB-RAT which is a self-report measure of IRB quality (Keith-Spiegel, Koocher, & Tabachnick, 2006) that consists of 45 statements ("items") that describe a variety of IRB activities and functions. The IRB-RAT functions as a self-report measure of IRB performance that is internally normalised to each respondent's standard of ideal quality for each activity or function.

Finally, is the Middle East Research Ethics Training Initiative (MERETI) tool that will be used in conducting this study. This tool was developed by bioethics experts in the Middle East under the auspices of the Middle East Research Training Initiative (MERETI). It is divided into the following categories; organizational aspects, membership and educational training, submission arrangements and materials, minutes, review procedures, communicating a decision, continuing review, and IREC resources.

This tool was chosen among the others because its aim is to achieve a more self-assessment that would reflect pragmatic aspects of human subject's protection, be based on international standards, be straight forward in its completion, and be relevant to the administrative process that exist in many ethics' committees during their early stage of development (Sleem et al., 2010). It further does not include too many detailed elements that would make its use to be overly burdensome to complete. The tool has been used before to study IRECs in the LMICs; in Egypt it was used in Identifying structures, processes, resources and needs of Research Ethics committees where Hany Sleem and colleagues concluded that IRECs should strive for a more diverse membership, and should receive more financial resources and administrative support personnel. It was further concluded that lack of ongoing training of IREC members presents challenges for their functioning. The MERETI tool has further been utilized to assess the effective function of an IREC in Kenya. It concluded that the tool was consistent irrespective of whether it was completed by the Chair or by the whole IREC, and is therefore a useful checklist for IRECs interested in improving their operations (Jaoko, Bukusi, & Davis, 2016).

CHAPTER THREE

RESEARCH METHODOLOGY

3.1. Study Design

This was cross-sectional descriptive study based on a Self-Assessment Tool for IRECs in developing countries.

3.2. Study Site

This study was conducted in the Kingdom of Eswatini in two universities at their Faculties of Health Sciences. The two universities are the University of Eswatini, Faculty of Health Sciences which is located in Mbabane the Capital City of the Kingdom with 543 students, 44 lecturers and 3 technologists. At the time of data collection, the Faculty offered the following programs: Post-Diploma Certificate programs in midwifery science, community mental health nursing. The Faculty further offers bachelor's degrees in nursing science and environmental health science. In the last academic year (2017-2018) the faculty had their first batch of Master of Nursing Practitioner and since August 2018, a Masters in Midwifery.

The second university being the Southern African Nazarene University, Faculty of Health Sciences which is located in Manzini, the second largest city of the Kingdom which had 300 students and 18 lecturers. The faculty offers the following programs: Diploma in pharmacy, Bachelors of: Science in nursing and midwifery, Medical Laboratory, and Nurse Anaesthesia.

These institutions were purposively selected because at the time of data collection, they are the only two universities which had institutional research ethics committees and which were both established less than five (5) years ago.

3.3. Target Population

IREC Members of both the University of Eswatini and Southern African Nazarene University were the target population. At the time of data collection, there were 5 IREC members at SANU and 15 members at UNESWA,

3.4. Eligibility Criteria

3.4.1 Inclusion criteria

IREC member must have experience of serving more than two years in the committee

3.4.2 Exclusion criteria

All IREC members with less than two years' experience serving in the committee

3.5 Sampling Procedure

This study used Purposive sampling for the two IRECs and convenience sampling for the IRECs members. The IRECs members were sampled simple because they were a convenient source of the data required for the study. At the time this study was conducted, there were only two IRECs in the country. Therefore, all of them were included in the study which translate to 100% sampling of all the unit. There were

twenty (20) members of the IRECS interviewed, 15 from UNESWA-FHSREC and 5 from SANU-SHSREC.

Sample size determination

The desired sample size for this study was calculated using Raosoft online sample size calculator (http://www.raosoft.com/samplesize.html), assuming a margin of error of 5%, a./95% confidence interval, a population size of 20 (which was the total number of members of both IRECs at the time), and a 50% response rate (which gives the largest sample size), the minimum desired sample size was 20. This sample size, even though small, was not of concern in this study as the study is purely descriptive and such a small sample size is not uncommon in this discipline as a number of published studies in referred journals have utilized similar sample sizes or even smaller than those in this thesis e.g., Jaoko et al (2016) and Sleem et al (2010a)

3.6. Data Collection Instrument

The MERETI tool was administered and responses used to assess the status and functionality of both committees. Each element in the tool is assigned 1, 2, or 5 points, whereby maximum point's score of 5 is assigned to those elements that are believed to represent significant aspects of effective functioning for IRECs. The maximum achievable point total in the tool is 200 points. The main reason of choosing this tool was its standardization and relevance to the early stages of IREC development that exist in most of the institutions in the developing countries (Silverman *et al*., 2015). Other reasons were that it includes standards that are important in the achievement of the protection of research participants yet avoid including those standards that represent narrow interpretations of guidelines that are not relevant to studies being conducted in the institutions. The tool is not too detailed

so to make it a little bit overly burdensome to complete and lastly, commentators have voiced concerns that the oversight of IRECs has been characterized by increasing requirements for meticulous documentation of compliance with regulations that are unrelated to harms to research participants (Fost & Levine, 2007).

