Research Ethics Committee member insights into the structures, processes, responsibilities and needs of Health Research Ethics Committees in Malawi: A mixed methods approach

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Abbreviations

BREC:	Biomedical Research Ethics Committee
CIOMS:	Council for International Organisation of Medical Sciences
COM:	College of Medicine
COMREC:	College of Medicine Research Ethics Committee
EC:	Ethics Committee
FWA:	Federal Wide Assurance
IRB:	Institutional Review Board
KCN:	Kamuzu College of Nursing
LMIC:	Low- and Middle-Income Countries
MoH:	Ministry of Health
NCST:	National Commission for Science and Technology
NHSRC:	National Health Sciences Research Committee
REC:	Research Ethics Committee
UKZN:	University of KwaZulu-Natal
UNIMA:	University of Malawi
USA:	United State of America
UK:	United Kingdom
WHO:	World Health Organisation
WMA:	World Medical Association

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Abstract

Background: The dearth of studies on the composition and functioning of Malawi's research ethics committees (RECs)prompted this study. The aim of the study was to describe Malawi's two health RECs. Towards better understanding REC members' insights into the structures, processes, responsibilities and needs of Health Research Ethics in Malawi, the following variables and components were considered: REC demographics, composition, training, guideline use, processes and procedures, financial and material resources, and affiliation.

Methods: This study used a mixed method approach where quantitative descriptive cross-sectional survey and a retrospective record review/document analysis design were used. The study focused on RECs which review health research protocols only. We targeted a sample size of 30 participants. Sample selection was through a convenience sampling method.

Results: The response rate for our study was 80% (24/30) of the total REC members from Malawi's two RECs. Medical doctors dominate in membership. Most members (87%) had official training in research ethics after joining the RECs. The types of research most commonly reviewed by these RECs included: Public health research, laboratory research and health systems research. REC meetings were held either monthly or bi-monthly. On average, 33.5 protocols were reviewed per month, inclusive of all minimal risk and continuing research. REC members report the Declaration of Helsinki (83.3%), ICH GCP guidelines (75%)and the CIOMS guidelines (45.8%)as the most commonly used international guidelines, in conjunction with Malawi's own ethical guidelines, law and policy. Application fees and research levies allow the RECs to generate their own income. This covers some of their basic expenses, the RECs lack the funding for a dedicated office space, transportation, and information and communication technologies. Eighty-three percent of members indicated the need for training in research ethics, especially in placebo-controlled clinical trials and scientific design issues in health research. Both RECs are accredited by a regulatory body in Malawi.

Conclusion: REC members highlighted many strengths and some challenges and weaknesses in their RECs which require some consideration for the RECs to function more effectively. Some of the strengths include record keeping, use of international and local law, policy and research ethics guidelines, creative means of income generation and training of

REC members. The RECs expressed a need for national audit and monitor ring mechanisms, and for specific research ethics training for their members.

Chapter one: Introduction and background

The high disease burden in Africa, the emergence of new diseases and efforts to address the 10/90 gap have led to an unprecedented increase in health research in Africa (Agunloye, Salami, & Lawan, 2014; Nyika et al., 2009). Consequently, there has been an increase in the volume and complexity of protocols that research ethics committees (RECs) in Africa have to review(Ijsselmuiden, Marais, Wassenaar, & Mokgatla-Moipolai, 2012; Nyika et al., 2009).

As in many other African countries, the number of protocols Malawian RECs receive for review every year has increased. Despite the fact that the majority of countries in Africa are reported to have at least some form of research ethical reviews in place (Kass et al., 2007), the review processes of the increased numbers of protocols are generally hindered by a combination of challenges. These include limited education and/or experience and lack of diversity in the RECs' composition (Enfield & Truwit, 2008; Milford, Wassenaar, & Slack, 2006; Nyika et al., 2009).

In spite of the increase in number of research protocols Malawi RECs receive to review, there is no documentation with regard to the composition and functioning of these RECs in Malawi. In addition, there is virtually no study that has been conducted to describe the roles and responsibilities, and training needs, of any of the RECs in Malawi. Therefore, this study set out to describe the composition and functioning of RECs in Malawi. The study also set out to investigate the most common challenges that the RECs in Malawi face, how they cope with such challenges, and to make suggestions to improve the functioning of the RECs.

We believed that many African countries share almost similar challenges and we anticipated similar challenges to be found in Malawi. However, we thought that we would find a wide variation on how Malawian RECs are composed, how they function, how they cope with the challenges and possibly their needs to function properly in relation to other African countries. This study was conducted in Malawi and it targeted both research ethics committees which review health research protocols in Malawi. All REC members were invited to participate in the study.

Understanding the functioning and coping mechanisms of the existing challenges for Malawian RECs in this regard was believed to provide necessary attention where required to enhance the application of responsible and ethical conduct of research in the country. The results from this study highlighted the functioning and the possible solutions to the

challenges faced by the RECs. The study also provided some solutions on how to cope with the challenges. These solutions might assist other RECs in Africa or abroad facing similar challenges. On the other hand, the highlighted needs and challenges could help to facilitate the establishment and implementation of solutions or lead to further investigations/studies.

Chapter two: Literature review

2.1 Introduction

Every proposal for biomedical research on human participants has to be submitted to an independent research ethics committee (REC) for review and approval (Druml, Wolzt, Pleiner, & Singer, 2009). This follows the recommendation of the Declaration of Helsinki which was adopted in Tokyo in1975 (World Medical Association, 2013). In the United States, research ethics review committees are called institutional review boards (IRBs) (45 CFR 46, 1991) and in Asia, they are called ethics committee (ECs) (Bhatt, 2004; Majumder, 2004), while elsewhere they are called research ethics committees (RECs) (Kass et al., 2007). RECs major responsibility is to protect the rights and welfare of research participants and give public assurance that biomedical research is conducted in a transparent and ethical way (Druml et al., 2009). For comprehensive understanding of this study the review is sub sectioned into; understanding historical perspectives of REC establishments, general overview of REC developments globally, specific composition and functioning of RECs in USA, Europe, ASIA, Latin America, Africa and finally in Malawi where this study was conducted.

2.2 Historical perspective: The establishment of RECs

The call for the establishment of IRBs/RECs/ECs originated from scientific and social injustices which can be traced back to as early as the 19th century. Due to high demand and need for knowledge, humans were subjected to scientific and experimental research (Vollmann & Winau, 1996). Vollmann and Winau (1996) report that these studies were conducted on either hospitalised human participants or prisoners of war, without their prior consent to participate in the research. Due to the lack of informed consent for participation in these medical studies, the century witnessed scientific misconduct and a number of social injustices, justified at the time by the need to promote scientific and medical progress (Lederer & Davis, 1995).

The notable instances of this research misconduct include the Neisser case in about 1888, where the researcher used patients who were also prostitutes to deliberately inject them with syphilis serum positive. The researcher aimed to develop a vaccine to be used for prevention of the disease (Vollmann & Winau, 1996). According to these authors, the serum was injected in these hospitalised patients who were admitted for other medical conditions. Once the patient developed the disease, they argued that it was not from the

serum injected in them but rather the disease was contracted from their act of prostitution (Vollmann & Winau, 1996). Another notable instance of research misconduct was the Nazi Holocaust during the 1930's and 40's, where Nazi doctors conducted various experiments including freezing experiments on Jewish prisoners of war (Brink, Van der Walt, & Van Rensburg, 2006). In the freezing experiments, the aim of the German doctors was to find out what freezing temperatures would kill a person; this was in preparation for their soldiers who were to fight in the freezing war zone (Brink et al., 2006; Vollmann & Winau, 1996).

The end of the Nazi holocaust led to the development of the Nuremberg Code (Brink et al., 2006). The Nuremberg code of 1947 was extensively used and is considered as first document regulating ethical conduct of research involving human subject with a promotion of informed consent (Lederer & Davis, 1995; Vollmann & Winau, 1996). It is where the informed consent originated from which is currently used extensively to conduct research involving human subjects.. Besides the Nuremberg Code, a series of internationally recognised research ethics guidelines have been developed to monitor the conduct of research involving humans, in order to prevent research misconduct and promote the welfare of research participants. These guidelines include but are not limited to: the World Medical Association Declaration of Helsinki, the Belmont Report, Council for International Organisation of Medical Science (CIOMS) guidelines and the UNAIDS ethical guidelines for HIV Preventative Vaccine Research.

However, the application of these ethical guidelines have shown some discrepancies globally (Brodwin, 2001). Factors that have contributed to the status quo include; social values, education, finances and independence of the evaluating bodies (Ijsselmuiden et al., 2012). As alluded to earlier, basing on development of different guideline and declarations, REC globally are developed with the same aim to protect the human participants who are involve in research studies. Despite different application of these guidelines as they are dictated by different social cultural norms REC goal and purpose remains similar globally.

2.3 The composition and functioning of RECs globally

The requirement for establishment of IRBs at research institutions in the United States of America (USA) was first introduced in 1966 (Marshall, 2003). Some argument indicate that there are disagreements and inconsistencies between IRBs, however efforts have been made to 'harmonise' their judgements in the USA (Edwards, Ashcroft, & Kirchin, 2004), a trend which Europe is adopting. Since then, there has been steady growth of their functioning and operation, despite some sectors, IRBs in the USA have been viewed as

ineffective due to increased responsibilities beyond those required by regulations (Grady, 2015). Likewise, some people complain that IRB review is time-consuming and burdensome without clear evidence of effectiveness at protection of human participants, while others argue that IRBs also operate inconsistently and inefficiently, and focus their attention on paperwork and bureaucratic compliance(Grady, 2015).

In Europe, RECs have been an integral part of clinical research since 1975, when they were introduced through an amendment to the Declaration of Helsinki(Druml et al., 2009). In Europe, it was observed that REC members attend training and attain expertise for their work (Davies, Wells, & Druml, 2008). Despite the training and attainment of expertise, some countries like the United Kingdom, Australia, Austria, Germany, Hungary, Ireland and Spain have identified administrative burden as one main bottleneck in the process of seeking research ethics approval in Europe (Hernandez et al., 2009). In related studies in Austria, France, Italy, Spain and the UK, lack of specific expertise in RECs concerning new fields of research has been identified as the main challenge RECs face to review research protocols effectively (Davies et al., 2008). This has necessitated a call for training in this specific and challenging new field (Davies et al., 2008).

There is a distinct gap in terms of research training education between high-income countries and low- and middle-income settings (e.g. some Asian countries)(Majumder, 2004). Medical research education has gained importance in most low- and middle-income countries; however, it has not received similar attention elsewhere, especially in Asian countries (Kadam & Karandikar, 2012; Majumder, 2004). Some of the challenges that have been identified as impacting on research conduct in Asia include poor socio-economic conditions, leadership crises, cultural and religious beliefs, faculty development and information poverty (Majumder, 2004).

Despite poor attention given to Asian countries with regard to the development of RECs, some countries such as India have over 200 RECs. Many of these RECs are, however, not accredited (Bhatt, 2004). A study on Indian RECs has revealed lack of knowledge among REC members, which has been linked to inadequate training, inability to enlist the essential documents for REC review, and failure to realize the important role of REC approval in biomedical research (Kadam & Karandikar, 2012). Despite the identified challenges, regulatory approvals in India usually take three months, which is comparable to most Asian and European countries, but longer than the general 30-day approval period in the USA (Bhatt, 2004).

A study conducted by Rivera and Ezcurra, (2001) in 25 centres in Latin America countries (including Argentina, Brazil, Chile, Columbia, Cuba, Mexico, Panama, Guatemala, Peru and Venezuela) revealed similar challenges to those identified in India, such as limited education and expertise, lack of diversity of the research ethics review committee, and lack of administrative support. It is noted from the literature review that countries regarded high income countries share almost similar challenges, similar countries from low – mid income countries have same problems which are different from the two economic stratum of the countries. Most African countries are low – mid income countries as most of them are developing. It is anticitipated that the challenges, system of operation, composition and experience might be similar to those of low – mid income countries from other regions of the globe.

2.4 The composition and functioning of RECs in Africa

In Africa, there is a relative dearth of published data on how RECs operate (Rivera & Ezcurra, 2001; Silaigwana & Wassenaar, 2015). There is limited information available regarding the structure, functions and outcomes of African RECs(Silaigwana & Wassenaar, 2015). However, a study by Ndebele, Wassenaaret al. (2014)and Boateng, Ndebele, &Mwesiga-Kayongo, (2014)has shown a significant increase in research ethics capacity-building of RECs in Africa over the past five decades. There are some strategies currently aimed at optimising REC review and oversight in Africa. Some of the notable initiative in Africa to parade this initiative include funding from the WHO-UNAIDS African AIDS Vaccine Programme (AAVP); the African Malaria Network Trust (AMANET); the National Institutes of Health's (NIH) Fogarty International Centre's South African Research Ethics Training Initiative (SARETI); the International Research Ethics Network for Southern Africa (IRENSA); the West African Bioethics Initiative (WAB); the Wellcome Trust; the European Union (EU); the Global Bioethics Forum; the World Health Organization (WHO), and the EU European Developing Countries Clinical Trials Partnership (EDCTP) which partially funds, for example, a high-level online capacity building programme known as TRREE(Ijsselmuiden et al., 2012; Ndebele, Wassenaar, et al., 2014). The first documented case of ethical review of health research in Africa is reported to be in South Africa at the University of Witwatersrand in 1966 (Ndebele, Wassenaar, et al., 2014). Research oversight has since then evolved and developed in both scope and complexity across African countries, with some countries having well-developed RECs.

In Africa and many low- and middle-income countries (LMICs) more generally, one of the significant challenges for RECs in resource-poor settings is that the application of human participant protection through review of research is limited by a lack of resources, training and standard knowledge on how best to apply ethical principles, regulations and guidelines (Hyder et al., 2004). For example, RECs and researchers do not always engage sufficiently with ethical-legal requirements when using human biological materials in LMICs for research purposes (Sathar, Dhai, & Linde, 2014). The recent growth of research involving human participants in LMICs necessitates attention to the vigilant oversight by RECs of the proposed conduct of research (Nyika et al., 2009; Rivera & Ezcurra, 2001). This implies that RECs should be competent and well trained (Council for International Organizations of Medical Sciences, 2002; Enfield & Truwit, 2008). Multiple studies over the last decade report the need for training REC members in Africa in order to enhance their competencies in reviewing research protocols (Abdel-Aal, Ghaffar, & El Shabrawy, 2013; Ijsselmuiden et al., 2012; Nyika et al., 2009).

The idea that, to be ethical, research must be socially valuable is widely accepted in the field of research ethics (Council for International Organizations of Medical Sciences, 2002; Emanuel, Wendler, & Grady, 2000; National Commission for the Proptection of Human Subjects of Biomedical Behavioral Research Bethesda MD, 1978; World Medical Association, 2013). This implies that, if research is being proposed by the international communities to poor resourced communities or countries, most often than not, would not be responsive to the needs or social values of the researched communities. Therefore in collaboration with the local rules, the plans could be made that the study is responsive to the researched communities/countries. This necessitates the need for the local guideline. Thus the benchmark of social value requires that society (or the field of health) should gain important generalisable knowledge from the research. Some authors argue that the populations that host research should also benefit from the results of the research, particularly when those populations are disadvantaged in other ways (Council for International Organizations of Medical Sciences, 2002; London, 2008; WMA Declaration of Helsinki, 2016; World Medical Association, 2013). The social value of a research project must be sufficient to justify the risks and burdens of the study for research participants and the communities from which they are recruited. This implies that the amount of *local* social value is also relevant to justifying research.

Most research in Africa is funded by high-income countries and international organisations based in high-income countries (Barsdof & Millum, 2016; Kass et al., 2007; Klitzman, 2012;

Milford et al., 2006). Arguably, however, the funding of such studies might largely pertain to clinical trials as opposed to the largest pool of studies from general research and other studies done by students, which are well supported by local funding. While some of these research efforts which are funded by high-income countries are intended specifically to benefit the lower income setting, much of the research is intended for high-income health markets. It is therefore imperative that if one accepts research that imposes risks and burdens on participants or communities, it has generally to be justified only when it has sufficient social value, for those communities where it will be conducted. Therefore African RECs need to give special consideration to the potential local social value of any proposed research to avoid research that may be exploitative or of no or little value for the local community and/or country studied. One mechanism that RECs can use to offset this risk is to require that the host country or community members assume active partnership in the research process, to work together collaboratively in an obligation to ensure studies meet the highest standards, and demonstrate (local) social value(Council for International Organizations of Medical Sciences, 2002; DuBois et al., 2011; Hyatt et al., 2009; World Health Organisation, 2000; World Health Organization, 2011). In addition to the above, proper use and application of the Emannuel et al. (2008) framework would help to direct the proper functioning of the RECs in African, as it highlighted a number of queries that the RECs desire to function such as informed consent, scientific validity, fair participant selection, and ongoing respect for participants (Tsoka-Gwegweni & Wassenaar, 2014).