According to Sleem *et al*. (2010), the elements assessed by the tool include: policies dealing with conflict of interest and establishment of the IREC); structural elements such as membership composition); processes like submission of protocols, communicating a decision; performance measures like consideration of certain ethical criteria in the review of protocols as well as human, financial, and material resources.

The tool described by Sleem et al (2010) is divided into the following categories: (a)Organizational Aspects, (b) Membership and Educational Training, (c) Submission Arrangements and Materials, (d) Minutes, (e) Review Procedures, (f) Communicating a Decision, (g) Continuing Review, and (h) REC Resources. Each element in the tool is assigned 1, 2, or 5 points, whereby maximum points score of 5 is assigned to those elements that are believed represent significant aspects of effective functioning for RECs. The maximum achievable point total in the tool is 200 points.

3.7. Data Collection

Data collection commenced from mid-October until December, 2017. A formal request letter was sent to both Deans of the particular faculties seeking permission to conduct the study in their respective institutions. Once granted, a meeting was arranged for each institution whereby each IREC was met and the proposed study presented. All present members were allowed to seek clarification. Thereafter, each member was engaged in their respective offices where more explanation was given, a

consent form signed and members were left with questionnaires and were all collected from their respective Chairpersons.

3.8. Data Management

Anonymous, but coded, raw data were entered into Epi info version 7. Data were then exported to STATA 13.0 for data analysis. Variables were renamed for ease of handling and this was done with the help of the codebook. Data was cleaned to remove outliers and inconsistent values and since the sample size is small to ensure data completeness hence there was no missing data. The computer where the data were stored was password-protected and only accessible to the principal investigator and supervisors.

3.9. Data Analysis

Data analysis was done using STATA 13. Descriptive statistics were used to summarise the data. Tables and frequencies (percentages) were presented to further show the distribution of the data. For continuous variables medians and interquartile range as measures of central tendency and spread, were used. The Means and standard deviations were computed for each domain of the MERETI; organizational aspects, membership and educational training, committee minutes, policies referring to review procedures, review of specific protocol items, communicating a decision, continue review and committee resources for each IREC. All the domains of the MERETI tool were continuous.

3.10. Study Validity

The MERETI is a valid tool and has been used in a number of previous studies where it has yielded valid results (Sleem et al, 2010b; and Chenneville et al 2016).

3.11. Ethical Considerations

The study received ethical approval from the MOI University/MOI Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC), formal approval number **0001909** and the National Health Research Review Board (NHRRB,) the Swaziland Ethics Committee REF: MH599C/IRB009688NHRRB **667/17**. Informed consent was obtained from each willing respondent (Appendix **II**) who had to sign before the questionnaire (Appendix **I**) was administered.

Participant responses were anonymized and any participant identifiers were removed to assure confidentiality of information provided. Participants were informed that they were free not to answer any questions they found difficult to answer and were free to withdraw from study any time they wanted to and that their refusal to participate would not jeopardize their usual service provision at their various universities nor be reported to their superiors. Lastly, participants were informed that this study involved no compensation and each respondent was to sign an informed consent.

3.12. Dissemination of Results and Publication Policy

The dissemination of the results will be done to the two institutional research ethics committees, the Eswatini Health and Human Research Review Board, the Deans of the two universities, and authorities of Eswatini ministry of Health. The results will further be shared by publishing in a scientific journal as well as in presentations at conferences and workshops.

CHAPTER FOUR

The results describe the following about the two IRECs. The IRECs scores on individual domains of the MERETI Tool, their profile and distribution: gender, qualifications, training, affiliation to the institution and composition; structural factors: organizational aspects, membership & education training and committee resources and functional factors; submission arrangements & materials, committee minutes, review procedures, review of specific items in protocol, communicating committee decisions, and continue review of approved studies

4.1 IRECs Scores on Individual Domains of MERETI Tool

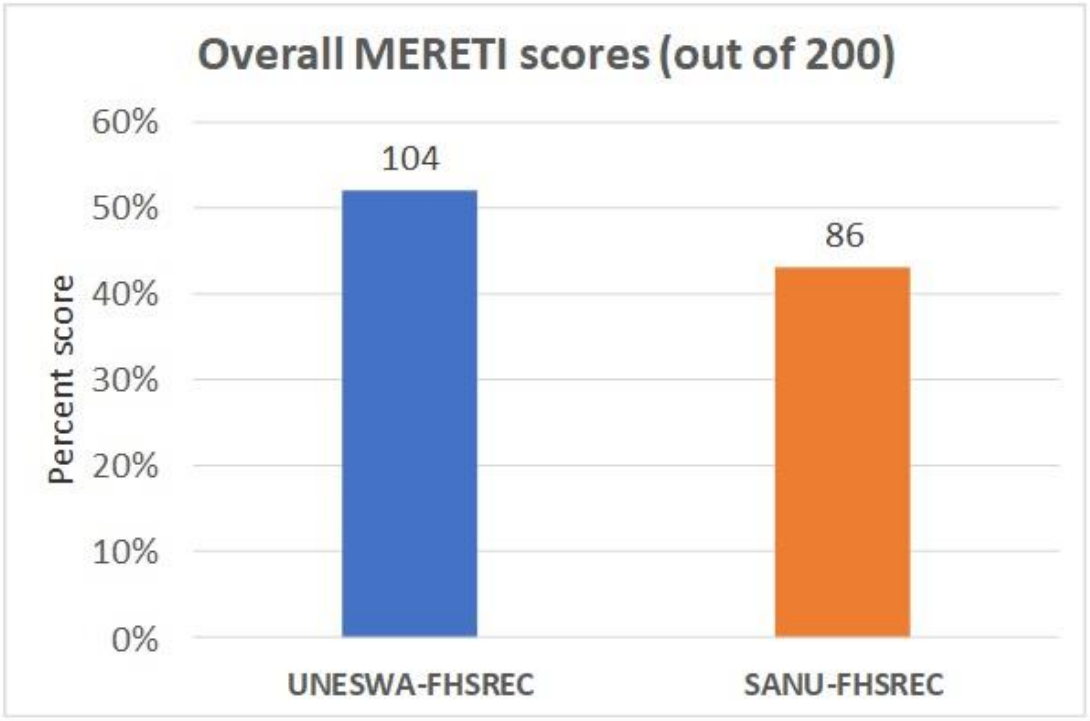

Figure 2: Institutional Ethics Committee Scores on Individual Domains of the MERETI

According to this finding both IRECs did not attain the maximum achievable score of 200 points in this assessment using the MERETI Tool.

4.2. Profile and Distribution

Table 1: Description of Study Participants (N=20)

	UNESWA-FHSREC		SANU-FHSREC	
Variable	**n**	**%**	**n**	**%**
Gender				
Male	10	66.7	3	60
Female	5	33.3	2	40
Qualification (Both IRECs)				
Masters (MSc)	10	66.7	5	100
Doctorate (PhD)	5	33.3	0	0
Training (Both IRECs)				
No	9	60	4	80
Yes	6	40	1	20
Affiliation to the institution				
No	0	0	0	0
Yes	15	100	5	100
Composition				
Non-scientific	0	0	0	0
Scientific	15	100	5	100

The majority of the members in both IRECs were males; of a total of 20 participants, there were 13 (65%) males. Only a limited number of the members had a PhD qualification; these were all from one of the institutions. The study further revealed that in both institutions IREC members had limited training in research ethics. All members were lectures at the institution, there were no non-affiliated IREC members.

4.3 Structural Characteristics

Table 2. Summary of structural characteristics of IRECs

Domains	Maximum possible score	UNESWA-FHSREC (%)	SANU-FHSREC (%)
Structural characteristics			
Overall score	100	42 (42%)	35 (35%)
Organizational Aspects	54	28 (51.9%)	23(42.6%)
Membership and Education Training	30	11(36.7%)	9(30%)
Committee Resources	16	3(18.8%)	3(18.8%)

The results show that both IRECs still had a number of gaps in their structural characteristics, none of the IRECs attained the maximum possible score in any of the domains; they actually scored less than 50% in almost all the domains.

4.4 Functional Characteristics

Table 3. Summary of functional characteristics

Domains	Maximum possible score	UNESWA-FHSREC (%)	SANU-FHSREC (%)
Functional characteristics			
Overall score	48 (48%)	100	72 (72%)
Submission arrangements and Materials	12	8(66.7%)	8(66.7%)
Committee Minutes	13	8(61.5%)	0
Review Procedures	11	6(54.5%)	3(27.3%)
Review of Specific items in the protocol	43	36(83.7%)	37(86%)
Communicating Committee decisions	5	4(80%)	0
Continue review of Approved Studies	16	0	0

These results show that both IRECs scored much better in the assessment when it comes to the functional characteristics. The scores across a majority of the domains were above 50%. This was true especially for the UNESWA-FHSREC. Noted gaps was on the committee minutes and communicating committee decisions for the SANU -FHSREC. Both IRECs did not perform well in the continued review of approved studies.

CHAPTER FIVE

DISCUSSION

5.1 Profile & Distribution

Worth noting is that the ethics committees under study are both located within universities that mainly train nurses. This consequently means that the majority of lecturers from whom ethics committee members are drawn are nurses by training. Both committees had more than 5 (five) members per IREC which is encouraging though the same cannot be said about the diversity of the members which seemed to be inadequate. In this, study all the members were lecturers and were both dominated by nurses and environmental health specialists and had no member who was not associated to the university or a community representative. Composition of committee membership is not necessarily prescribed, WHO guidelines (2011) suggest membership to comprise of a layperson and one non-affiliated member whereas then, the REC quorum must include a basic medical scientist, a clinician, a legal expert, a social scientist/philosopher/ethicist, and a layperson from the community. Enfield and Truwit, 2008, also state that members must be of different specialities; scientist, non-scientist, community representative, legal practitioner and expert in the field that will be reviewed. It is also suggested that members be diverse not only in disciplines but also in backgrounds, cultural beliefs that includes consideration of racial and cultural heritage and should be sensitive to issues that include community attitudes and involvement (Enfield & Truwit, 2008). Either than being multidisciplinary, it is recommended that members should be appointed in their own right as equal individuals of sound judgement, relevant experience and have adequate training in research ethics (Enfield & Truwit, 2008). Some of these recommendations in literature on the considerations that should be made in appointing members of an

ethics committee appear not to have been made when appointing the members of the two IRECs assessed in this study.