As alluded to earlier, research studies in most African countries and other LMICs across the globe, are largely dependent on funders from high-income countries (Ijsselmuiden et al., 2012; Ndebele, Wassenaar, et al., 2014). As such, vigilance of RECs is of importance to limit compromising the application of ethical principles. The need for local guidelines in this case cannot be understated. If there are no local guidelines and frameworks for the conduct of research, the independence of the RECs can be compromised with such funding, as research may be conducted according to the regulatory framework of wealthier sponsoring countries (Agunloye et al., 2014; Milford et al., 2006; Nyika et al., 2009). Some authors have suggested that the reasons for conducting research in Africa and other LMICs (rather than high-income settings) include lower costs, lower risk of litigation and less stringent ethical review. RECs in LMICs are not always sufficiently capacitated to uphold the highest standards for the protection of research participants, and there is lack of finances, as well as inadequately trained human resources (Agunloye et al., 2014; Ijsselmuiden et al., 2012; Ikingura, Kruger, & Zeleke, 2008; Kass et al., 2007; Matar & Silverman, 2013; Moodley & Myer, 2007).

Few studies have examined procedural strengths and challenges of RECs in low-income settings (Kass et al., 2007). The creation of many more RECs in Africa and the attainment of training by a few members of the REC are some of the identified strengths (Kass et al., 2007). However, there are considerable variations amongst RECs within and between different countries in Africa, with some being better developed than others (Silaigwana &Wassenaar, 2015). The most frequently mentioned challenges for LMIC RECs are: inadequate training (Abdel-Aal et al., 2013; Enfield & Truwit, 2008; Ikingura et al., 2008; Kass et al., 2007; Matar & Silverman, 2013; Milford et al., 2006; Sleem, El-Kamary, & Silverman, 2010) and funding (Ijsselmuiden et al., 2012; Kass et al., 2007; Matar & Silverman, 2013).

It is imperative that the investigators who conduct research with human participants are responsible for the protection of research participants' rights, safety and welfare, as well as the scientific integrity of their studies(Kass et al., 2007; Merritt et al., 2010); hence, there is a need for a well-trained REC body. The purpose of the RECs in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants (Enfield & Truwit, 2008; Kass et al., 2007; Nyika et al., 2009; World Health Organization, 2011). The roles of the REC are: to review study proposals (Kass et al., 2007; Organization, 2000; World Health Organization, 2011), inform investigators when their study protocols fall short of conventional ethical standards, approve ethically sound protocols, and monitor studies over their duration to ensure that ethical standards are adhered to throughout the course of the study (Boateng, Ndebele, & Mwesiga-Kayongo, 2014; Kass et al., 2007; World Health Organization, 2011). RECs also provide administrative support through internal audits and record-keeping (Enfield & Truwit, 2008).

Enfield and Truwit (2008) elaborate that the composition of a REC must provide the professional competence necessary to review research activities and to ascertain the acceptability of proposed research in terms of institutional commitment, and according to the regulations and standards of professional conduct for practice. A review of RECs in sub-Saharan Africa revealed that RECs are dominated by medical professionals (Silaigwana & Wassenaar, 2015). Enfield and Truwit (2008), as well as Rivera and Ezcurra (2001), emphasise the importance of diverse membership of the committee to facilitate appropriate review of human research. In addition, RECs must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds (Enfield & Truwit, 2008; Matar & Silverman, 2013).

A review of studies has revealed that, currently, African RECs do not have adequate structures or functioning (Silaigwana & Wassenaar, 2015). Despite this, literature has also revealed that a number of activities are taking place in an effort to develop and shape RECs in many African countries (Ndebele, Mwaluko, et al., 2014), and research ethics capacity-building has improved significantly (Silaigwana & Wassenaar, 2015). Some studies have also appreciated that REC members have attained some formal education in research ethics (Kass et al., 2007; Ndebele, Mwaluko, et al., 2014).

Contrary to Malawi, in other developing African countries such as Egypt, it was found that training was a challenge, as REC participants lacked expertise. As such, they advocated for formal training to be given to REC members (Abdel-Aal et al., 2013; Sleem et al., 2010).In Nigeria, it was found that very few members had undertaken the formal training in research ethics, but there were also challenges of lack of independence of RECs due to lack of finances. In addition, there were challenges associated with the application of social values which were contradicted by various cultures and religious beliefs(Agunloye et al., 2014), to mention a few. Following these challenges, they recommended training in health research ethics for undergraduate students, while to enhance their independence, they advocated for more funding from the government.

In South Africa, on the other hand, it was discovered that there was a wide variation among RECs in terms of their training in research ethics, such that some institutions' RECs had well-trained members in research ethics compared to others. Another challenge was observed in terms of lack of membership diversity, which was dominated by some categories of members (Moodley & Myer, 2007). Similar challenges outlined for South Africa, Nigeria and Egypt were mentioned for Tanzania, with the addition of high workload, with erratic infrastructure and member commitment (Ikingura et al., 2008); as such, these authors proposed payment to the REC members to enhance their commitment. For Democratic Republic of Congo, Ghana, Kenya, Nigeria, South Africa, Sudan, Tanzania, Zambia and Zimbabwe, the lack of training and infrastructure were the biggest challenges members encountered (Kass et al., 2007), thus a call for formalised training to members was recommended as one effort in capacity-building. The literature has revealed different challenges for RECs in Africa, requiring attention to improve their efficacy in functioning and structural developments to meet standards that will promote generation of scientific knowledge for consumption without compromising the responsible conduct of research and research integrity. If RECs are compromised, it might be even worse challenging for newly

developed REC existing in low – mid income countries which has a high burden of disease. This potentiates the need for more exploration by researcher. It is therefore imperative that these new developed RECs have robust structures that would promote ethical conduct of research in their countries or regions. Malawi is one such example of the country that recently developed its two RECs and highly burdened with diseases and a low – mid income country.

2.5 The composition and functioning of RECs in Malawi

The high disease burden in Africa, the emergence of new diseases and efforts to address the 10/90 gap have led to an unprecedented increase in health research in Africa (Agunloye et al., 2014; Nyika et al., 2009). This increase in the burden has not spared Malawi. In this respect, the country has also experienced an increase in the number of research studies that it conducts, as other many African countries are experiencing. Consequently, the majority of countries in Africa are reported to have at least some form of ethical review in place (Kass et al., 2007) to review these studies.

With respect to Malawi, studies have shown the availability of two RECs in the country: namely COMREC and NHSRC (*The Framework of requirements and Guidelines for Research in the Social Science and Humanities in Malawi*, 30th May, 2011; Kirigia, Kathyola, Muula, & Ota, 2015; Mfutso-Bengo, Manda-Taylor, Jumbe, Kazanga, & Masiye, 2014; *National Health Research Agenda 2012 - 2016*, January, 2012; Ndebele & Mfutso-Bengo, 2007). The *National Health Research Agenda 2012-2016* of the Ministry of Health (MoH) in Malawi indicates that the conduct of biomedical research in Malawi dates back to the pre-independence era (i.e. years before 1964). The regulations on conducting research in Malawi are governed by the National Commission of Science and Technology (NCST) Act, also known as the Research Act(*The Framework of requirements and Guidelines for Research in the Social Science and Humanities in Malawi*, 30th May, 2011; Mfutso-Bengo et al., 2014; *National Health Research Agenda 2012 - 2016*, January, 2012). The Science and Technology Act delegates its powers to the National Health Sciences Research Committee (NHSRC) and the College of Medicine Research and Ethics Committee (COMREC) to review all health research in Malawi ("African Health Observatory: Health Research," ; *The Framework of requirements and Guidelines for Research in the Social Science and Humanities in Malawi*, 30th May, 2011; *National Health Research Agenda 2012 - 2016*, January, 2012).

However, there is limited published information with regard to functioning of these RECs in Malawi. On the other hand, some studies have advocated for the health research management forum to be proactive in advising on national health research policy and promote development of health research activities in Malawi (Kirigia et al., 2015). Therefore, there is a need for a functioning national health research system (NHRS) (Kirigia et al., 2015), that should work in collaboration with the RECs in ensuring the generation of scientific knowledge and promoting its use in pursuit of universal health coverage for the populace.

In Malawi, there are local laws and guidelines that guide the conduct of research in the country, such as law on informed consent(*Constitution of the republic of Malawi* 1993), as well as policy that guides issues of insurance on research-related matters (*National policy requirement and guidance for the provision of insurance cover for research participants in clinical trials in Malawi*, December, 2012), and law on the conduct of genetic studies in Malawi (*Policy requirements, procedures and guidelines for the conduct and review of human genetic research in Malawi*, September, 2012).

2.6 Study rationale

As described above, the responsibility to review and oversee the ethical conduct of health research in Malawi is delegated to the country's only two research ethics committees, namely the NHSRC and COMREC; each has distinct jurisdictions. The COMREC reviews and approves general health research proposals. These include clinical trials involving well-known and registered medications and vaccines, submitted by members of staff and students of the College of Medicine (COM) and Kamuzu College of Nursing (KCN), both constituent colleges of the University of Malawi (UNIMA), as well as their collaborators and research affiliates. All other types of health research, including clinical trials involving new drug and vaccine development, as well as genetic studies, are reviewed and approved by the NHSRC. Researchers and students who are not affiliated to the University of Malawi or its research affiliates also submit their health research proposals to the NHSRC. In this regard, the need for these REC bodies to be vigilant in overseeing the conduct of research in the country cannot be underestimated. This necessitates that these RECs should satisfy prescribed regulatory requirements to meet international standards (Council for International Organizations of Medical Sciences, 2002; Enfield & Truwit, 2008)and be well trained (Enfield & Truwit, 2008), in order to take up these responsibilities effectively.

As evident from the literature, there are several problems with the review and monitoring of health/biomedical research in Africa (Ndebele, Wassenaar, et al., 2014). Some of the challenges include: inadequately developed RECs (erratic meetings, poor leadership, etc.); lack of resources (computers, office space, etc.); limited or outdated legislation; overworked, and/or untrained REC members; low awareness of research ethics guidelines, and lack of training in bioethics and research ethics (Ndebele, Wassenaar, et al., 2014). However, some countries in Africa now have well-developed decentralised ethical review systems, whereas others have centralised systems (Ndebele, Mwaluko, et al., 2014; Silaigwana & Wassenaar, 2015).

Malawi being one of the low-income settings, where its RECs have just recently been developed and are developing, there is very limited information with regard to their functioning, as there is no documentation or studies that have been found on their composition and functioning. It is not known how Malawian RECs function and what challenges they encounter or whether these are similar to the challenges faced elsewhere in Africa. Hence, these areas are worth studying or exploring in the Malawian context.

It is against this background that this study explored and describes REC member insights into the structures, processes, responsibilities and needs of these RECs amidst the identified challenges faced by RECs in many African countries. Understanding the functioning and coping mechanisms and/or the existing challenges for Malawian RECs in this regard will necessitate proper attention to be given where it is due, to enhance the application of responsible and ethical conduct of research in the country. The results from this study may help to highlight the needs of RECs in the country. The highlighted needs and challenges may help to facilitate the establishment and implementation of solutions or lead to further investigation/studies that may help establish the root cause so as to rectify such challenges. Therefore, it may lead to finding better and informed solutions that could be devised to ensure the RECs meet internationally acceptable standards.

2.7 Aims and objectives

This study aimed to describe the structures, processes, responsibilities and needs of Malawi's two RECs.

Primary objective: To describe REC member insights into

1. The RECs' composition
2. The RECs' structures and affiliations;
3. The roles and responsibilities of REC members;

4. The RECs' processes and procedures;
5. The RECs' use of research ethics guidelines and frameworks;
6. The RECs' financial and material resources;
7. Perceived needs for REC training and/or capacity-strengthening; and
8. The review of the social value of research when reviewing protocols.

Secondary objective: To describe the common types of protocols these RECs review.

Chapter three: Research methodology

3.1 Study design

This study used a mixed method approach where quantitative descriptive cross-sectional survey and a retrospective record review/document analysis design were used. Descriptive cross-section design was chosen because it is used where more information is required in a particular field, as it occurs naturally, with no intention of establishing a cause-effect relationship (Brink et al., 2006). Cross-sectional studies are used to examine data at one point in time, on one occasion only, and with different participants(Brink et al., 2006). In this study, the data were collected at one point in time with different participants of different experiences and different numbers of years having worked in their respective RECs. Hence, we selected a cross- sectional survey design for this study. The gathered information helped in describing the structures, processes, responsibilities and needs of the RECs. The following variables and components were assessed using a survey questionnaire: each REC member's demographics, training, guideline use, REC procedures, financial and material resources, affiliation, and composition.

The cross-sectional survey had some challenges especially with participants who had very little experience and had worked with the RECs for a short period of time; these participants thus had limited knowledge with which to answer some of the questions in the questionnaire. The questionnaire had a combination of both closed and open-ended questions which gave direction and guidance where the participants felt lost or unfamiliar with the questions (see Appendix 1).On the other hand, adopting this design gave us more advantages than disadvantages, in that it provided a combination of long-serving and experienced members with novice members. This gave the strength to the study in that those who served the HRECs longer and with experience gave out their vast knowledge and experiences of the HRECs, while on the other hand, the novice members were able to identify some of the challenges, which they considered to be a normal routine considering their lack of knowledge, experience and expertise. To establish the trend and common types of protocols these RECs review, I reviewed the minutes, and agenda where the titles and aims of the studies where documented. These documents were retrospectively analysed.

3.2 Sampling

The study focused on RECs which review health research protocols; those RECs whose focus was on other disciplines of research were not eligible and were not included in this study. The biomedical research ethics committees were chosen in this study because, most

of the time, they review studies which have a variety of risks; this requires constant vigilance and protection through the knowledgeable committees. Therefore, since Malawi had only two RECs which review health research protocols, both of these RECs were invited to participate in the study. All REC members and members of the secretariats of the two RECs who gave consent to participate were included in the study. There were a total of 31 REC members from the two RECs. However there was a cross-representation of three members from one REC and two from the RECs into the sister RECs. This cross-representation made the prospective total study population to be 26 REC members to be invited to participate in the study, if they consented as the cross-representing members would not be invited twice from the same study despite they belonged to both two REC. In addition to the REC members, two members were also invited from the secretariat of each REC to participate in the study, which made a total targeted study population size to 30.

The minimal sample size that was required for this study was 30. This minimal sample size was reached in consideration of the rule which states that "preferably a minimal of 30 participants is needed per variable or phenomenon"(Brink et al., 2006:137). Therefore, since this study had a limited number of potential participants who could be invited to participate, therefore one of the rules of factors that influence the choice of samples size was applied, in this regard the required minimal number of 30 was adopted to substantiate the limited number of potential participants.

Following this limited number of potential participants, the non-probability convenience sampling method was used to recruit the participants. Convenience sampling involves choice of readily available participants that happen to be in the right place at the right time (Brink et al., 2006). This sampling method was used since other sampling methods could not have been used to yield valid data due to the few participants who were available for the study. The study got an 80% response rate as outlined in the Table 3.1 below.

Table 3.1: Total population and sample size

	(N)	**(n)**
NHSRC	16	13
COMREC	14	11
Total	**30**	**24**

Key: **(N)** = Targeted number of participants
(n) = Actual number of participants recruited

3.3 Data collection

A self-administered questionnaire was developed by adapting two pre-published data collection instruments by Milford et al.(2006) and Kass et al. (2007). However minor modifications were made to suit the aim and the purpose of our study on Malawi RECs that review health research. The self-administered questionnaire aimed to gather information on demographics, composition, functioning, training, guideline use, REC procedures, laws regulating research, financial and material resources and affiliations of the RECs. The questionnaire contained both close ended and open-ended questions. For the open-ended questions, the participants were asked to explain and elaborate their experiences, perceived ideas and description of the phenomenon being asked.

The questionnaires were self-administered to the members of RECs by the student investigator. The questionnaire aimed at gathering information from the prospective participants that helped to describe the RECs in Malawi. Proper arrangements were made so that the questionnaires were handed to the prospective participants during their meetings. REC members who were not available for meetings were contacted by telephone or email, to ask them if they were willing to participate in the study. The contacts of the REC members were collected from the RECs' respective secretariats. The completed questionnaires were collected back by the student investigator.

Those who did not complete the questionnaire immediately were given one week to complete and send it back to the student investigator. The participants who were contacted telephonically or by email either sent their questionnaires back by personally getting the questionnaire back, or some scanned the questionnaires and emailed them back to the student investigator. The participants were asked not to write their names on the questionnaires; instead number coding system was used. The number coding system was used to facilitate confidentiality of the participants, but also helped with the follow-up of the collected information by ensuring that the number of questionnaires which were issued and those which had been responded to (or not)could be noted for data analysis purposes.