However, the member composition in the two IRECs were similar to what has been reported in other countries and regions. In South Africa, doctors, scientists and pharmacists together made up the 61% of the membership (Moodley & Myer, 2007). In another survey of IRECs in South Africa that reviewed HIV vaccine trials, doctors, scientists, and nurses comprised 67% of the membership (Milford, Wassenaar, & Slack, 2006). Both IRECs were under Faculties of Health Sciences and they are relatively newly established. Neither was established under a high-ranking authority (like the President's office or Ministry of Health) but under the respective faculty of that particular university. All respondents were affiliated to their institutions which can have an effect since they may tend to be protecting their institutions rather than protecting the research participants.

It is also recommended that the members in the committee can range from 5 and above. Although there is no rule that males and females be evenly distributed on institutional research committees, there is mention in literature that members should comprise of both sexes; this is because the female voice as a minority may be particularly problematic when reviewing protocols focused on women's issues (Enfield & Truwit, 2008, Yaghoobi, 2011). Although IRECs were aligned with the recommendation of having 5 or more members, both Committees had more male members.

Best practice suggests that members of research ethics committee members should ideally receive training in the international and local ethical and legal standards governing research, as well as in the process the committee uses to review and

approve protocols. Non-scientific members should be given an understanding of medical terminology and research methodology sufficient to enable them to participate intelligently in the committee's discussions. A good knowledge of the social and cultural context is also important. Training should not be a single occurrence, but instead should be an ongoing process in which all committee members participate (World Health Organization, 2011).

Results from this study indicate that members of both ethics committees possessed senior academic qualifications with the majority holding Masters Degrees. Only (7) 35% members were trained on research ethics in both IRECs. There was no evidence of continuing education for members nor no documentation of any other type of training for the respective committee members which might compromise the protection of human subjects by the IRECs. This is a key step towards strengthening attention to research ethics within countries so that they meet the standards of protecting participants in research as outlined in key international documents such as the Declaration of Helsinki and the Council for International Organizations of Medical Sciences guidelines (Organizations & Sciences, 2008). If not continuously trained on research ethics, this may compromise the quality of research and science and the quality of the results (Chenneville et al., 2014). These sentiments combined with findings from similar studies, provide evidence of the need for continued support and infrastructure for IRECs in LMICs such as that provided by the National Institutes of Health (NIH) Fogarty International Training Programs. The utility of such programs has been documented; benefits of a Fogarty sponsored and other sponsored ethics training programs in the Middle East were described by (Matar & Silverman, 2013), and Ndebele *at al* 2014 further provided a review of Fogarty-sponsored programs addressing research ethics capacity building in sub-Saharan

Africa. The WHO suggests that an IREC should include a layperson and one non-affiliated member whereas ICMR has no such requirements unless the review is of a drug trial.

5.2 Structural Characteristics

Overall structural characteristics scores were 42% and 35% for UNESWAFHSREC and SANUFHSREC respectively. While it is difficult to assign a qualitative weight to such a result (such as ‘excellent’, ‘good’, ‘fair’ or ‘poor’), the results indicate that IRECs have considerable room for improvement (Matar, A., & Silverman, H.2013). Both IRECs further responded not to have a formal policy for appointment of the IRECs chairs, members and lacked of policy for addressing conflict of interest and had no other mechanism in place. This is similar to findings elsewhere on the regulation of biomedical research in Africa, where it is thought to be ineffective to have research ethics committees without policies to guide them (Chima, 2006).

Both IRECS further reported to have had no budget and limited human resources, and this is not different from other studies that report that many IRECs lack essential financial and capital resources thought to be essential for a well-functioning committee. These findings regarding financial and material resources are similar to those reported by IRECs in South Africa (Milford et al., 2006), for example, all of the IRECs operated without a budget and many were without a dedicated office, computer, and secretarial support. Kass *et al, 2007* in their study, the structure and function of research ethics committees in Africa had similar findings that most IRECs lack finances, no human resource and these limitations make it difficult to create committees with sufficient expertise and diversity.

5.3 Functional Characteristics

Out of a maximum achievable score of 100, UNESWAFHSREC achieved a score of 62% yet SANUFHSREC scored 48%. While it is difficult to assign a qualitative weight to such a result (such as ‘excellent’, ‘good’, ‘fair’ or ‘poor’), the results indicate that IRECs have considerable room for improvement (Matar, A., & Silverman, H.2013)

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study revealed gaps in the requirements of membership with regards to specific standards for electing their members into the committees. The study further highlighted that most of the members of both IRECs were not trained in research ethics, had limited education on the subject matter nor records of any capacity building. Both IRECs lacked resources as they reported no budget allocation nor personnel.

Overall, the two IRECs differed in their structural and functional characteristics. The study showed that both IRECs have limited resource and functional capacity which may compromise their ability to perform their oversight role in protecting human participants in biomedical research within their institutions.

As stated previously, Research Ethics Committees are formed with the intention to protect rights, the dignity and welfare of research participants; achieving this is dependent on the extent development and effectiveness of the IRECs. To establish this development and effectiveness, an assessment of the IRECs is necessary. In a majority of African countries and academic institutions research ethics committees have been put in place, most of these committees have been found to be generally underdeveloped (Kruger M et al., 2014) and the quality of their performance is also generally not known (Sleem H et al., 2010). Data on the development status and effectiveness of research ethics committees is not readily available particularly given that their evaluation remains a challenge and institutional specific assessment tools are still being developed in many developing countries, An assessment on the

development and effectiveness of IRECs was a gap in Eswatini which this study sort to address and from the findings of the study it can be concluded that like in other countries the IRECs in Eswatini were underdeveloped and a number of structural and functional characteristics were not in place which could possibly have a negative impact on their effectiveness in caring out their mandate of protecting the rights, the dignity and welfare of research participants.

The findings of this assessment will provide both IRECs with a better understanding of the necessary changes needed to be incorporated in policies, processes, and educational requirements of the members. Finally, this assessment will provide national policymakers and international organizations an opportunity to better understand the state of affairs regarding the maturity and functionality of the two IRECs and such information can further assist with the allocation of necessary resources as well as the development of educational opportunities that can optimize the functionality of these IRECs.

6.2. Recommendations

The relevant government agencies and institutions should consider the following recommendations:

1. Effort must be put in place to enact policies that regulate the conduct of research in the country and further support to the institutions to develop their documents.
2. Mandatory training of IREC committee member during orientation and ensuring continuing education must be instituted in order to strengthen their structural and functional characteristics.

3. The findings call for the Government of Eswatini, the University authorities and the national board to assist the IRECs with resource mobilization, protocol review mentorship among others to improve both their functional and structural capacities.

6.3. Study Strengths

1. According to the researcher's knowledge, this is the first study to assess the structural and functional characteristics of IRECs in Eswatini using the MERETI self-assessment tool.
2. The study will give baseline information concerning ethics committees in the country
3. A self-assessment tool can provide helpful information:
    - For quality improvement as it can serve as a mechanism by identifying which standards need improvement.
    - For quality improvement projects for best practices
    - That will assist to develop educational initiatives

6.4 Study Limitations.

1. Since the study involved self-reporting by IREC members, it is subject to information bias, the responses were based on a process of self-reporting and accordingly, there might have been a tendency to over report the achievements of individual IRECs as well as underreport weaknesses.
2. This study was not equivalent to an audit, which might be a more accurate though costly way of verifying the reported data. However, it provides preliminary data to focus on in more detailed research.
3. This study could have more power if the qualitative method was also utilised.

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APPENDICES

Appendix I: MERETI TOOL

MERETI Research Ethics Committee (REC) Quality Assurance Self-Assessment Tool
The maximum total number of points is 200.
For 'yes/no' questions, points are given for a 'yes' response.

ORGANIZATIONAL ASPECTS (Maximum 54 POINTS)

What year was the REC established? _____

1. Is the REC subject to registration with a national authority?
___ Yes ___ No **2 points.**

2. How often does the REC meet as a full committee to review research studies?
___ once/week
___ Twice/month
___ once/month
___ every two months
___ Other

For meeting frequency equal or greater than once/month, 1 point

3. Was the REC established under a high-ranking authority (e.g., President's office, Ministry of Health, etc.)? ___ Yes ___ No **5 points**

4. Does the REC have written Standard Operating Procedures? __ Yes __ No **5 points**

5. Does the REC have a policy that outlines the process for appointing the REC Chair? ___
Yes ___ No **2 points**

6. Which of the following criteria are used to select the Chair of the REC? (Check all that apply.)
___ Prior training in ethics **1 point**
___ Publication in ethics **1 point**
___ Prior research experience **1 point**
___ Other (please describe) _____

7. Does the REC have a policy that describes the process for appointing the members of the REC and details the membership requirements and the terms of appointment?
___ Yes___ No **2 points**

8. Which of the following criteria are used to select REC members? (Check all that apply.)
___ prior training in ethics **1 point**
___ publication in ethics **1 point**

___ prior research experience **1 point**
___ other (please describe) _____

9. Does the REC have a policy for disclosure and management of potential conflicts of interest for the members of the REC?
___ Yes ___ No **5 points**

10. Does the REC have a policy for disclosure and management of potential conflicts of interest for members of the research team? ___ Yes ___ No **5 points**

11. Does the REC have a quality improvement (QI) program for itself?
___ Yes ___ No **5 points**

If yes, describe what was done in the last year and any changes that were made as a result of the QI program. _____

12. Does the institution/organization regularly evaluate the operations of the REC (e.g., budgetary needs, adequacy of material resources, adequacy of policies and procedures and practices, appropriateness of the membership given the research being reviewed, and documentation of the training requirements of the REC members)? ___ Yes ___ No **5 points**