With the help of the supervisor, the questionnaire was only piloted to establish the minimal time that would be required to complete the questionnaire and the questions themselves in the questionnaire were not piloted since we adopted pre-established questions which had been already used on other studies

3.4 Data analysis

The data collected from the questionnaires were analysed using descriptive statistics. Descriptive statistics are used to describe and summarise data (Brink et al., 2006). Descriptive statistics convert and condense a collection of data into an organised visual representation, in a variety of ways, so that data have some meaning for the readers of the research report (Brink et al., 2006). As highlighted above, the questionnaire contained open and closed ended questions. The responses to closed-ended questions were captured on the data capturing sheet. These data were analysed by the statistician using statistical software STATA 2016 (See Appendix 5). The mean or median with standard deviation for continuous data was described. The nominal outcome used Fisher's exact test and/or Chi-square test to determine the significance of the association of variables. The error of margin for this study predicated was 50%$\pm$5%. In order to determine the trend of REC's composition in Malawi but also to assess the workload REC members have with regard to reviews of the protocols; research agendas and minutes were be used. The minutes and agendas, contains, number of protocols reviewed per meeting as well as the reviewer profession, therefore the data was manually analysed through reading and counting numbers. The results of the closed-ended questions were presented in descriptive statistics including frequencies or percentages for categorical data as outlined in Chapter four.

The open-ended questions were analysed using content analysis/inductive analysis. The content analysis involved multiple readings and interpretations of the raw data from participants' explanations and descriptions(Thomas, 2006). The student researcher then read through all the responses to the open-ended questions and coded them. All similar responses were categorised and colour coded (See Appendix 4). Where possible, the themes or common responses were generated from these coded responses. These themes were analysed in relation to the existing literature. The results are presented in a thematic descriptive format in chapter four.

3.5 Ethical considerations

This study used Emanuel's framework (Emanuel et al., 2004) to ensure implementation of the ethical considerations during the conduct of the study by adhering to the eight ethical benchmarks as described below (Emanuel, Wendler, Killen, & Grady, 2004; Wassenaar & Mamotte, 2012).

Collaborative partnership

Collaborative partnership is synonymous with the coalition which is a formal alliance of organisations, groups and agencies that have come together to work for a common goal(Centers for Disease & Prevention, 2005).We sought the collaboration of the NCST and respective RECs in order for us to conduct this study with the members of the RECs. This study requested active participation and involvement of the REC members. We also got the RECs' approval and input to ensure that the research was in line with their interests and needs, which helped to ensure that they got the benefit of the research and were not exploited.

Scientific validity

To ensure the scientific validity of this study, the study was reviewed by the Higher Degree Postgraduate Committee of the University of KwaZulu-Natal. The student investigator also adopted the pre-established data collection instruments by Milford et al. (2006) and by Kass et al. (2007), which were scientifically validated already which enhanced the scientific validity of this study. The adoption of the data collecting instruments rendered the study its rigor, justifiability, and feasibility which led to valid answers to the research question, and thereby yielding ethical results that could be generalised.

Social value

As outlined in a study by Wassenaar& Mamotte (2012), research should address questions that are of value to society or particular communities in society. One aspect of this study aimed at establishing the capacity of the RECs to review protocols. This aspect was not previously known for the Malawian RECs. Understanding their functioning and composition, as well as other components of their day-to-day work of reviewing protocols would benefit their capabilities in reviewing them. Therefore, this study highlighted areas requiring strengthening in RECs, so that their oversight could consider the social value of the studies presented to them. By addressing the identified shortfalls that emerged from the results of this study, it is hoped that effective approaches to addressing such shortfalls will help to improve reviewing health/biomedical research protocols that will benefit the populace of Malawi and abroad.

Fair participant selection

The study population needs to be those participants who will give valid and authentic information about the phenomenon that is being investigated(Brink et al., 2006). In this

study, to gather such valid and authentic information about the composition and function of RECs in Malawi, all REC members were eligible to participate. The selection criteria provided a fair platform for all members to share their views of the composition and functioning of RECs in the country. Fair participant selection was based on the objectives of this study and availability of the participants. This study used the convenience sampling method, which rendered all prospective participants available to participate.

Risk and benefits

There were no risks involved in this study. This study did not interfere with participants' professionalism, cultural beliefs, or their dignity. Participants were requested to complete a questionnaire. Concerns about the reputation of the RECs were taken care by ensuring the disassociation of the names of the participants and/or the RECs they belonged to, so that the report generated from this study does not impact on a specific participant or REC. Participants' responses were kept anonymous by number coding of the questionnaires and letter coding of the prospective REC. Therefore, the reputation of each REC was maintained.

The benefit of this study was to highlight/identify the challenges that exist which will prompt devising solutions to rectify the problems and challenges faced, or it will prompt further studies to establish solutions.

Oversight: Independent ethical review

To ensure public accountability and to minimise concerns regarding the student investigator's conflicts of interest, this study was subjected to an independent, competent, and transparent ethical and scientific review. The proposal was reviewed and approved for ethical and scientific rigour by the Biomedical Research Ethics Committee of the University of KwaZulu-Natal approval number BE090/17. In addition, local ethical clearance was received from the National Health Sciences Research Committee (NHSRC) in Malawi approval number 1766 (see appendix 3).

Informed consent

Informed consent shows respect for research participants and their autonomy. It is also a way of empowering research participants to make their own decisions whether or not to participate in the study. To ensure voluntary participation and autonomous decision-making, the participants of this study were provided with the information leaflet (see Appendix 2)which provided information about this study, and as a requirement, the prospective

participants were required to read through, understand the information and provide their own informed and autonomous decision and written consent (Brink et al., 2006). Informed consent was then obtained from each of the participants who took part in this study.

Post-study obligation

Disseminating the research results and providing feedback to participants normalises and contextualises their reaction and experience (Wassenaar & Mamotte, 2012). The student investigator will give feedback to the participating HRECs through their chairpersons. Arrangements will also be made for the student investigator to present the findings to the REC members during their monthly/bi-monthly REC review meetings so that wide memberships can be reached and appreciate the findings of the study they participated in. The results will help the participants and participating HRECs to make improvements where necessary.

3.6 Validity and reliability

The validity, reliability and rigor of this study were maintained by the use of a pre-established data collection instrument (questionnaire), adopted from Kass et al. (2007) and Milford et al. (2006), which was already tested and proven to be valid. Milford et al. (2006) instrument had been used in other studies like the study by Ikungura et al. (2007)on the REC review of institutional research ethics committees in Tanzania. The instrument proved to yield valid results. Therefore, adopting this pre-established data collecting instrument enhanced the conformity of the results this study with other studies, therefore ensuring validity, reliability and trustworthiness of the findings for this study. This meant that the finding might be transferable to other setting with similar environments. The questionnaire contained open-ended-questions which sought to get personal opinion from the participants. By including the open-ended questions, we wanted to assess the degree of similarity of opinions from the participants on the same variable. Obtaining the same or similar responses in these variables ensured the trustworthiness of the information that we gathered from the study; as such, it rendered our study valid.

Chapter four: Results

4.1 Introduction

This chapter presents results of the analysis of the structures, processes, responsibilities and needs of RECs that review health research in Malawi, with a focus on the RECs' structure and affiliations; the roles and responsibilities of REC members; the REC processes and procedures; the RECs' use of research ethics guidelines and frameworks; the RECs' financial and material resources; perceived needs for REC training and/or capacity-strengthening; and where relevant, the assessment of research according to the benchmark of social value when reviewing protocols.

4.2 REC structure and affiliations

4.2.1 Demographics

Table 4.1 presents results of analysis of participants' demographic characteristics. Of the sample of 24 participants who consented to participate in the study, two were REC chairpersons (8.3%), one was a vice-chairperson (4.2%), 19 were REC members (79.2%) and two were REC administrators (8.3%).

Twenty-one REC members(91%) indicated that they were paid for REC work. Among the 21 participants who indicated that they were paid for their work, 11 (52%) were paid for each meeting they attended, 7 (33%) were paid per diem, 1 (4%) and 2 (9%) indicated being paid on salary and honoraria respectively. Among the 22 participants who responded to a question about their position at the institution, 9(41%) were lecturers, while 13 (59%) had other positions than 'lecturer' position. Among these other positions were: director of research, nurse, medical doctor, administrator, ethicist, clinical pharmacist, nutritionist, biomedical scientist and teacher. Seventy-one percent of the participants (17) had gone as far as Masters Level in their education, 5 (20%) had PhD and 2 (8%) only had a certificate.

The maximum and minimal number of years of participants on the REC was 22 years and 1year. On average, the participants had been on the REC for 5.29 years (SD=4.59). One of the participating RECs was a national REC while the other one belonged to an institution. When asked when the RECs were created, only 5 (20%) responded to the question and indicated different years: 1974 (3), 1988 (1) and 1993 (1). One hundred percent of the participants responded that the RECs were created to promote high quality research, and safeguard/protect the human participants from harm that may be generated from the

research. All respondents indicated that the HRECs had received Federal Wide Assurance (FWA), but none was sure of the date they received it.

Table 4.1: Demographics

Characteristic	*n* (%)
Position in REC	
Chairperson	2 (8.3)
Member	19 (79.2)
Vice-chairperson	1 (4.2)
Administrator	2 (8.3)
Paid for REC work	
No	2 (8.7)
Yes	21 (87.5)
No response	1(4.2)
Type of pay	
Per diem	7 (29.2)
Per meeting	11 (45.8)
Honoraria	1 (4.2)
Salary	2 (8.3)
No response	3(12.5)
Position at institution	
Lecturer	9 (37.5)
Other	13 (54.2)
No response	4 (8.3)
Educational level	
MSCE	2 (8.3)
Masters	17 (70.8)
PhD	5 (20.8)
Number of years on REC	Mean = 5.29 (4.59)

In the preceding section the researcher aimed at assessing the REC member's training history on research ethics besides their academic qualifications.

4.2.2 Training history

The understanding of REC members training in research ethics provided the researcher with knowledge of how many the REC members had knowledge of research ethics, in what area and to what extent. In the same vain this highlighted areas that need further training.

Figure 4.1 presents results of participants' training history prior to and since joining the RECs. In the sample of 24 participants, only 8(33.3%) had research ethics training prior to joining the RECs, compared to 20 (83.3%) who had research ethics training since joining the RECs. All REC members indicated that training included attending a two-three day training workshop.

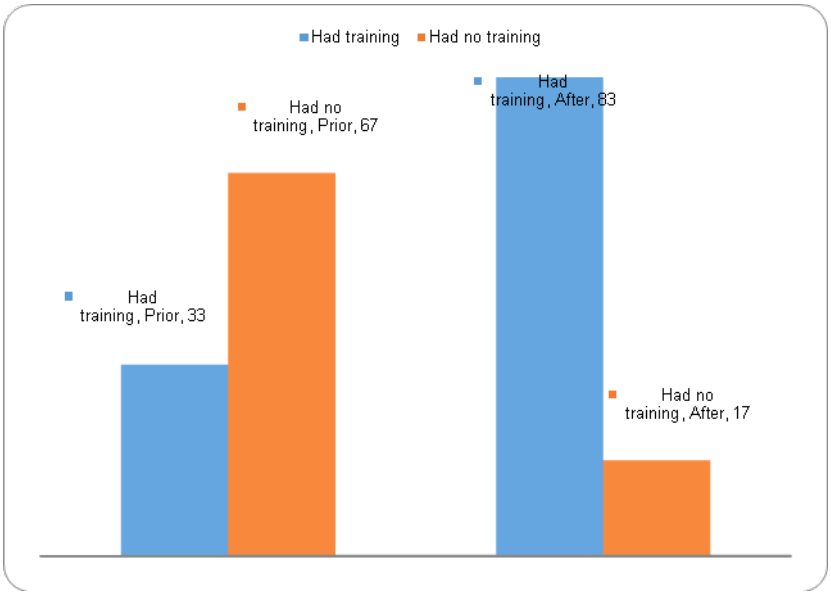

Figure 4.1: Research Ethics training history

The table above reflects that few people had training in research ethics prior to joining the RECs, however in the course of their membership many members were trained in research ethics.

4.2.3 Professions of REC members

It is imperative to have a diverse composition of the research ethics committee. This section aimed at establishing to understood the diversity of members forming the RECs in Malawi. Table 4.2 presents the results of the professional background of participants for the two RECs. REC A had 41% who were medical doctors, while the rest (59%) of the members' occupations included biomedical scientist, ethicist, nutritionist, nurse, health manager, public health officer, epidemiologist and social scientists. REC B had 71% of its members who

were medical doctors. Nurses made up14.3% of this REC's members, while 7.1% was made up of a teacher and an ethicist, respectively.

Table 4.2: Professions of REC A and B members (2017)

Characteristics REC A	Year 2017 n (%)	Characteristics REC B	Year 2017 n (%)
Medical doctors	7 (41)	Medical doctors	10 (71.4)
Nurses	1 (5.9)	Nurses	2 (14.3)
Bioethics/Ethicists	1 (5.9)	Bioethicist/Ethicist	1 (7.1)
Teachers	1(5.9)	Teacher	1(7.1)
Biomedical scientist	1 (5.9)		
Epidemiologist	1(5.9)		
Nutritionist	1 (5.9)		
Social Scientist	1 (5.9)		
Health Manager	1 (5.9)		
Pharmacist	1 (5.9)		
Public Health Officer	1 (5.9)		

4.2.4 Composition of RECsfor the past five years (2012 to 2017)

As reflected in Table4.3,the medical doctors have throughout the period of five years dominated the composition of the REC A, with average of 41.5% of the composition being medical doctors, with the remaing 58.5% being distributed among other professions. There has been a greater diversity in its composition for REC A, as its composition reflects a number of members with different professional background.

Table 4.3: Composition of REC A for the past five years (2012 – 2017)

BACKGROUND	2012	2013	2014	2016	2017
Nurse	2	2	2	1	1
Biomedical scientist	1	1	1	1	1
Medical doctor	7	8	8	7	7
Ethicist	2	1	1	1	1
Biostatistician	1	1	1	0	0
Teacher	1	1	1	1	1
Epidemiologist	1	1	1	1	1
Nutritionist	0	0	0	1	1
Social scientist	1	1	1	1	1
Health system manager	0	0	0	1	1
Pharmacist	1	1	1	1	1
Public health officer	2	2	2	1	1

Similar to REC A, REC B has also been dominated by medical doctors for the past five-year period, with an avarage dominance of 67.2%, withthe remaing 32.8% distributed among other professions as reflected in table 4.4 below. However,there is a contrast in the diversity of REC B as compared to REC A, in that there is little diversity of member background in REC B. It is limited to few professional backgrounds.The data was adopted from the RECs' archived minutes of2012 to 2017.

Table 4.4: Composition of REC B for the past five years (2012 – 2017)

BACKGROUND	2012	2013	2014	2016	2017
Nurse	2	0	2	2	2
Medical Doctor	9	8	8	8	10
Ethicist	0	1	1	1	1
Biostatistician	0	1	1	0	0
Teacher	1	1	1	1	1
Pharmacist	0	1	0	1	0

4.2.5 Common professions of REC members

Our study revealed that, the most common professionals which were found in both REC A and REC B included: medical doctor, nurse, ethicist/bioethicist, and teacher. Member representation of these professionals was represented as indicated in the table 4.5 below for REC A and REC B.

Table 4.5: Common professions in REC A and B (2012 – 2017)

REC A

Profession	Year	n (%)
	2012 (n=17)	
Medical doctor		7 (41.2)
Nurse		2 (11.7)
Bioethicist/Ethicist		2 (11.7)
Teacher		1 (6)
	2013 (n=19)	
Medical doctor		8 (42)
Nurse		2 (10.5)
Bioethicist/Ethicist		1 (5.3)
Teacher		1 (5,3)
	2014 (n=19)	
Medical doctor		8 (42.1)
Nurse		2 (10.5)
Bioethicist/Ethicist		1 (5.3)
Teacher		1 (5.3)
	2016 (n=17)	
Medical doctor		7 (41.2)
Nurse		1 (6)
Bioethicist/Ethicist		1 (6)
Teacher		1 (6)
	2017 (n=17)	
Medical doctor		7 (41.2)
Nurse		1 (6)
Bioethicist/Ethicist		1 (6)
Teacher		1 (6)

REC B

Profession	Year	n (%)
	2012 (n=14)	
Medical doctor		9 (64.3)
Nurse		2 (14.3)
Bioethicist/Ethicist		0 (0)
Teacher		1 (7.2)
	2013 (n=14)	
Medical doctor		8 (57.2)
Nurse		0(0)
Bioethicist/Ethicist		1 (7.2)
Teacher		1 (7.2)
	2014 (n=13)	
Medical doctor		8 (61.5)
Nurse		2 (15.4)
Bioethicist/Ethicist		1 (7.7)
Teacher		1 (7.7)
	2016 (n=13)	
Medical doctor		8 (61.5)
Nurse		2(15.4)
Bioethicist/Ethicist		1 (7.7)
Teacher		1 (7.7)
	2017 (n=14)	
Medical doctor		10 (71.4)
Nurse		2 (14.3)
Bioethicist/Ethicist		0 (0)
Teacher		1 (7.2)

4.2.6 Community members on theREC

When asked,all REC members confirmed that they had community members serving ontheir RECs. While majorityof REC members indicated they were not aware how the community memberswere recruited, only 5 (21%) said that advertisement is published and those interested apply; interviews follow after which the succesful community member is hired to

work.Only two community members particitipated in our study found that one from each REC. All the community members in both RECs had‘education’ as their professional background.One community member had degrees in education as his/her highest qualification and the otther one had a certificate.