13. Does the REC have a mechanism whereby enrolled research participants can file complaints or direct questions regarding human subject's protection issues? ___ Yes ___No **5 points**
If yes, please describe the mechanism._____

14. How are records of the REC stored? **1 point**
____ paper folders in a locked file cabinet **1 point**
____ electronic in a password-protected computer **1 point**
____ on an open shelf
____ other

15. Quorum: Does the REC require that there be a certain number of members present in order to make the meeting official to review protocols? ___ Yes ___ No **5 points**

MEMBERSHIP AND EDUCATIONAL TRAINING (Maximum 30 POINTS)

1. How many members are there on the REC? ____ **If ≥ 5 members, 2 points**

2. How many are women? _____ How many are men? ____
If female/male gender ratio is between 0.4 and 0.6, then 2 points

3. Are any of the members not affiliated with the institution, that is, the member is not employed by the institution and is not related to a person who is employed? ___ Yes ___ No **2 points**

4. Are any of the members considered to be a non-scientist? ___Yes ___ No (A **Non-Scientific Member** is any member who does not have a terminal degree in a medical or scientific field.) **2 points**

Please note that one member may fulfill both criteria of non-scientist and non-affiliated, in which case, please check Yes for both #3 and #4.

5. Is there a requirement that the REC Chair (or the designee who is in charge of running the committee) has any prior formal training in research ethics? ___ Yes ___ No **5 points**

If yes, what type of training is required? (Check all that apply.)
___ web-based training
___ workshop in research ethics
___ course
___ other (please describe)
_____

6. Does the institution require that REC members have training in research ethics in order to be a member of the REC? ___ Yes ___ No **5 points**

If yes, what type of training is required? (Check all that apply.)
___ web-based training
___ workshop in research ethics
___ course
___ other (please describe)
_____

7. Does the institution require that investigators have training in research ethics in order to submit protocols for review by the REC? ___ Yes ___ No **5 points**

If yes, what type of training is required? (Check all that apply.)
___ web-based training
___ workshop in research ethics
___ lecture
___ course
___ other (please describe)
_____

8. Does the REC conduct continuing education in research ethics for its members on a regular basis?
___ Yes ___ No **5 points**

9. Does the REC document the human subject's protection training received by its members?
___ Yes___ No **2 points**

SUBMISSION ARRANGEMENTS AND MATERIALS (Maximum 12 POINTS)

Submission Arrangements of Research Protocols	**1point each**	
Item	**Yes**	**No**
Does the REC publish guidelines for submission of applications for the review by the REC?		
Does the REC require investigators to use a specific application form for the submission of their protocols to the REC?		
Does the REC have an informed consent template to help guide investigators in the writing of their informed consent forms?		
Does the REC require approval and signature of the department chair (or another individual) of the research protocol prior to the submission?		
Does the REC require a deadline for investigators to submit protocols for full committee review?		

SUBMISSION ARRANGEMENTS AND MATERIALS (Maximum 12 POINTS)

Submission Materials	**1 point each**	
Which of the following items are requested from the Principal Investigators when they submit their research protocol to the REC?		
Item	**Yes**	**No**
Full protocol		
Informed consent form		
Investigator's qualifications [e.g., CV, medical license(s), etc.]		
Conflict of interests disclosure forms for members of the research team		
Recruitment material (e.g., advertisements, signs, posters, etc.), if applicable		
Questionnaires/surveys that will be used in the research, if applicable		
Investigators' Drug Brochure or materials describing the nature of the drug being used in a clinical trial, if applicable		

MINUTES (Maximum 13 POINTS)

Does the REC maintain minutes of each meeting? ___Yes ___No	**5 points**	
If minutes are kept, please answer the following questions regarding the minutes.	**1 point each**	
Item	**Yes**	**No**
Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be discussed and indicate that such members did not participate in the decision making process of the relevant protocols?		

Do the minutes document that a quorum was present for all actions requiring a decision?		
Do the minutes document that all actions included at least one scientist in the review and participated in the decision making process?		
Do the minutes document that all actions included at least one non-scientist in the review who participated in the decision making process?		
Do the minutes document that all actions included at least one person who is not affiliated with the institution in the review and participated in the decision making process?		
Do the minutes record the name of REC members who abstained from the decision making process and provided the reason for abstention?		
Do the minutes record the name of REC members who were excused from the discussion and decision making process due to a conflict of interest?		
Do the minutes reflect, when applicable, a discussion of the controversial aspects of the research protocol?		

POLICIES REFERRING TO REVIEW PROCEDURES (Maximum 11 POINTS)

Policies Referring to Review Procedures	**1 point each**	
Item	**Yes**	**No**
Does the REC have a policy regarding how protocols will be reviewed?		
Does the REC bring in a consultant when necessary to provide scientific or other relevant expertise for review of a particular protocol? Do REC members receive the protocol and other		
Do REC members receive the protocol and other materials at a specified time prior to the meeting?		
Does the REC require that reviewers use a checklist to document their ethical assessment of the research submission?		
Does the REC have a policy on the conditions for expedited REC review?		
Does the REC have a policy on the conditions for when studies may qualify for exempt status?		
Does the REC determine the interval of continuing review based on the risk of the study?		
Does the REC have a policy for how decisions are made (e.g., consensus or a vote)?		
Are members asked at the beginning interest regarding any the meeting as to whether they had a conflict of the protocols to be discussed and indicate that such members did not participate in the decision on the relevant protocols? Does the REC have a policy for follow-up review?		
Does the REC have a policy for communicating a decision?		
Does the REC have a policy for follow-up review?		