4.3 Roles and responsibilities of REC members

This section presents results of analysis of the roles and responsibilities of the REC members, focusing on type of research they review and review of clinical and vaccine trials.

4.3.1 Roles of the chairperson and vice-chairperson

All the participants indicated that the responsibilities of the chairperson were to chair meetings and invite expert reviewers. Some participants also indicated that REC chairs provide advice to REC members and ensure maintenance of law and order. Vice-chairs worked as above in absence of the chairperson.

4.3.2 Types of research reviewed by REC members

Beside understanding the diversity of the REC members and the different roles that they do. The researchers aimed also to understand the types of research they commonly review. As indicated in table 4.6 below, all 24 participants acknowledged that they routinely review public health, laboratory, and health systems research. A total of 22 (91.6%) indicated that they equally review product intervention and/or implementation research, while about 13 (54.2%) indicated they review social science research.

Table 4.6: Types of research reviewed by REC members

Research type		n (%)
Public health	Yes	23 (95.8)
	NR	1 (4.2)
Laboratory	Yes	23 (95.8)
	NR	1 (4.2)
Health systems	Yes	23 (95.8)
	NR	1 (4.2)
Product and intervention	Yes	22 (91.6)
	No	1 (4.2)
	NR	1(4.2)
Implementation	Yes	22 (96.1)
	No	1 (4.2)
	NR	1 (4.2)
Social sciences	Yes	13 (54.2)

	No	10 (41.6)
	NR	1 (4.2)
Clinical trials		
	Yes	20 (83.3)
	No	3 (12.5)
	NR	1(4.2)
Clinical trials type/phases		
Phase I	Yes	5 (20.8)
	No	7 (29.2)
	NR	12 (50)
Phase II	Yes	11 (45.8)
	No	1(4.2)
	NR	12 (50)
Phase III	Yes	12 (50)
	NR	12(50)
Phase IV	yes	6 (25)
	No	6 (25)
	NR	12 (50)
Vaccine trials		
	Yes	17 (70.8)
	No	5 (20.8)
	NR	2 (8.3)
Types of vaccine trials		
Malaria	Yes	14 (58.3)
	No	1 (4.2)
	NR	9 (37.5)
HIV	Yes	8 (33.3)
	No	7 (29.2)
	NR	9 (37.5)
TB	Yes	7 (29.2)
	No	8 (33.3)
	NR	9 (37.5)
HPV	Yes	2(8.3)
	No	11 (45.8)
	NR	11 (45.8)
Hepatitis	Yes	1 (4.2)
	No	12 (5)
	NR	11 (45.8)

4.3.3 Clinical trials reviewed by RECmembers

With reference to table 4.6 above, eighty-three percent (20) of the participants acknowledged that they review clinical trials.

On enquiry, those who said they do not review clinical trials said this was because most clinical trials are of national interest and they are reviewed at a higher level, thus they rarely review them.The participants indicated that mainly they review Phase II and III clinical trials and a few Phases I and IV.

Participants were also asked whether they review vaccine trials;¨17 (70.8%)indicated that they review vaccine trials.However, similar to clinical trials, those who indicated that they do not review vaccine trialsexpressedthe same reason that vaccine trials were of national interest and are reviewed at a higher level.Participants acknowledged malaria vaccine trials were the most common trials they had reviewed, followed by HIV and TB vaccine trials. The least common were HPV and hepatitis trials as referenced from table 4.6 above.

In pursuit to enhance the protection of human participants involved in various studies, it was imperative for the research to assess and understand the processes that the RECs follow in reviewing the studies. In the next section the process and procedures were examined for the two participating RECs

4.4 REC processes and procedures

This section presents results of the analysis of processes and procedures that RECs follow in relation to: frequency of meetings; use of electronic review; forming a quorum; number of protocols per meeting; discussions where members vote at meetings; annual review processes; operating manual guidelines; minutes of meetings; and challenges they face for the smooth operation of the review process.

REC A met bi-monthly, while REC B used to meet monthly. Both the RECs used to meet in person. REC B had an electronic review system; however, it was never in use, as most members indicated that it was not user friendly. Another challenge which was highlighted was internet connectivity, as they experienced intermitted internet connectivity. Since all RECs met in person, they both reported that they never experienced any challenges with forming a quorum for their deliberations.

4.4.1 REC review workload per meeting

Malawi faces a high influx of protocols that the RECs need to review. It is evident from the registries and agendas of RECs that there has been a steady increase in the number of research protocols (new applications) that Malawi's RECs A and B receive for review almost

every year, as illustrated in Figures 4.2 and 4.3 below from. The data is adopted from the RECs' agendas from 2004 to 2016.

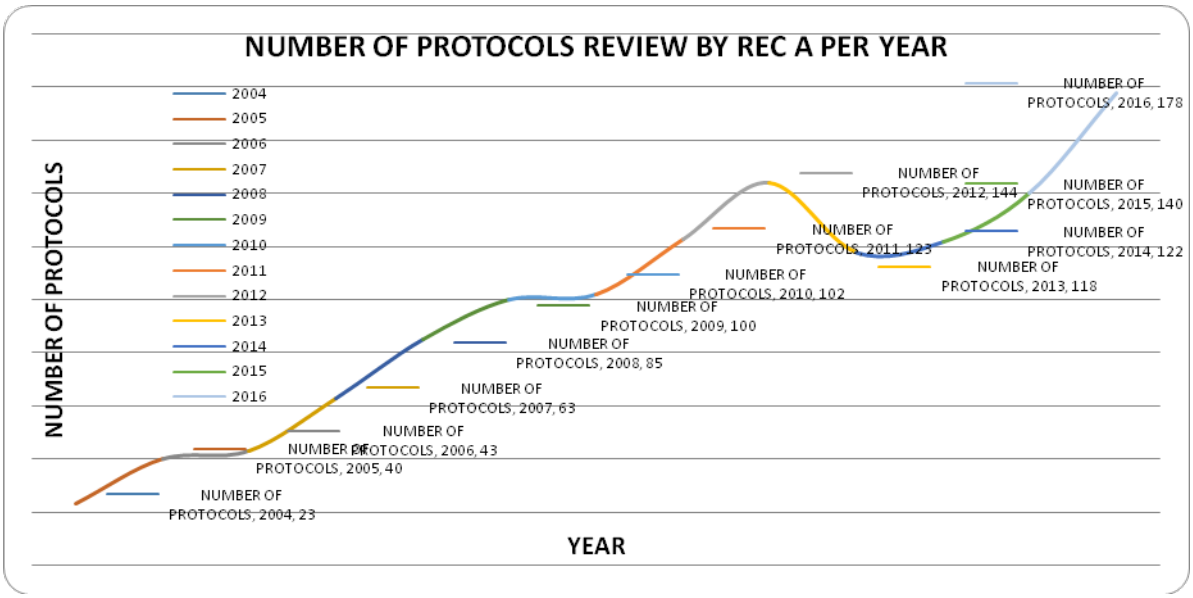

Figure 4.2: Number of protocols reviewed by REC A per year

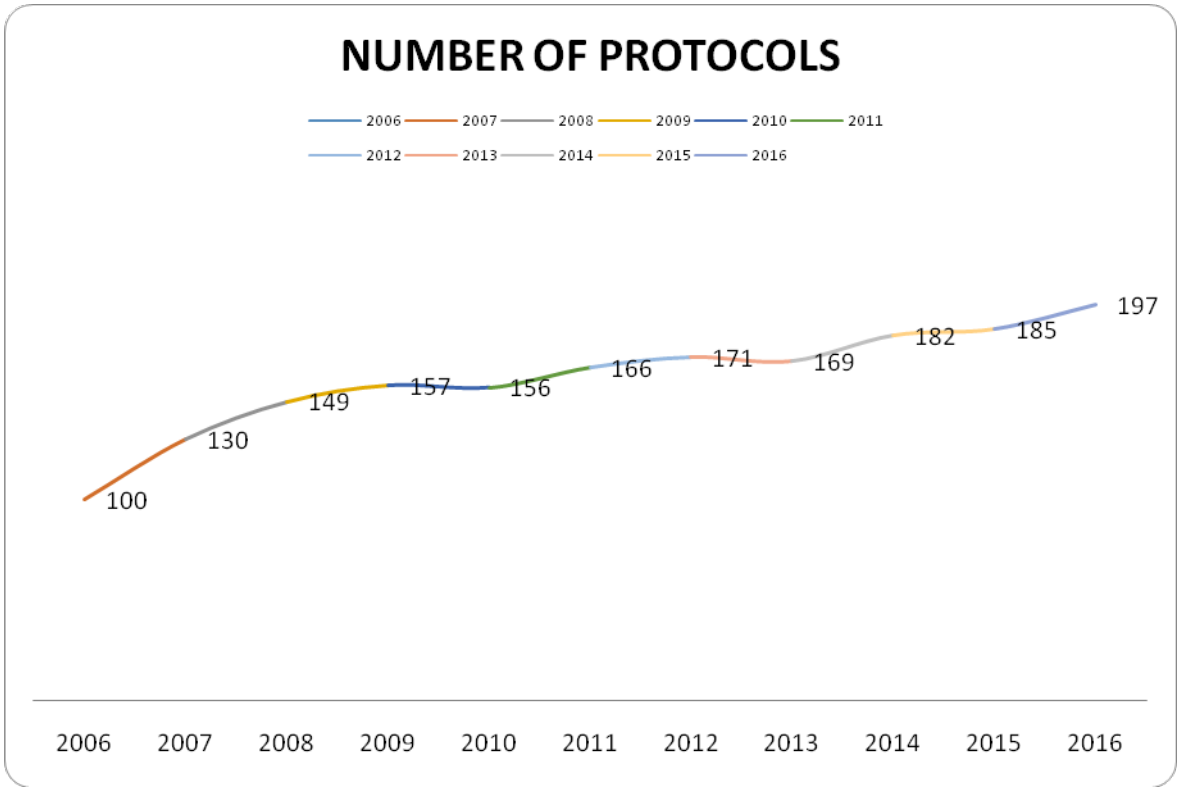

Figure 4.3: Number of protocols reviewed by REC B per year

On average, both RECs reviewed 33.5(SD:11.4) protocols per month, which included all protocols, whether minimal or more than minimal risk research. During the review meeting, the REC members reported that they discussed or voted on submissions of either serious adverse effects, minimal risk research, amendments, and more than minimal risk research, as well as final reports and annual progress reports as outlined in figure 4.2 below.

Table 4.7: Issues voted on or discussed during REC processes

Voted/Discussed	**n (%)**
Serious adverse events (SAEs)	
Yes	22 (91.7)
NR	2(8.3)
Minimal risk research	**n(%)**
Yes	22 (91.7)
NR	2(8.3)
Amendments	**n(%)**
Yes	21 (87.5)
No	1 (4.2)
NR	2 (8.3)
More than minimal risk research	**n(%)**
Yes	20 (83.3)
No	2 (8.3)
NR	2 (8.3)
Final report	**n(%)**
Yes	19 (79.2)
No	3 (12.5)
NR	2 (8.3)
Annual progress report	**n(%)**

Yes	19 (79.2)
No	3(12.5)
NR	2 (8.3)
Separate review of minimal risk research	**n(%)**
Yes	11 (45.8)
No	11 (45.8)
NR	2 (8.3)
Separate review for continuing research	**n(%)**
Yes	8 (33.3)
No	14 (58.3)
NR	2 (8.3)

Separate review of minimal risk research: The results reflect equal response rates as noted from table 4.7 above. This reflects that one of the RECs, especially the academic REC, reviewed all research proposals whether for minimal risk or more than minimal risk studies during their review cycle. On the other hand, the other REC did a separate review of minimal risk researches reflected by the 11 (45.8 %) of the responding participants who indicated “No”. The other11 (45.8%) (11) who acknowledged to conducting separate reviews for minimal risk research indicated that the process is done through expedited review where a minimal of three reviewers or a chairperson advises.

Continuing research: Seemingly, there is no separate review for continuing research as most participants responded that they do not do this or they were not sure if they do. For those who said that they do conduct separate review of continuing studies, they indicated that it is done by at least two members of the committee as reflected in table 4.7 above.

4.4.2 RECSOPs, manuals and guidelines

Ninety five percent(23)of the participants who responded to this question indicated that their REC had SOPs, manuals and guidelines. The participants indicated that these materials can

be obtained/accessed on the respective REC's website, while some indicated that these can be accessed directly at the secretariat.

The participants also acknowledged that their REC keeps minutes of its meetings. When the members were asked if their REC brings in consultants, most participants indicated that they rarely bring in consultants as their committee has all the expertise they require. Thus, they only bring them in when a special consultant is essential. However, it was also reported through this study that the most common types conflict of interest were: REC member submissions, relative or friend submission and financial conflicts, which were apparent for both RECs.

4.4.3 Challenges RECs face

Figure 4.4 presents results of challenges that these RECs face in implementing their operations. In the sample of 24 participants, 14 (58.3%) agreed that lack of audit mechanisms was the main challenge (among others) that RECs in Malawi face which sets back their functioning. Other challenges that the participants highlighted infrastructural challenges such as lack of adequate office space for storage, lack of adequate ICT services and transport challenges.

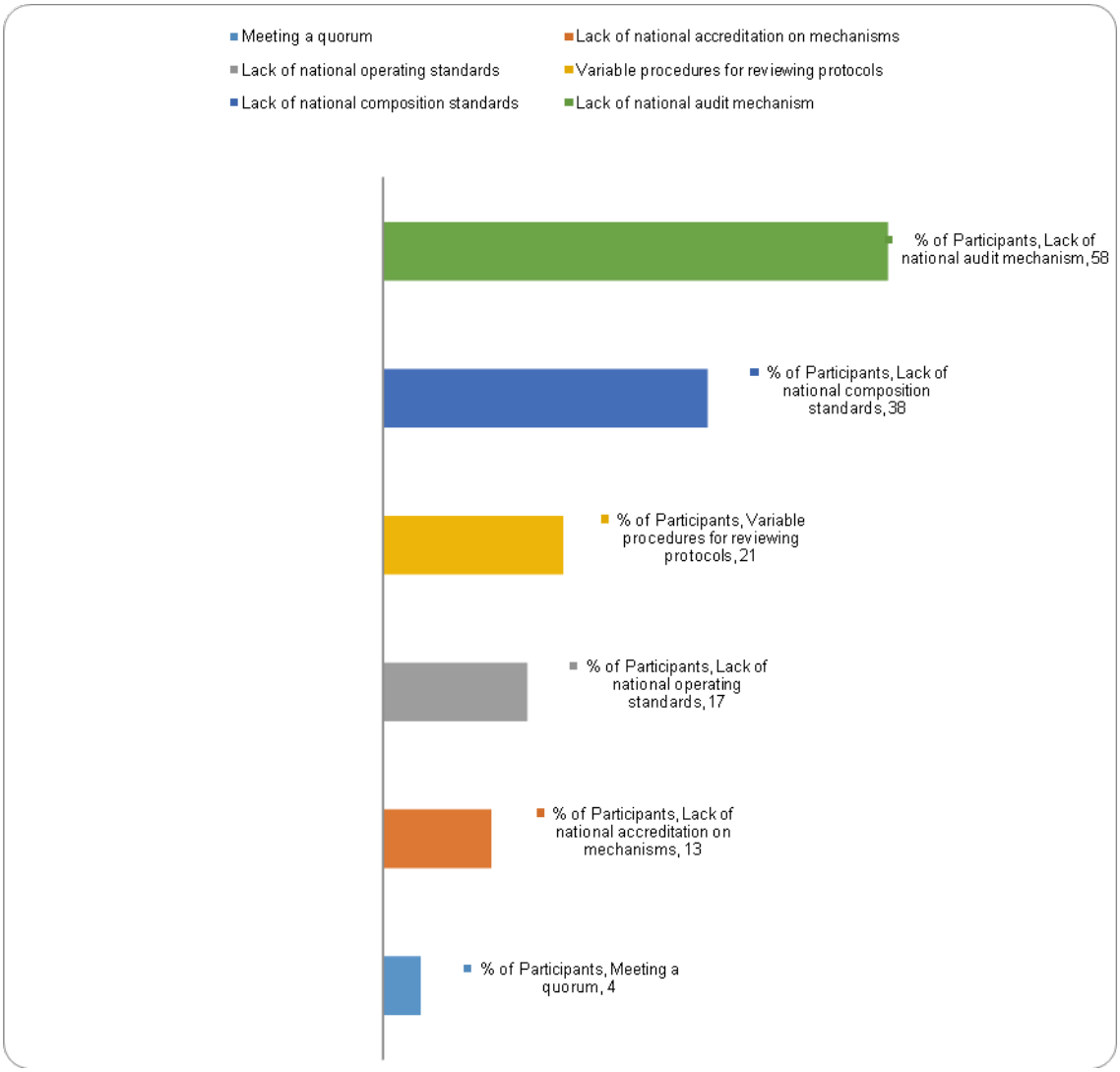

Figure 4.4: Challenges faced by RECs

In order for the system to function or run smoothly, there were need for guiding principles, such as terms of references, frames works, ethical guiding principles etc. In the next section the researcher examined the structures that were used or put in place to ensure that their review of protocols run smoothly

4.5 REC use of research ethics guidelines and frameworks

This section presents results of the analysis of the RECs' use of research ethics guidelines and frameworks, focusing on: whether they use both local and international guidelines; how they rate the international guidelines, and challenges they face in implementing them.

4.5.1 Use of local research ethics guidelines

Figure 4.5 presents results of analysis of use of local research ethics guidelines. It is clear from the results that 20 (83.33%) of the participants indicated that they use local research ethics guidelines.

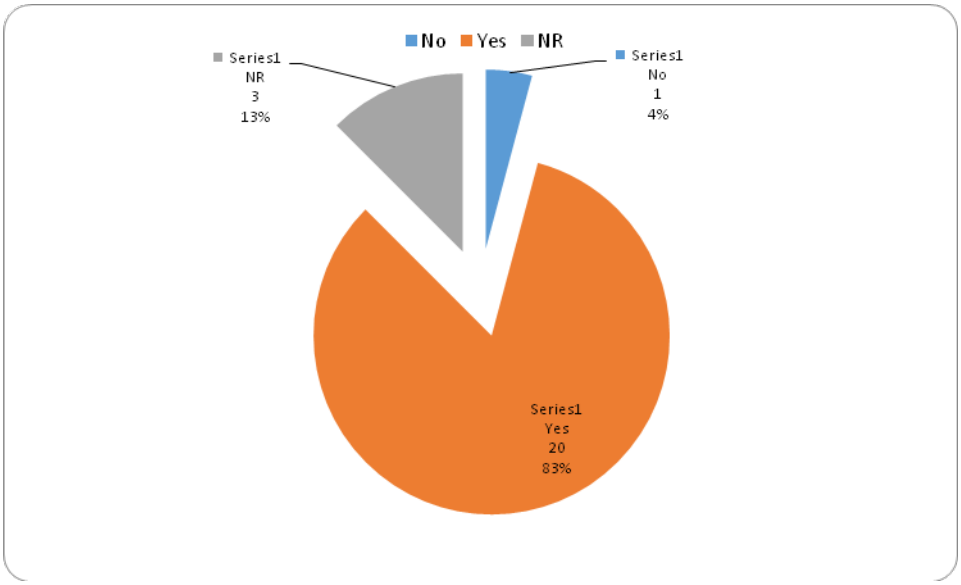

Figure 4.5: Use of local ethical guidelines

Some of the guidelines that the participants acknowledged using include: the guideline for the conduct of genetic studies, guidelines for handling biospecimens, guidelines for provision of insurance cover, and general national guidelines(*National policy measures and requirements for the improvement of health research co-ordination in Malawi*, November, 2012; *National policy requirement and guidance for the provision of insurance cover for research participants in clinical trials in Malawi*, December, 2012; *Policy requirements, procedures and guidelines for the conduct and review of human genetic research in Malawi*, September, 2012).

4.5.2 Use of international guidelines

Figure 4.6 indicates that, ninety-one percent (22) indicated that they use the World Medical Association Declaration of Helsinki (2013); 20 (83.33%) indicated they use Good Clinical Practice(GCP); 18 (75%) indicated they use the Council for International Organisation of Medical Science(CIOMS); 11 (45.83%) indicated they use the Belmont Report (1979); 10 (41.61%) indicated they use the United Nations Programme on HIV/AIDS(UNAIDS). The rest of the participants indicated either “No” or “Don’t know” to other international guidelines.

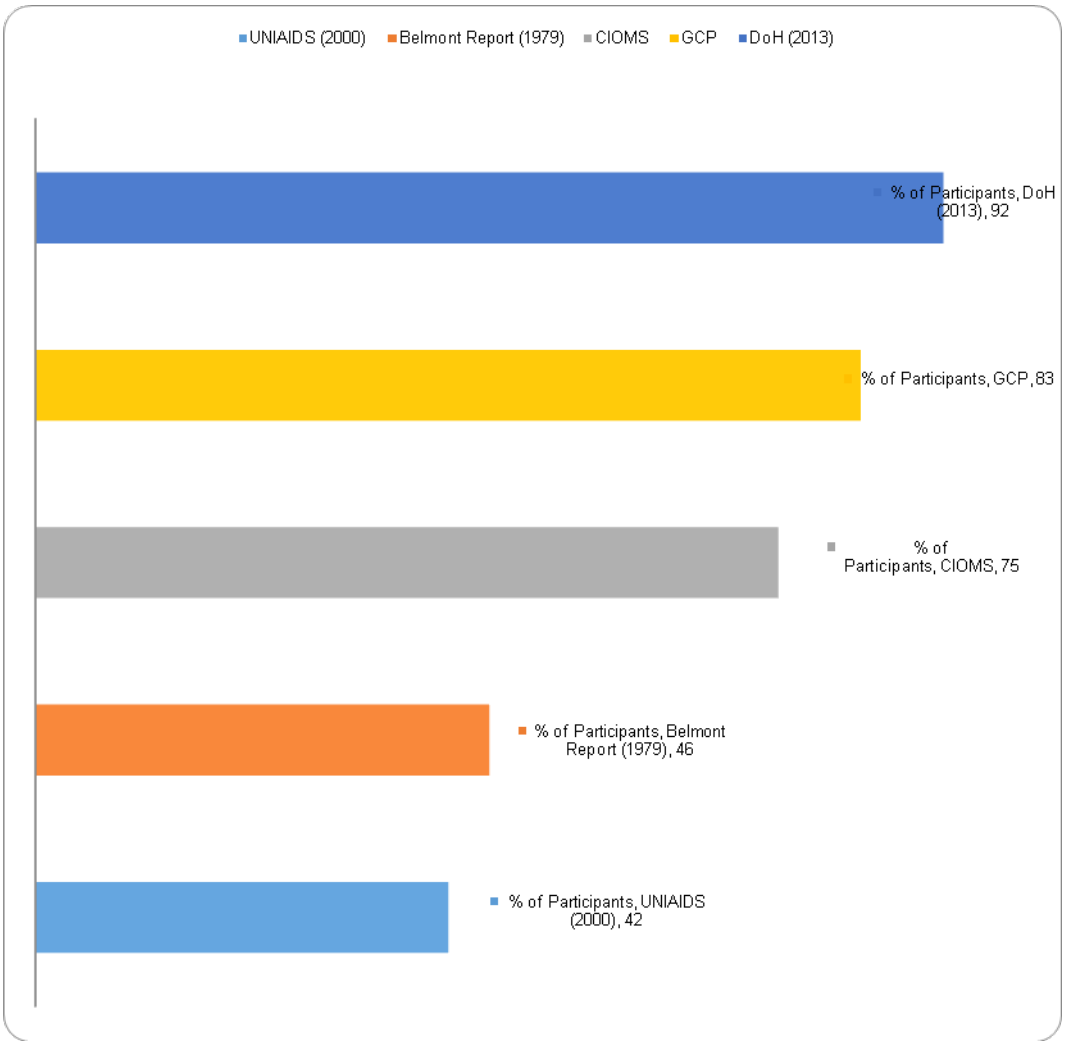

Figure 4.6: Use of international guidelines

4.5.3 Relevance rating of international guidelines

Participants were also asked to rate the relevance of the international guidelines they use. Figure 4.7 presents the results of this analysis. The findings reflected that 19 (79.2%) of the participants rated the GCP guidelines as very relevant; 19 (79.2%) rated the Helsinki Declaration (1979) as very relevant; and 12 (50%) rated the CIOMS guidelines as relevant.10 (42%) rated the Belmont Report (2013) as not applicable, 9 (38%)) rated the UNAIDS (2000) guidelines as not applicable;

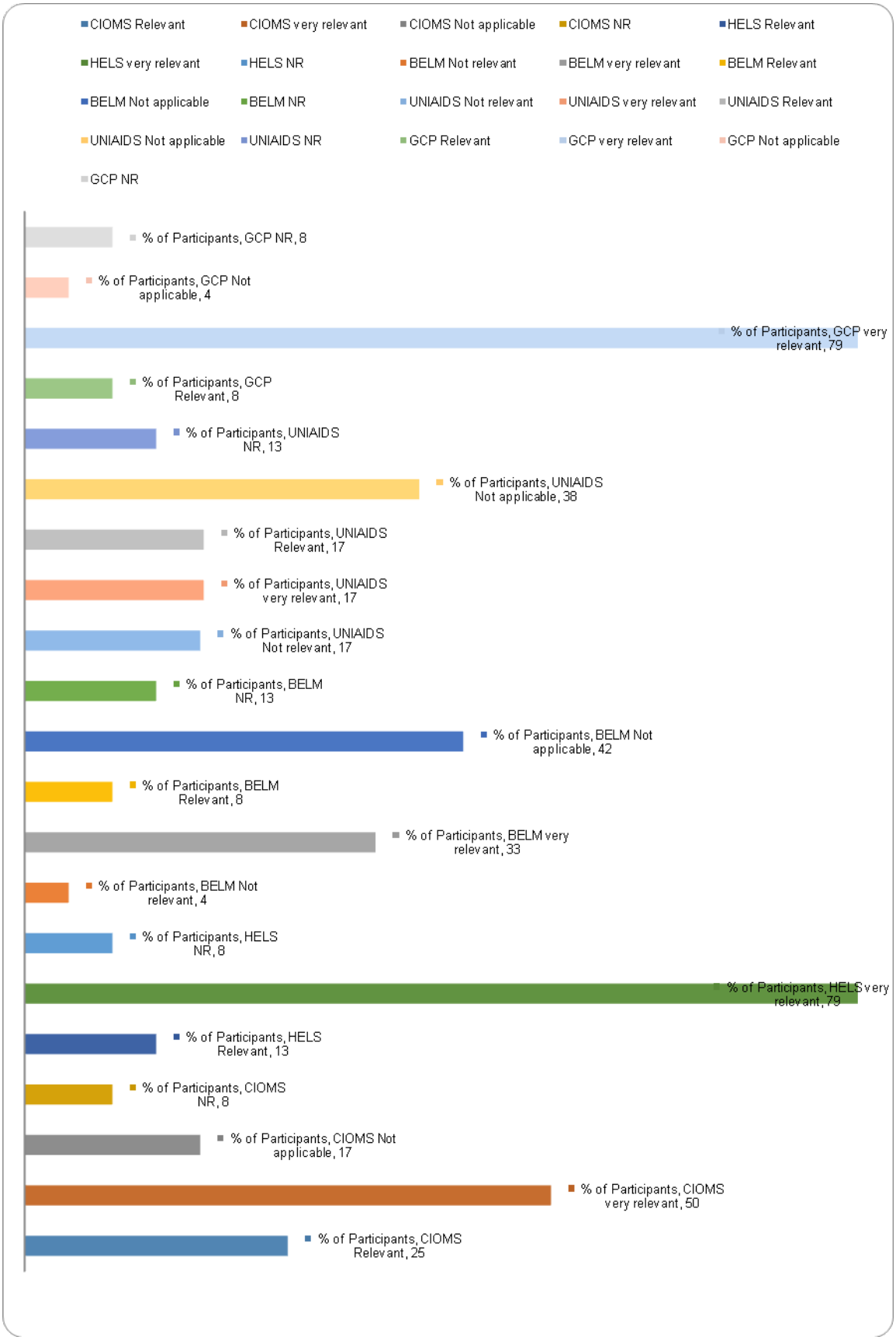

Figure 4.7: Relevance rating of international guideline

4.5.4 Challenges using ethical guidelines

The participants acknowledged variable use of research ethical guidelines as the main challenge in the use of ethical guidelines in Malawi as outlined in table 4.8. Other challenges that were highlighted included developing national guidelines and adopting such guidelines, while lack of sensitivity to local context was rated to be the least of the challenges. Other participants had no idea of the challenges that RECs face when using ethical guidelines.

Table 4.8: Challenges using ethical guidelines

Challenge		n(%)
Variable use of ethical guidelines	Yes	6 (25)
	No	12 (50)
	Don't know	4 (16.2)
	NR	2 (8.3)
Developing national guidelines	Yes	5(20.8)
	No	14 (58.3)
	Don't know	3 (12.5)
	NR	8 (33.3)
Difficulty in adopting international guidelines	Yes	5 (20.8)
	No	14 (58.3)
	Don't know	3 (12.5)
	NR	2 (8.3)
Lack of sensitivity to local context	Yes	4(16.7)
	No	14 (58.3)
	Don't know	4(16.7)
	NR	2 (8.3)

4.5.5 Use of frameworks for reviews

All of the seven participants who responded to whether RECs use frameworks in their reviews indicated that they do use them. Some of the respondents indicated that they use SOP frameworks and guidelines(*The Framework of requirements and Guidelines for Research in the Social Science and Humanities in Malawi*, 30th May, 2011; "General Guidelines on Health Research: College of Medicine Research and Ethics Committee (COMREC)," 29th September, 2010.), while others acknowledged they have adopted Emanuel's framework (Emanuel et al., 2000), which they have modified to fit their needs.

4.5.6 Evaluating the social value of research when reviewing protocols

This section presents results of the analysis of whether and how RECs assess the social value of research when reviewing protocols. As in table 4.9, very few participants seemed to know what evaluating social value meant; as such, not many participants responded to the question about what they understood by evaluating the social value of research. Among the nine participants who responded to whether RECs evaluate the social value of research, only three indicated that their REC does this, while six indicated they do not know.

Table 4.9: Social value of research assessment and ethical-legal application

Variable measured	**n(%)**
Evaluating the social value of research	
Yes	3 (12.5)
Don't know	6 (25)
No response (NR)	15 (62.5)
Conduct research without ethical approval in Malawi	**n(%)**
Yes	3 (12.5)
No	15 (62.5)
Don't know	1 (25)
NR	2 (8.3)
Use of local laws in Malawi when reviewing protocols	**n(%)**
Yes	20 (83.3)
No	1(4.2)

Don’t know	1(4.2)
NR	2 (8.3)
Body regulating scientific rigour of health research	**n(%)**
Yes	17 (70.8)
No	4 (16.7)
Don’t know	2(8.3)
No response	1 (4.2)
Laws regulating national research agenda	**n(%)**
Yes	12 (50)
No	7 (29.2)
Don’t know	3(12.5)
No response	1 (4.2)
Researchers register with professional body	**n(%)**
Yes	2 (8.3)
No	22 (91.7)
Professional body disciplines REC members	**n(%)**
Yes	4 (16.7)
No	5 (20.8)
Don’t know	11(45.8)

No response	4 (16.7)
REC registers with professional body	**n(%)**
Yes	17 (70.8)
No	4 (16.7)
Don't know	2(8.3)
No response	1 (4.2)

4.5.7 Conduct of research without ethical approval in Malawi

As in table 4.9 above seventy five percent (18) of participants responded that it was not possible to conduct research in Malawi before or without ethical clearance from the RECs.

4.5.8 Use of local laws when reviewing protocols

This study revealed the RECs apply local laws when reviewing protocols. Participants acknowledged the use of local laws such as laws that regulate the conduct of genetic studies in Malawi through genetics laws and the anatomy act. They also acknowledged use of laws that regulate how research participants are compensated through research insurance policies, if they happen to sustain research-related injuries. Participants also acknowledged the use of laws that enforce issues on informed consent; this is stipulated in the Constitution of the Republic of Malawi under section 21. There are also laws that regulate the general conduct of research and the NCST Act, that the participants acknowledged to be in use

In Malawi, to ensure scientific rigour of the studies that take place, there are established bodies that oversee the scientific and ethical part of the studies. The bodies entrusted with such responsibility include COMREC, NHSRC and the National Research Ethics Committee in the Social Sciences and Humanities (NRECSH). With respect to the existence of all the governing laws, the participants were confident to say that no researcher is required to register with any of the research regulating bodies to conduct his or her study in the country. This implies that researchers are at liberty to conduct any research as long as its within the confines of the local laws. REC members, however, expressed ignorance as to whether professional bodies discipline the REC members if they offend against the laws. Despite

their ignorance on the issue of discipline, members acknowledged that RECs were registered with professional bodies. The professional body that registers all the RECs in Malawi as per participants' responses is the National Commission for Science and Technology (NSCT), which oversees the functioning of all RECs in Malawi.

Inspire of all things in place, (qualification, training in research ethics, availability of guiding principles etc)organization would operate smoothly if there is financial muscle that would support the day to day function of the activities. In the preceding section the research would like to know how much of the financial and material resources did the RECs had, who supported or how they generated support for the smooth running.

4.6 REC financial and material resources

This section presents results of the analysis of the RECs' financial and material resources, with a focus on whether REC was funded; whether the REC receives institutional support; and whether REC members are paid; type of pay REC members receive, if they are paid; whether administrative staff are paid; and type of pay administrative staff receive, if they are paid.