REVIEW OF SPECIFIC PROTOCOL ITEMS (Maximum 43 POINTS)

Scientific Design and Conduct of the Study	**1 point each**	
Item	**Yes**	**No**
Does the REC review the suitability of the investigators' qualifications to conduct the study?		
Does the REC review the adequacy of the clinical site, including the supporting staff, available facilities, and emergency procedures?		
Does the REC take into account prior scientific reviews or do they review the appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for addressing the objectives with the smallest number of research participants?		

Considerations of Risks and Benefits	**1 point each**	
Item	**Yes**	**No**
Does the REC identify the different risks of the research protocol?		
Does the REC determine whether risks have been minimized?		
Does the REC determine whether the risks are greater than minimal risk based on a written definition of minimal risk?		
Does the REC evaluate the probable benefits of the research to the participants?		
Does the REC evaluate the importance of the knowledge to society that may reasonably be expected to result from the research?		
Does the REC evaluate whether the risks to research participants are reasonable in relation to any anticipated benefits to participants and the importance of the knowledge to be gained by society?		

Selection of research participants	**1 point each**	
Item	**Yes**	**No**
Does the REC review the methods to identify and recruit potential participants?		
Does the REC review recruitment processes to ensure that the selection of subjects will be equitable in regards to gender, religion, and ethnicity?		
Does the REC identify the potential of the research for enrolling participants who are likely to be vulnerable to coercion or undue influence (such as children, prisoners, persons with mental disabilities, or persons who are economically or educationally disadvantaged)		
Does the REC consider the justification for including vulnerable populations in the research?		
Does the REC consider and require that additional safeguards be included in the study to protect the rights and welfare of the subjects?		
Does the REC consider the appropriateness of any financial or material incentives offered to participants for their participation in		

the research?		
Privacy and confidentiality	**1 point each**	
Item	**Yes**	**No**
Does the REC preserve privacy by evaluating the setting in which participants are recruited?		
Does the REC evaluate the methods for protecting the confidentiality of the collected research data?		

Community and consultation	**1 point each**	
Item	**Yes**	**No**
Does the REC review whether the potential benefits of the research are relevant to the health needs of the local community/country?		
Does the REC review whether any successful study product will be reasonably available to the concerned communities after the research?		
Does the REC review whether the community was consulted regarding the design and implementation of the research, if applicable?		
Safety Monitoring and Adequacy of Insurance to Cover Research-Related Injury	**1 point each**	
Item	**Yes**	**No**
Does the REC require, when appropriate, that the research plan include adequate provisions for monitoring the data collected to ensure the safety of subjects?		
Does the REC consider whether the sponsors of the research have adequate insurance to cover the treatments of injury related to the research?		

Pediatric Research	**1 point each**	
Item	**Yes**	**No**
Does the REC evaluate the need to obtain the child's assent?		

Informed Consent	**1 point each**	
Item	**Yes**	**No**
Suggested ways to assess the consent form might include: • evaluate the reading level of the consent document • have a community member read the consent form • require investigators to assess subjects' understanding of the consent form		
Does the REC waive the requirement to obtain informed consent that is based on written criteria?		
Does the REC waive the requirement to have a written signature on the informed consent document that is based on written criteria?		

Basic Elements of Informed Consent		
Does the REC evaluate whether informed consent forms contain the following basic elements of informed consent?	**1 point each**	
Item	**Yes**	**No**
A statement that the study involves research		
An explanation of the purposes of the research		
The expected duration of the subject's participation		
A description of the procedures to be followed		
Identification of any experimental procedures		
A description of any reasonably foreseeable risks or discomforts to the participant		
A description of any benefits to the participant or to others that might reasonably be expected from the research		
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject		
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained		
For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what the treatments consist of or where further information may be obtained		
An explanation of whom to contact for answers to pertinent questions about research		
An explanation of whom to contact for answers to pertinent questions about research participants 'rights		
A statement that participation is voluntary		
A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled		
A statement that participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled		

COMMUNICATING A DECISION (APPROVAL LETTER) Maximum 5 POINTS

Please answer the following questions regarding the approval letter sent to the PI. If no approval letter is sent to the investigator, please skip this section.

Which of the following items are in the approval letter?	**1 point each**	
Item	**Yes**	**No**
Provide an expiration date that is 1 year from the date of the convened REC meeting in which the study was approved.		
Require the investigators to submit to the REC as an amendment any changes that occur in the research plan; for example, change in investigators, change in drug doses, change in the sample size, etc.		
Require the investigators to promptly report to the REC any adverse events or unanticipated problems.		
Require the investigators to promptly report to the REC any		

protocol deviations.		
Require investigators to use the REC-approved informed consent form that is stamped with an expiration date.		