Table 4.10: REC financial and material resources

Variable	**n(%)**
REC funded	
Yes	12(50)
No	9(37.5)
Don't know	2 (8.3)
No response (NR)	2 (8.3)
Institutional support to REC	**n(%)**
Yes	17(70.8)
No	1(4.2)
Don't know	3(12.5)
No response	3(12.5)
REC member paid	**n(%)**
Yes	15 (62.5)
No	6 (25)
NR	3 (12.5)
Type of pay	**n(%)**
Per diem	8(33.3)
Per meeting	8(33.3)
NR	8 (33.3)

Administrative staff paid	n(%)
Yes	21 (87.5)
NR	3(12.5)
Type of pay	**n(%)**
Salary	20 (83.3)
NR	4(16.7)

In table 4.10 above, the participants of this study acknowledged that their respective RECs were funded.

Institutional support: When the participants were also asked whether their RECs receive institutional support, it was reported that the RECs received institutional support; however, there was a considerable number of participants who were not aware if their REC received institutional support.

Payment of administrative staff: There were four administrative staff for REC A and three for REC B. All participants indicated that these administrative staff were on the payroll, thus, they were paid on salary schemes.

In the last section of this study, the I wanted to find out from the REC members who participated in this study on areas that they felt they needed training in order for them to execute their duties well. Members were given opportunity to choose among many needed training option, they were also able to identify on their own training need other than the ones which were listed on options. The section below highlighted areas that either needed training or not.

4.7 Perceived needs for REC training and capacity-strengthening

This section presents participants' perceived needs for REC training or capacity-strengthening in terms of whether training is required; whether it is important to participate in training; and specific training that RECs would need.

4.7.1 Training is required

Figure 4.8 presents results of the analysis of whether training is required. Twenty (83%) indicated that training is required, while only 1 (4%) considered training not necessary. Thirteen percent (3) did not respond to the question

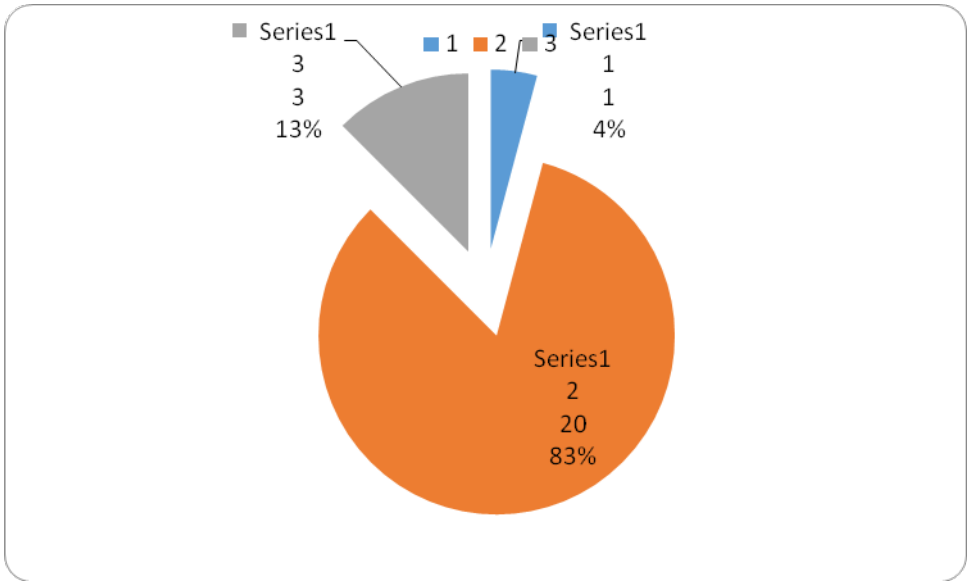

Figure 4.8: REC members' need for training

4.7.2 Specific training needs

Figure 4.11 presents the results of the analysis of specific training RECs would need. In the sample of 24 participants, 18 (75%) equally indicated RECs needed training in use of placebo-controlled trials and scientific design issues in health research; 17 (70.8%) indicated RECs needed training in determination of potential risks of research; 16 (66.7%) equally indicated RECs needed training in monitoring and oversight, and in interpretation of pre-clinical studies; 15 (62.5%) indicated RECs needed training in assessment of anticipated benefits of research; 14 (58.3%) indicated RECs needed training in provision of incentives for participation; 13 (54.2%) equally indicated RECs needed training in post-trial care, assessing understanding of informed consent, and community participation; 12 (50%) indicated RECs needed training in determinations to run Phases I, I, and III trials, in a country; 11 (45.8%) equally indicated RECs needed training in post-trial access to successful treatment, privacy and confidentiality, cultural sensitivity of research, determination of appropriate subject selection, and provision of appropriate risk-reduction intervention; and only 9 (37.5%) indicated RECs needed training in social and behavioural studies.

Table 4.11: Specific training needed by REC members

TYPE OF TRAINING		n (%)
Scientific design issues in health research	Yes	18 (75)
	No	2 (8.3)
	NR	4(16.7)
Use of placebo-controlled trials	Yes	18 (75)
	No	2 (8.3)
	NR	4(16.7)
Interpretation of pre-clinical studies	Yes	16 (66.7)
	No	4 (16.7)
	NR	4 (16.7)
Determinations to run Phase I, II, III trials in the country	Yes	12 (50)
	No	8 (33.3)
	NR	4 (16.7)
Determinations of potential risks of research	Yes	17 (70.8)
	No	3 (12.5)
	NR	4 (16.7)
Provision of appropriate risk-reduction interventions	Yes	11 (45.8)
	No	9 (37.5)
	NR	4 (16.7)
Assessment of anticipated benefits	Yes	15 (65.5)
	No	5 (20.8)
	NR	4 (16.7)
Provision of incentives for participation	Yes	14 (58.3)
	No	6 (25)
	NR	4 (16.7)
Determination of appropriate subject selection	Yes	11 (45.8)
	No	9 (37.5)
	NR	4 (16.7)
Community participation	Yes	13 (54.2)
	No	7 (29.2)
	NR	4 (16.7)
Assessing understanding of informed consent	Yes	13 (54.2)
	No	7 (29.2)
	NR	4 (16.7)
Cultural sensitivity of research	Yes	11 (45.8)
	No	9 (37.5)
	NR	4 (16.7)
Privacy and confidentiality	Yes	11 (45.8)
	No	9 (37.5)
	NR	4 (16.7)
Social and behaviour studies	Yes	9 (37.5)
	No	11 (45.8)
	NR	4 (16.7)
Monitoring and oversight	Yes	16 (66.7)
	No	4 (16.7)
	NR	4 (16.7)
Post-trial access to successful treatment	Yes	11 (45.8)

	No	9 (37.5)
	NR	4 (16.7)
Post-trial care	Yes	13 (54.2)
	No	7 (29.2)
	NR	4 (16.7)

Other than the above tabulated training needs, participants also suggested that training in: participants protection, general process of review, ethical principles, ethical issues of genetic studies, participant insurance, and general orientation to new REC members be included in training packages and be offered to REC members.

The chapter has highlighted a number of crucial issues that the RECs perceive important for them to function effectively. They had acknowledged also the need for training in different specialised areas, to enhance the capacity, need for monitoring bodies, dedicated spaces as well as transportation challenges. Despite these need, REC members acknowledged that they are able to review various kind of protocols and that they had no problem forming their column. Another striking finding from the result was an issue of income generation that they have put in place.

The preceding chapter will discuss these finding in relation to other studies that have studied the same or related studies in other countries in Africa or oversees.

Chapter five: Discussion

5.1 Introduction

Due to erratic publication on how RECs operate in Africa, there is particularly limited information available regarding the structure, functions and outcomes of African RECs. This study aimed to describe REC member insights into the structures, processes, responsibilities and needs of Malawi's two RECs. In this chapter, the study findings are discussed in relation to existing literature. These findings add evidence to the existing limited knowledge base on the composition and functioning of RECs in Africa more broadly.

Over the past five decades There has-been an unprecedented increase in research ethics capacity-building of RECs in Africa. Malawi, like many other African countries, has embraced this capacity building in research ethics such that currently in Malawi there are two RECs(COMREC and NHSRC) which review all health/biomedical research protocols..Besides the existence of these RECs, local laws and guidelines also govern the conduct of research in the country. To date nothing has been published on the composition and functioning of Malawi's RECs. This study, details and reflects on the RECs' structure and affiliations, roles and responsibilities of REC members, REC processes and procedures, RECs' use of research ethics guidelines and frameworks, RECs' financial and material resources, and perceived needs for REC training and/or capacity-strengthening.

For the sake of this study, 'composition' is defined as the nature of something's ingredients or constituents, the way in which a whole or mixture is made up (Stevenson & Waite, 2011). This means that the constituents of the RECs must be made up of professionals from different professional backgrounds, who have competencies and knowledge in their area of expertise to make up the ingredients for the RECs. This signifies that, to function properly, RECs should be well diversified in their composition. In a similar manner, 'functioning' in this study is defined as fulfilling the purpose or task of (a specified thing) (Stevenson & Waite, 2011).

5.2 Lack of diversity in REC composition

The findings of this study are not unique as they showed that medical doctors (MD) dominated the composition of both RECs for a period of five years consecutively, followed by nurses (medical personnel or scientists).

These findings are similar to the results of a recent study by Salaigwana and Wassenaar (2015), which revealed that RECs in sub-Saharan Africa are dominated by medical professionals. They are also similar to a study that was conducted in Egypt, which revealed that physicians or scientists dominated the composition of RECs, reaching close to 88% (Sleem et al., 2010).

Dominance of one profession in the compositions of RECs are not acceptable as they exceed international membership trends(De Vries & Forsberg, 2002). It is argued that in a trend where there is dominance of one profession, this creates a challenge in terms of lack of diversity of the RECs and, as such, its functions are compromised, and issues of bias usually creep in. Besides bias, the other less-represented members are likely to feel left out, and their voices may not be heard in decisions that are made by the RECs. This may lead to a lack of commitment from such members to REC work, which may compromise the responsibility for which the body was established. Therefore, issues of diversity cannot be underestimated. Therefore it is imperative that REC's have a diverse composition to facilitate appropriate review of human research(Enfield & Truwit, 2008; Rivera & Ezcurra, 2001)

5.3 Function of RECs in Malawi

RECs are generally established to protect research participants in biomedical research(Druml et al., 2009). REC's major responsibility is to protect the rights and welfare of research participants and give public assurance that biomedical research is conducted in a transparent and ethical way (Druml et al., 2009). REC members in Malawi alluded to the fact that these RECs were created with the aim of achieving the same purpose as described by Druml et al. (2009). In this study, we found that there were a number of procedures that the RECs had put in place in order to function properly and to make sure that the goals of their establishment were reached.

The purpose of this study was to investigate REC member insights into the structures, processes, responsibilities and needs of Health Research Ethics Committees in Malawi. To establish this, the study focused on the RECs' structures and affiliations; roles and responsibilities of REC members; the RECs' processes and procedures; ethical guidelines and frameworks used by RECs; their financial and material resources; and perceived needs for training and or capacity-strengthening for REC members. Each of these is discussed below.

5.3.1 REC structure and affiliations

In this study, the researcher aimed to assess REC member perceptions of the structures, and affiliations of Malawi's RECs. In addition, we wanted to ascertain if these RECs were supported by the institutions to which they belonged. We cannot refute the fact that a conducive REC structure is of paramount importance, as good structure creates a good environment that will attract and can accommodate varied expertise. This accommodating structure is a necessary catalyst to diversity on the committee, which should result in more effective review of varied research content and potentially reduce bias during the review process(Sleem et al., 2010).

Despite the structures in place, it used to be known that RECs were not profit-making bodies, and that, for the most part, REC members work on a voluntary basis. However there is currently a shift from non profiting to commercial independent research ethics committees(Lemmens & Freedman, 2000). The commercial RECs receives their financial support from the levy they charge for review. It is therefore generally preferable that RECs are non profiting, are affiliated to a research organisation or institution from which RECs can tap voluntary expertise. These affiliating bodies could be institutional, national or local entities. REC affiliation is also an important component that ensures support to the REC so that it can function properly. RECs' challenges that may be associated with lack of structure and affiliation would include lack of diversity of the research ethics review committee, and lack of administrative support, resulting in poor functioning of the REC(Rivera & Ezcurra, 2001).

It was encouraging to note that the biomedical RECs in Malawi belong either to an academic institution or are nationally affiliated. Through these affiliations, they receive some financial support and are able to draw expert members. It is not unique for Malawian RECs to receive such support from their mother institutions. A study conducted by Nyika et al. (2007), found that 31 RECs in sub-Saharan Africa are financially supported by the institutions to which they are affiliated.

The composition of RECs in Malawi included the REC Chair and Vice-chair, an administrative secretary and REC members, including community members, a composition similar to that of other RECs in the rest of sub-Saharan Africa. The RECs also had administrative staff who were full-time employees responsible for the REC duties at the designated institutions/offices. Some of the REC members belonged to the institutions to

which these RECs were affiliated while others were recruited from different institutions, which was also a common trend in the study conducted in Egypt by Sleem et al. (2010).

While almost all REC members interviewed reported they have community members on their RECs, who constitutes a community member that appropriately represents the interests of the research community warrants some discussion here. According to Moodley& Myer (2007), a 'community member' or representative refers to a non-professional, non-scientific member who belongs to the community which is being researched and who would more likely reflect the culture and values of the involved community. Given this definition of who is regarded as an appropriate REC community representative, the community members represented on the Malawian RECs, all professional teachers, would not meet this standard. According to Moodley and Myer (2007),professionals from a given community are considered to be lay representatives; lay people are defined as being non-scientific or non-medical professionals, such as teachers, lawyers, ethicists, and priests(Moodley & Myer, 2007). It would be worth further exploring whether these teachers are considered as appropriate representation by the local community. For now, it is noted that both RECs had earnestly attempted to garner representation from outside of the affiliated institution in the form of a member who belongs to the community being researched, albeit a professional. Towards appropriate community representation we would therefore advocate for increased attention to the process through which community members are selected to serve on the REC. This selection process should, at a minimal, follow some consultation with community gatekeepers as to whom would best represent them in the REC. In addition, moving forward the governing bodies and all REC members should be made aware of whom to consider as community member on the REC, towards appropriate representation of a community voice on their committees..

According to Kass et al., (2007) one of the requirements for RECs to function properly is that a REC should have a minimal of five members, with no upper limit. This study revealed positive findings with regard to the size of REC membership. The minimal number of members serving these RECs was reported to be twelve. In many sub-Saharan African countries, it has been reported that membership is a problem for some RECs, where some had as few as three members(Nyika et al., 2009).

In addition, Malawi's, REC members were committed to the REC's work. Our study participants indicated that they never had any challenges in forming a quorum for their protocol review meetings. The factors that led to this commitment were not part of this study,

but it might be assumed from the findings of this study that this commitment could be attributed to the appreciation that the members are accorded following their meeting attendance. Malawi's REC members are given a token of appreciation for attending meetings; in the form of money paid either per diem or per meeting. In other countries, it has been reported that there has been unwillingness on the part of potential members to participate in the committees over and above their normal duties, and the lack of compensation for the personal costs incurred in taking time for reviews and REC meeting attendance (Kass et al., 2007) contributed to membership challenges as well as to the ongoing commitment of REC members. It is not known whether compensating/paying REC members in order to gain membership and commitment is an ideal approach to this problem, but in this case it may have been an incentive towards maintaining commitment and membership. The concept of paying REC members was observed in Tanzania through a study conducted by Ikingura et al. (2007). Members were, however, not always rewarded for their time spent on REC activities. Only in circumstances where finances allowed, were the members compensated for their time.

This study revealed that administrative REC staff were employed full time and paid a salary for this job. This was contrary to the study that was conducted in Egypt which revealed that the chairperson performed the administrative duties (Sleem et al., 2010) and, as such, was not entitled to getting a salary for the REC work, although he/she may receive a small token of appreciation.

In order to sustain paying the members for REC work each time they meet, Malawi's RECs have put in place a mechanism to generate income. Researchers have to pay an application fee when they want their study be reviewed by these RECs. This money is used to pay for the REC members attendance at meetings and it also helps in paying for some utility bills around the premises. Similar systems are also implemented in some other African countries, notably in Tanzania where RECs charge a fee to review proposals brought forward to the REC; this supports the functioning of these RECs(Ikingura et al., 2008).

Besides commitment to REC review work and meeting attendance, members should have a good working knowledge and education in research ethics in order to adequately review proposals. The majority of the REC members in both RECs in Malawi were holders of masters-level degrees, followed by those having a PhD as their academic qualification. Despite having these high qualifications, which are really an essential component for the REC to function properly, the need for knowledge in research ethics cannot be

underestimated. Thus, there is a need for community representatives who will look at the protocols from a local community perspective, as well as for other members with a more generally comprehensive knowledge of research ethics.

This study showed that many current REC members lacked prior knowledge of research ethics before joining the RECs. This is not a unique finding from Malawi, as many east and west African countries showed similar results (Milford et al., 2006). Most members had never received any formal training in research ethics, prior to joining the REC.

The study conducted by Nyika et al. (2007) in sub-Saharan Africa showed very few members to have undergone formal training in research ethics. However, most of the members had attended a training workshop which lasted from one to three days. The challenge of lack of training in research ethics has been a long-standing one among many countries globally, including those in Africa (Agunloye et al., 2014; Hyder et al., 2004; Ijsselmuiden et al., 2012; Ikingura, Kruger, & Zeleke, 2007; Kass et al., 2007) and in LMICs of Latin America(Rivera & Ezcurra, 2001),as well as in Asia(Kadam & Karandikar, 2012; Majumder, 2004). However, the fact that participants in Malawi have shown interest in attending training in research ethics implies that there is room for capacity-building in research ethics. In some other African countries, there has been a significant increase in research ethics capacity-building of RECs in Africa over the past five decades (Ndebele, Wassenaaret al., 2014).

5.3.2 Roles and responsibilities of REC members

The members of the RECs are there to facilitate the accomplishment of the core reason why RECs were established. Members review health/biomedical research to contribute to promoting and safeguarding the dignity, rights, safety and well-being of potential research participants (Enfield & Truwit, 2008; Kass et al., 2007; Nyika et al., 2009; World Health Organization, 2011). It is therefore the responsibility of the REC members to ensure that they achieve the purposes of the REC's establishment in the country. Every member serving on the REC is there to facilitate its proper functioning; this requires leadership to steer its functionality and sufficient expertise to enable the review of specific areas of research.

Some of the notable responsibilities of various members include that of the chairperson which is to steer the meetings, to solicit and invite independent reviewers, where required, to provide guidance to and maintain order in the REC, and of course, be involved in the review processes.. In addition to the responsibilities which the chairperson had to undertake in

Malawi, in Egypt also had to take on the administrative duties (Sleem et al., 2010). Contrary to the Egyptian scenario, the administrative work in Malawi was solely for the administrative staff who were responsible full time for the day-to-day running of REC's administrative work. In Malawi, the administrative staff are not involved in the review process; only REC members are responsible for this. This is definitely different in Egypt, as it is undisputed that the chairperson has to take charge of the protocol review process.

In Malawi, the most common types of protocols that were submitted to the biomedical RECs for review were mainly in the field of public health research, laboratory studies and health system studies, while less common studies that were reviewed by these members included product and intervention studies, implementation studies, and social science research. REC members reported reviewing clinical trials and vaccine trials less frequently or not at all. Clinical trials and vaccine trials are categorised as studies of national interest in Malawi and can only be reviewed by the national REC. It was not surprising to find that the institutional REC was not involved in reviewing any of these. This followed the stipulated local laws that govern the conduct of research in the country. Our study showed that the national REC commonly reviewed Phase III clinical trials but very few Phase I, II or IV trials. Regardless of the challenges that RECs face in reviewing clinical trials and vaccine trials, vaccine trials have also been reviewed in Malawi. The notable vaccine trials which have been reviewed so far by the RECs include: malaria vaccine trials, HIV vaccine trials, TB vaccine trials, and HPV and hepatitis vaccine trials.

5.3.3 REC processes and procedures

REC processes and procedures can arguably either facilitate or hinder the review process and REC efficiency. In our study we report on REC standard operating procedures, REC workload, and challenges faced by RECs.

There is variation between Malawi's two RECs in term of meeting frequency. One REC meets monthly, while the other bi-monthly. Similar scheduling of meeting frequencies were found in the study conducted in Egypt (Sleem et al., 2010). Malawi's REC members participate in review processes on a voluntary basis over and above their normal duties and it is not known whether the token of appreciation given to REC members has an influence on their attendance. The meetings are conducted in person.

One of the participating RECs has an electronic review system. The REC reported they do not use it because of challenges of erratic internet connectivity, ICT infrastructure, and

funding to run the system. The system was also considered not to be user-friendly. These challenges of infrastructure, ICT connectivity and funding are common challenges and similar to those experienced by RECs in other African countries such as Tanzania (Ikingura et al., 2007) and Egypt(Sleem et al., 2010), as well as in sub-Saharan Africa (Nyika et al., 2009)

Amidst the challenges that RECs in Malawi experience, there has been a steady increase in the number of protocols that they review. This increasing influx of protocols could be linked to the high disease burden in Malawi, but also to the emergence of new issues. For example, efforts to address the so-called 10/90 gap, as was highlighted in Nyika et al.'s (2009) study, has resulted in an increase in research protocol production. This major effort to address the 10/90 gap has led to an unprecedented increase in health research in Africa (Agunloye et al., 2014; Nyika et al., 2009)and consequently, there has been an increase in the volume and complexity of protocols that RECs in Africa have to review (Ijsselmuiden et al., 2012; Nyika et al., 2009); this increase has also been reflected in our study.

The protocols submitted to Malawi's RECs vary in their complexity and the risks they carry. This being the case, they are reviewed for approval in different ways. The RECs discuss and vote on serious adverse effects and more than minimal risk research in a full committee meeting. Minimal risk research, including, most student research, in one of the RECs receives expedited review. For protocols reviewed through the expedited process, the chairperson or the director and/or two other REC members must give approval for the study, The expedited review process is similar to what happens in Egypt, where the chairperson or designated person approves the protocol (Sleem et al., 2010). All amendments, unless of more than minimal risk, are never reviewed by a full committee; rather, expedited review is employed here also. Similar findings were seen in the study of Kass et al., (2007).

The minimal period for a protocol to be reviewed in Malawi is seven to 14 days from making the application. An application must be made within prescribed dates prior to the meeting and researchers can cross-check with the REC with regard to meeting dates towards appropriately planning for submission of their protocols. The review period for RECs in Malawi take is good when compared to other countries. RECs in India have reported review periods of three months (Bhatt, 2004)and 30 days in the USA (Bhatt, 2004; Kadam & Karandikar, 2012). Malawian RECs also conduct routine annual reviews, where the principal investigators submit progress reports. This puts Malawian RECs among the few RECs in Africa which conduct annual reviews (Kass et al., 2007).

Malawi's RECs use standard operating procedures (SOPs) to guide their functioning and the conduct of the review processes. The RECs' secretariat keep minutes of REC meetings. It is always imperative that SOPs and minutes, as well as laws both international and local, be put to use for the proper functioning of RECs and to act as reference materials. It is unfortunate that some RECs in sub-Saharan Africa do not have SOPs, while a few did have them and did keep minutes, according to the study of Kass et al. (2007).The most common conflicts of interest that were identified by REC members included: REC member submission of a protocol, relative or friend submission, financial conflict of interest and political pressure which is similar to the findings in a study by Milford et al., (2006). These reflect the common conflicts of interest identified in a similar study in Africa, where members who identified a conflict of interest excuse themselves from reviewing, discussing or voting on these protocols (Kass et al., 2007).

The main challenge that REC members reported constrained the functioning of the RECs in Malawi was the lack of a national audit mechanism. Having a national audit mechanism in place would ensure that the conduct of studies was monitored so as to prevent misconduct in research. Establishing such a body or mechanism would aid in promoting the purpose of the establishment of the REC, which is safeguarding and protecting human research participants. This challenge is not unique to Malawi. Sleem et al. (2010), found that RECs in Egypt also lacked the ability to monitor approved protocols. Lack of an audit mechanism leaves RECs not knowing whether or not researchers conducted their research according to the approved protocol. Two other key challenges were mentioned by participants. The first is the lack of national composition standards for Malawi's RECs - this means that currently each REC recruits any REC members that are willing to serve, without meeting some national standard of composition diversity. The second is the variable procedures for reviewing protocols among REC reviewers – REC members currently review protocols as they deem fit for their institution or organisation; this does not foster consistency in REC decision making and may be problematic.

5.3.4 REC use of research ethics guidelines and frameworks

Research ethics guidelines and frameworks are used by RECs to guide the research ethics review process and to ensure that research meets both local and international research ethics standards. In the view that ethical principles are perceived rather differently from one region to the other referred to as relativism and not the same "Universalism" across nations and culture. Despite relativism of application of ethics, there are some fundamental ethical

principles that ought to be applied across the boundaries (Brodwin, 2001).Regardless of this universalism application to fundamental ethical principles, they still tend to be influence by a number of factors in its application and varies from region to region and between communities and countries. Some of the factors that will influence the application of the fundamental principle are issues of gender, religion/spirituality, indigenous explanatory models of the person (cultures, values, beliefs, customs etc.), health & illness, power differences(Brodwin, 2001). Therefore the application of ethical principles as far as conduct of research in communities or various countries is concerned, requires to take in consideration all the fore mentioned aspects. In some instances the frameworks of the sponsoring countries, may not take on board the interest of the communities with regard to their cultures, values, believes and interest etc. This therefore necessitates the need for developing research ethical guideline and ethical frameworks on how to go about conducting research in indigenous communities or countries. This would facilitate to critical look and enable to scrutinise the values, interests, cultures, beliefs, gender issues, health and illness, and incorporate them in such frameworks so that the researched communities are never exploited but rather, they also benefit from the finding of the research.

In this study both RECs acknowledged they use research ethics guidelines during the review process. Among the international research ethics guidelines RECs in Malawi considered the Declaration of Helsinki as the most relevant guideline for their review procedures, followed by the Good Clinical Practice Guidelines and finally CIOMS guidelines. The Belmont Report, UNAIDS and the Singapore statement were considered not applicable, or were used sparingly. These findings echo the findings of the Egypt study where participants considered some international guidelines less relevant, with limited application in their local setting(Sleem et al., 2010).This reflects that some international research ethics guidelines are applied differently in the global context(Brodwin, 2001), depending on a country's respective social values, education, finances and independence of the evaluating bodies (Ijsselmuiden et al., 2012).

Besides the adoption and use of international ethical guidelines, Malawi's RECs also use local research ethics guidelines. REC members reported that these supplement international documents and steer the review process. RECs also use laws dedicated to protecting research participants, as well as laws on general requirements to conduct research in Malawi. Some of the local guidelines used include guidelines for handling biological specimens, guidelines for the provision of insurance cover, and general national guidelines on the conduct of research in Malawi.

General local laws

One such local law governs genetics studies. Sections 3.4.7and 3.4.8 of the *National Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi*(2012),stipulate non-permissible areas and forms of research related to the collection, storage and use of human biological specimens in Malawi. Similarly, Section 3.4.8 stipulates that "plans, attempts and requests for the obtaining of human biological/genetic materials for future research is also non-permissible" (*Policy requirements, procedures and guidelines for the conduct and review of human genetic research in Malawi*, September, 2012).

Studies of national interest

According to the National policy requirement, most health research being conducted in Malawi is generally of national interest. However, there are some studies that deserve particular attention because of their sensitivity, and their political and safety implications. Studies regarded as examples of national interest studies include all vaccine trials, all drug trials, where patent issues are involved and/or where safety issues remain fully unknown, all human genetic studies, stem cell research, cloning research, and national health surveys. All studies of national interest, regardless of the origin of the study protocol, are reviewed by the NHSRC or an ad hoc committee which is formed by the NHSRC for that specific project.

Multi-centre studies

In Malawi, multi-centre studies, irrespective of their origin, require special national consistency and uniform ethical and regulatory standards in their review, in order to not only enhance the safety and welfare of the research participants, but also to safeguard national interests and serve researchers better. In keeping with this, and in avoiding duplication and inconsistencies in the review environment for the benefit of both participants and researchers, the NHSRC is lawfully designated and mandated to be the research ethics committee that will review, approve, inspect and monitor such studies,(*National policy requirement and guidance for the provision of insurance cover for research participants in clinical trials in Malawi*, December, 2012)

Participant-dedicated local laws

Some local laws and policy are dedicated to the protection of potential research participants REC members mentioned these included first and foremost respect for personal dignity and privacy. Section 19, subsection 5 of the Constitution of Malawi states that "No person shall

be subjected to medical or scientific experimentation without his or her consent" (*Constitution of the republic of Malawi* 1993). This focuses on promoting the dignity and privacy of the participant through their informed consent. Section 21 of the Constitution of Malawi also focuses on privacy when it states that "[e]very person shall have the right to personal privacy"(*Constitution of the republic of Malawi* 1993).

Also included in local policy is the issue of participant insurance. (*National policy requirement and guidance for the provision of insurance cover for research participants in clinical trials in Malawi*, December, 2012).

The use of local law, policy and guidelines promotes the independence of Malawi's RECs in that they are self governed, and protect the interests of their local communities through local regulation. This study finding is in agreement with the finding of various studies in Africa that indicated that 60% of RECs indicated they were independent against 10% who indicated that they were not independent due to various reason (Silaigwana & Wassenaar, 2015). This indicates that there is a progress in the capacity building of the RECs with regards to their independence in Africa. However the few contrary findings of Nyika et al. (2009),which indicated that RECs in sub-Saharan Africa lacked independence and relied on the institutions providing funding, which had their own regulations. The responsibility of ensuring the ethical conduct of research is vested in the RECs. This can be more effectively achieved when committees can enforce their own local ethical guidelines for the conduct of research in their respective communities. This would be possible with the capacity building in the direction of RECs independences, the direction the African RECs are currently taking.

Despite acknowledging the use of local research ethics guidelines, our study revealed that the way these guidelines are used for the review of protocols varies considerably between Malawi's RECs.REC members also reported variable use of the national guidelines pointing to a need for proper training of the REC members on the use of ethical guidelines be it local or international, so that RECs in a country function with as much consistency as possible. In addition to the use of guidelines, Malawi's RECs also use frameworks in the review process. RECs in Malawi have adopted the Ezekiel J. Emanuel framework (Emanuel et al., 2004), with some minor modifications that suited their local standards. The use of this framework is another strength that Malawi RECs had registered.

Evaluating the social value of research when reviewing protocols

It has be observed that most research in Africa is funded by high-income countries and international organisations based in high-income countries (Barsdof & Millum, 2016; Kass et

al., 2007; Klitzman, 2012; Milford et al., 2006).Benchmarking the social value of a study entails identifying and assessing the value the research will bring to the targeted community or country, rather than to the scientific community alone. If the benchmark of social value has been met in a study, it justifies the rationale for doing multi-site research in a particular setting and can be used to offset exploitation.

It is not known whether, nor to what extent, Malawi's REC members consider the social value of research when they review studies. The terminology seemed unfamiliar to most REC members, such that only a few indicated that they benchmark social value when reviewing research protocols. The benchmark of social value requires that society (or the field of health) should gain important generalisable knowledge from the research. Some authors argue that the populations that host research should also benefit from the results of the research, particularly when those populations are disadvantaged in other ways (Council for International Organizations of Medical Sciences, 2002; London, 2008; WMA Declaration of Helsinki, 2016; World Medical Association, 2013). The social value of a research project must be sufficient to justify the risks and burdens of the study for research participants and the communities from which they were recruited. This implies that the *local* social value is also relevant in justifying research.

Despite that most REC members did not know much regarding the benchmarking of social value when reviewing research, our study showed that all members acknowledged that research studies in Malawi cannot take place without being approved by a REC, which is one way to safeguard and protect the participants from being harmed or exploited; it may also ensure that participants benefit from the study they were involved in. It was also noted that the NCST Act regulates the national research agenda in the country.

Besides reviewing the ethical aspect of the studies, we also found that the RECs were responsible for reviewing the scientific part of the proposals. When conducting research in Malawi, as a researcher, there is no need to be registered with any professional bodies; however, the REC itself needs to be accredited by registering professional body. This was a positive finding in Malawi since in some other countries, RECs are not accredited by any regulating bodies. For example, in India, there are over 200 RECs but these are not accredited (Bhatt, 2004). In Malawi, RECs are accredited by the NCST which is an overall professional body regulating the conduct of research in the country.

5.3.5 Financial and material resources

Like any other organisation, RECs would not function effectively if they lacked the financial muscle and material resources, regardless of the availability of human resources. In addition it is also imperative to have institutional support for the day-to-day running of REC activities. Institutional support for both participating RECs included: finances, human resources, and offices. Nevertheless, most members complained of limited office space for the RECs.

In many studies, funding of RECs has been identified as one of the most common and significant challenges that African RECs face (Ijsselmuiden et al., 2012; Ikingura et al., 2008; Kass et al., 2007; Nyika et al., 2009). It is more likely for this study therefore to conclude that the RECs never get any kind of funding as they generated their own funds from the income generating activities they have, which is why members are not aware whether their RECs get funding or not. However, RECs in Malawi have never experienced any financial setbacks/bottlenecks. This is attributed to the institutional support that they receive and also to the income-generating system they put in place.