CONTINUING REVIEW (Maximum 16 POINTS)

Does the REC request a continuing review report from the investigators on at least a yearly basis? ___Yes ___No	**5 points**	
If yes, which of the following items are requested in the continuing review report?	**1 point each**	
Item	**Yes**	**No**
Number of subjects enrolled		
Gender and ethnic/religious breakdown of enrolled subjects		
Number of subjects withdrawn from the research by the investigators		
The reasons for withdrawal		
Number of subjects who dropped out of the research		
The reasons why subjects dropped out		
Verification that informed consent was obtained from all subjects and that all signed consent forms are on file		
Number and description of serious adverse events in the previous year (SAEs)		
List of any protocol violations or deviations		
Any safety monitoring reports		
If the study is completed, submit a final report describing the study results.		

REC RESOURCES (Maximum 16 POINTS)

Does the REC(s) have its own yearly budget? __ Yes __ No **5 points**
If yes, is there a budget for training of administrative staff and REC members?
__ Yes __ No **1 point**

2. Please check below the physical resources of the REC (check all that apply): **1 point**
   __ access to a meeting room
   __ access to a computer and printer
   __ access to the internet
   __ access to a facsimile
   __ access to cabinets for storage of the protocol files

3. Does the REC have administrative staff assigned to the REC? __ Yes __ No **5 points**
   If yes: Is the person full-time? __ Yes __ No
   Is the person half-time? __ Yes __ No

WORKLOAD OF THE REC (0 POINTS)

Average number of protocols reviewed annually? _____
Average number of clinical trials reviewed annually? _____
Average number of epidemiologic/observational studies reviewed annually? _____

After a brief review of three recent REC minutes, complete the following table with a specific number or N/A (not applicable).

REC Workload Table	**1st Meeting**	**2nd Meeting**	**3rd Meeting**
Duration of the meeting			
Number of new protocols reviewed by full committee			
Number of protocols disapproved			
Number of continuing review protocols approved by expedited review that were reported to the REC			
Number of continuing review protocols reviewed by full committee			
Number of amendments approved by expedited review that were reported to the REC			
Number of amendments reviewed by full committee			
Number of adverse reactions reviewed by full committee			

Appendix II: Informed Consent

Participant Consent Form

Assessment of structural and functional characteristics of two Institutional Research Ethics Committees in Swaziland

Principal Investigator

Babazile Shongwe

PURPOSE

This study proposes to conduct an assessment of the Institutional Research Ethics Committee of the Southern African Nazarene University, and Swaziland University of Swaziland, Faculty of Health Sciences with purpose of generating information on structural factors affecting their performance.

PROCEDURES AND DURATION

If you decide to participate, you will be asked to answer the questionnaire that will be soliciting information concerning the institutional research ethics committee you are serving in. You are kindly requested to state your qualification and your sex on the top of the questionnaire.

RISKS AND DISCOMFORTS

There are no risks associated with participating in this study.

BENEFITS AND/OR COMPENSATION

This research study will not provide direct benefits to participants, but the findings will assist in generating data on the development and assessment of individual Research Ethics Committees for purposes of devising improvement strategies. In the case of the proposed study, generated data will be used for characterizing the development and performance status of the two Institutional Research Ethics Committees in Swaziland. No compensation is offered for participating in this study.

_____ _____

Signature of Participant Date

_____

Signature of Researcher Date

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any further questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject. Feel free to contact the secretariat of the Eswatini Health and Human Research Review Board at phone number **2404 7751/2404 9553**

Appendix III: Formal Approval from IREC

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2017/91
Approval Number: 0001909

22nd June, 2017

Babazile Shongwe,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
22 JUN 2017
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Ms. Shongwe,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Assessment of Structural and Functional Characteristics of Two Institutional Research Ethics Committee in Swaziland using the MERETI Self-Assessment Tool".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1909*** on 22nd June, 2017. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 21st June, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

Research Protocol clearance certificate

Type of review	Expedited	X		Full Board		
Name of Organization	STUDENT					
Title of study	Assessment of structural and functional characteristics of two Institutional Research Ethics Committees in Swaziland using the MERETI self-assessment tool					
Protocol version	1.0					
Nature of protocol	New	x		Amendment		
List of study sites	University of Swaziland (Mbabane) Southern African Nazarene University (Manzini)					
Name of Principal Investigator	Bubanzile Shongwe					
Names of Co- Investigators	N/A					
Names of steering committee members in the case of clinical trials	N/A					
Names of Data and Safety Committee members in the case of clinical trials	N/A					
Level of risk (Tick appropriate box)	Minimal			High		
	X					
Clearance status (Tick appropriate box)	Approved	X		Disapproved		
Clearance validity period	Start date	25/09/2017		End date	25/09/2018	
Signature of Chairperson						
Date of signing	25/09/2017					
Secretariat Contact Details	Name of contact officers		Ms Simangele Masilela			
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MINISTRY OF HEALTH
27 SEP 2017
HEALTH RESEARCH REVIEW BOARD
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