It is no longer news that nowadays there are commercial research ethics committees. The growth of the market for commercial research review is latest development in the history of REC(Lemmens & Freedman, 2000).The RECs in Malawi have followed the commercial way and have devised a system to ensure that the review procedure functions smoothly in terms of monetary issues, whereby they introduced review fees for all the studies they review. Non-student research is charged one hundred and fifty US dollars (US$150) as an application fee, and thereafter, the researcher(s) needs to pay 10% of the total budget to the reviewing REC. Student research also attracts an application fee of five thousand Malawi kwacha (MK5,000) but no 10% payment from the total budget of the research. The money generated from these fees goes a long way in helping the functioning of the RECs. In Most African Countries seems that commercial research ethics review has been established in many RECs, however there is a wide variation in how the charge for the services are decided and offered form one REC to another within country and across borders. It was observed in the study conducted by Kass et.,2007 in Africa that some RECs used a “sliding scale,” charging US$5 for proposals submitted by students, US$10 for studies submitted by post-graduate trainees, and US$20 for all other research proposals. Other RECs did not charge for institutional applications, but required US$365 for external applications and US$585 for industry studies. Some used a “fixed fee” structure, such as US$100 for all applications or 1% of the study’s budget, once funded. The commercial ethics review system

is good as it assist to generates some income which facilitates the day to day running of the activities. In USA, In some sectors, IRBs have been viewed as ineffective due to increased responsibilities beyond those required by regulations (Grady, 2015). Likewise, some people complain that IRB review is time-consuming and burdensome without clear evidence of effectiveness at protecting human subjects, while others argue that IRBs also operate inconsistently and inefficiently, and focus their attention on paperwork and bureaucratic compliance(Grady, 2015).However it is not known in Malawi how effective these RECs are despite the fees they charge for the review, however this argument is not for this study, as this study focuses on different objectives.

5.3.6 REC challenges and specific training needs

The main challenges in Malawi were lack of training, infrastructure(specifically, dedicated office spaces, and computer or ICT problems), and transportation. These challenges are also some of the common challenges that most African countries face, for example, in Tanzania(Ikingura et al., 2007), in Egypt (Sleem et al., 2010), and other sub-Saharan Africa countries(Kass et al., 2007). In India, Latin America and parts of Asia, training and member dedication were also identified as common challenges (Bhatt, 2004; Kadam & Karandikar, 2012). The central challenge identified in this study is lack of training for REC members. Capacity-strengthening, focused on strengthening the capabilities REC members need to review protocols effectively and consistently will help to alleviate this challenge. It was therefore imperative for further inquiry towards what the REC members specifically felt was important to them to carry out their REC responsibilities effectively and efficiently. Training cannot be uniformly delivered as each of the two RECs might have different areas of need; thus tailor-made training would be appropriate. The need for training for REC members, be it on scientific or ethical aspects, can never be overstated in this regard.

More knowledge and training in understanding the scientific part of research studies is one of the areas highlighted by Malawi's REC members. Similarly, knowledge and training on the use of placebo-controlled trials are deemed to be of high need, so that RECs are able to evaluate clinical and vaccine trials properly. Milford et al. (2006) noted that it requires intensive knowledge and technical know-how to evaluate and conduct clinical trials. The findings from our study support these needs, and this has been highlighted in a number of other studies (Nyika et al., 2009; Sleem et al., 2010).

In general terms, it is clear that REC members in Malawi need training in many aspects of research ethics as reflected in the respondents' various reported needs for training. Only

33% of the respondents had training prior to joining the REC, with 83% receiving training after joining the REC. However, the training was for a maximum of three days, this is a step towards capacity building in research ethics. As much as the development of the various training is a very welcome idea, it will be imperative to have a formalised form of training that REC members would undergo during their tenure of membership. This would ensure that the REC members have adequate knowledge of research ethics..

5.4 Limitations of the study

The study had a limited number of RECs that took part since it targeted RECs that review health/biomedical research protocols only. This led to reduced variation in responses and available experience within the RECs. This meant that there was limited comparative information that could be gathered regarding the functioning and composition of the RECs, since the two RECs that were available shared similar procedures and experience, as well as expertise of their members. This was evident from the cross-representation of some members, which meant that, in some instances, the study gathered the same information from the two participating RECs.

There was also erratic record-keeping, by the RECs such that some information was not gathered in the chronological order in which it happened. However, this did not compromise or limit the data that was collected, but it was reflected in some gaps in the continuity and flow of the information when needed.

In many instances, the participants were either not very sure of what to write or they did not understand the questions that were asked or they were not very willing or cooperative, as most questionnaires were incomplete in a number of sections. This led to compromises in terms of some information and this impacted on the outcome of this study.

Chapter six: Conclusions and recommendations

6.1 Conclusions

The aim of this research was to describe the REC member insights into the structures, processes, responsibilities and needs of Malawi's two health RECs. This study has shown that Malawian RECs have a number of strengths, and of course some weaknesses requiring improvement. One of the weaknesses is the lack of diversity in the composition of one of the RECs. The committees were each composed of ten to twenty members. The most frequent professional categories which were represented on the committees included medical doctors, nurses, ethicists and teachers. In each committee, there was one community member. There was a dominance of medical doctors on both RECs, which needs to be kept in check in order to enhance diversity. On the strengths side, it was noted that most REC members seemed to have attended some kind of training in research ethics through a one-to-three day workshop. Although most members have attended training, some members have never attended any training so far; therefore, there is still a need that those who have never attended any training be trained.

The responsibilities of the chairperson in both RECs is to steer the meetings and invite independent reviewers where needed. The responsibilities of the chairperson were handled by the vice-chair in his/her absence. The REC members were responsible for the review of protocols. The most common type of research proposals that the RECs reviewed were public health, laboratory, and health system studies; rarely did they review social science proposals. Both RECs review clinical trials, especially Phase II and III, as well as vaccine trials for HIV, malaria and hepatitis. However, clinical trials involving new investigational products and vaccine trials as well as genetic/genomic studies are deemed to be studies of national interest and are reviewed solely by the national REC.

Both RECs' members meet in person despite one REC having an electronic review system; however, this was considered to be not user friendly. The committees either meet monthly or bi-monthly. During REC meetings, forming a quorum is not a problem for either REC. The members review an average of 33.5 protocols per meeting. During the meetings, members also discuss or vote on serious adverse effects, amendments and minimal risk research. Both RECs conduct annual reviews for all applications, while they also conduct separate reviews for minimal risk research and continuing research.

The RECs use SOPs and guidelines to review protocols and keep minutes of the meetings. Common conflicts of interest which these committees encounter include: REC members' submission of their proposals, and submission of a relative or friend's proposal. The solutions to the conflict of interest are, as suggested by members, to excuse the interested member(s) or the member(s) to declare if he/she has any interest in the proposal that is submitted. The main challenge which RECs face in executing their operation is lack of a body that monitors the conduct of research in the country. RECs alone are overwhelmed with other duties and also considering that its members are only volunteering on top of their daily work schedule so to effectively carry out the monitoring activity would be almost impossible. Members felt that this necessitates the establishment of a dedicated monitoring body in the country.

The most frequently used international guideline by both RECs is the Declaration of Helsinki, followed by the Good Clinical Practice Guidelines and CIOMS guidelines; the least used is the Singapore statement. Besides the use of the international guidelines, RECs in Malawi also use local laws and research ethics guidelines which include: guidelines on handling bio-specimens, guidelines on provision of insurance, and guidelines on genetics studies. RECs consider variable use of research ethics guidelines between and among RECs in Malawi as the main challenge to the use of research ethics guidelines in reviewing protocols. Besides the use of research ethics guidelines, the RECs also developed frameworks which aid their review process. The frameworks used by these RECs were adapted from Ezekiel J. Emanuel's benchmarks paper (Emanuel et al., 2000), with minor modifications to fit Malawi's perspective.

For RECs in Malawi to carry out their duties and responsibilities effectively, they devised mechanisms to generate their own income. These RECs ask an application fee of researchers who want their studies to be reviewed. In addition to the application fee, researchers also pay 10% of their total budget as research overhead fees. The 10% research overhead fee is not applicable to students' research. The money generated helps in paying electricity, water and rental bills, but it is also used to pay REC members for their time spent on reviews. The members are paid either per diem or per meeting. In addition to the income-generating systems that these RECs have in place, they are also supported by the institutions to which they are affiliated. Despite the financial sustainability and institutional support, these RECs face challenges in terms of lack of dedicated office space, transportation, and information and communication technology (ICT) issues.

Putting aside effective and proper function of these RECs and financial sustenance, the study revealed a need for training in research ethics, specifically REC members expressed a need for training on placebo-controlled trials and on how to evaluate scientific design in health research. Members seemed not to be familiar with the benchmark of social value and how to apply this when reviewing research; this may also be an area where training would benefit REC review. Research cannot be conducted in Malawi without research ethics approval by an REC. In addition to international research ethics guidelines, local law, policy and guidelines enforce how protocols are handled by RECs towards protecting participants, regulating the national research agenda, and promoting REC independence.

Malawi's RECs are accredited by the National Commission for Science and Technology, which is the regulatory body for all research ethics committees in the country. Researchers are, however, not required to register with the regulatory body in order for them to conduct research in Malawi.

6.2 Recommendations

6.2.1 Improve ddiversity of the REC composition

Both RECs should work towards improving the diversity of REC members as the current situation indicates dominance of medical doctors. A number of studies have explicitly indicated the need for diversity of RECs, as it was revealed in a desktop review of RECs in sub-Saharan Africa that RECs are dominated by medical professionals (Silaigwana & Wassenaar, 2015). This is not a good composition as it can easily cause bias and other professions may also feel intimidated by the dominating profession. Enfield and Truwit (2008), as well as Rivera and Ezcurra (2001), emphasise the importance of diverse membership of the committee, to facilitate appropriate review of human research. **The diversification of the REC's composition should include the community representations.** This seems very simple, but it is crucial, if the social value of research to the communities under study is to be upheld. In Malawi there are community members on the RECs, however, the process through which these community members are recruited need to be revised so that it really reflects the community representation rather than the current means of advertising and conducting interview which might demean the community member notion as it has been argued the study by Moodley and Myer (2007).

6.2.2 Harness Electronic Review process and Procedures

REC members commitment to timely review of protocols is very crucial, although these REC members review protocols on voluntary basis beside their normal work schedules. With

regard, in some instance members would lack such dedication toward the review processes due to commitment they have toward their normal duties. It is therefore imperative that RECs in Malawi embrace the development of electronic review system in the country. Despite that this is one of the challenges that has affected a number of African countries such Tanzania,(Ikingura et al., 2007) and Egypt (Sleem et al., 2010), as well as in sub-Saharan Africa (Nyika et al., 2009). However it is arguable that RECs would be in a position to support the system from the review fees and protocol budget percentage fees they charge. Embracing the system would go a long way in improving how the review process and procedures would be done. The system will ease the burden the REC members face as they commit to their work schedules. This would improve on both, finances on REC secretariat as well as time for the reviewers

6.2.3 Adapt some research ethics guidelines to suit in the contemporary world

There are some ethical issues that have significantly affected the conduct of research especially in most African countries especially on biobanks, tissue transfers and other areas considered cultural sensitive which has been a contentious issue (Matimba et al., 2008; Staunton & Moodley, 2013). However it is advocated that the emergence of DNA biobanks and the power they lend to genomics research promise substantial advances in disease prevention and treatment(Buseh, Underwood, Stevens, Townsend, & Kelber, 2013). It is argued that greater participation of racial/ethnic minority populations is necessary to assure a future of personalized medicine for all(Buseh, Underwood, Stevens, Townsend, & Kelber, 2013. However in most Africa context there are a lot of ethical issues that revolves around health and other, which include culture sensitivity, norms, family issues (Brodwin, 2001) to mention a few. These factors have impacted on how research ethics guidelines have been developed from country to country and region to the other. These guidelines in some instances have negatively impacted on the progress of some research studies as they restrain the conduct of such. Similarly Malawi has some local research ethics guideline that hinder the progress of research of a particular interest and direction. It is therefore imperative that following the high disease burden in Africa, the emergence of new diseases, that some of these local research ethics guideline be re-looked at for the interest of development of new medicines or other solutions that would go a long way for the development of the countries.

6.2.4 Engaging local communities to their understand social needs

Community engagement is a process of working collaboratively with groups of people who are affiliated by geographic proximity, special interest, or similar situations with respect to

issue affecting their well-being(Centers for Disease & Prevention, 2005). The REC members need to once in a while invite meetings with gate keepers of various communities to establish areas these communities deem necessary for their livelihood. The process will aid the REC members on understanding the different social values of various communities and regions. Understanding these social values will help the REC members to critically apply the social values when reviewing the protocols. Due to this collaboration between the REC members and communities, it will result in partnerships and coalitions that will help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices. In the long run, the process will promote the ownership of the project, support and encourage volunteerism. This will promote scientific evidence based reports and conduct in the country.

6.2.5 Harmonise research ethics review fees and charges (Fixed Charges)

It is well acknowledged that nowadays there are a number of commercial RECs. In addition some government and other institution also charge for their research ethics review and approval. However some have expressed that ethics fees and charges as either an ethical or impermissible(Dunn, Arscott, & Mann, 2000). In addition to this these fess have been described as exorbitant(Dunn et al., 2000). These charges negatively impacts on the zeal of number of researchers and research that would be conducted in the countries. Most researchers may find it difficult to conduct some studies because of financial challenges. At times also, these charge may result in production of poor studies as people might try to reduce their budges so to avert high percentage fees payment from their high budgets. This may also lead to issues of falsification and cheating in order to avoid high charges. Therefore RECs need to consider some of the disadvantages of the current fee system and explore the feasibility of other fee models (for example, where the REC fee matches the complexity of the burden on the REC and not eh seize of the budget) in their setting.

6.2.6 Advocate for national monitoring and auditing mechanisms

It has been found that the main challenge that the RECs face in Malawi in the operation of their duties is the lack of audit mechanisms. An audit mechanism helps to monitor how research is being, or has been, conducted. The aim of such establishment is to ascertain whether the researcher(s)adhered to the ethical and scientific principal which the RECs approved their project, therefore, establishing a dedicated team and fostering/empowering such an auditing and monitoring mechanism will help to monitor the degree to which studies adhere to the ethical standards set in their REC approved protocol..This, therefore, necessitates the formulation of a machinery/system that will be responsible for such monitoring and where issues of suspected deviation from the REC’s approval can be

reported. It should also be noted that RECs are responsible for ensuring that research protocols are ethically sound. RECs alone cannot positively promote the protection of the participants without physically monitoring the on ground activities of the researcher, as such, the work of RECs must be complemented by the active efforts of the audit and monitoring mechanism that could be put in place. This being the case, there is a need to formulate a body that will focus solely on research integrity (i.e. a Research Integrity Office)which will not be undermined.

6.2.7 Invite specific research ethics training

REC members had attended some training in research ethics, but this alone seems insufficient to support their functions properly. The findings in this study reflect that there is need for some specific training that members felt important for their functioning. This included training on: use of research ethics guidelines, use of placebo-controlled clinical trials, and scientific research designs. If RECs could ask members what they lack, they will be able to come up with the most necessary training. Therefore, it is imperative that RECs need to offer appropriate and essential training to members to support their core functions; this may need to be out-sourced to knowledgeable and experienced personnel who can facilitate such training.

6.2.8 Infrastructural support to RECs in Malawi

RECs in Malawi indicated they were doing well in terms of their finances; this is achieved through their income-generating system that they had established. However, the RECs are required to have adequate space/offices for storage so that they can function freely and effectively, as the current offices are too small. ICT was also highlighted as one of the areas needing improvement, while issues of transport were also frequently mentioned. It is high time that such issues were addressed so that the functioning of the RECs in Malawi could improve and grow even better.

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1. Appendix 1: Self-administered questionnaire

Instructions

1. Please do not write your name on this questionnaire
2. This questionnaire will take you **20 to 25 minutes** to complete

Section A: Participant demographics

Position on REC	☐ REC Chairperson ☐ REC Vice chairperson		☐ REC Member ☐ REC Administrator		☐Other (specify)	
No. of years on REC						
Paid for REC work	☐Yes☐No	If yes:	☐per diem	☐per meeting	☐honoraria	☐salary
☐ Other *[please describe]*						
Institutional affiliation						
Position at institution						
Area of expertise						
Education level	☐ MSCE	☐Certificate	☐Diploma	☐Degree	☐Masters	☐PhD
	☐Other (specify)					

Formal ethics training/education ***prior to*** assuming position on REC	☐Yes☐No	*[Please specify below]*
Name of ethics training/education	Level of training	
1.	e.g. workshop/course/diploma/degree	
2.		
3.		
Formal ethics training/education ***after*** assuming position on REC	☐Yes☐No	*[Please specify below]*
Name of ethics training/education	Level of training	
1.	e.g. workshop/course/diploma/degree	
2.		
3.		

Section B: Research Ethics Committee (REC) demographics

Name of REC			
REC institutional affiliation			
Is this REC	☐National	☐Regional	☐Local/institutional
When was the REC created?			
Why was the REC started?			
Does the REC have an FWA?	☐Yes☐No	What year did the REC receive an FWA?	

Section C: Constitution of REC

How many members currently serve on the REC?	

What are each of their backgrounds / areas of expertise? *[Please select ALL that apply]*

☐Anaesthesiology	☐Epidemiology	☐Nephrology	☐Primary health care
☐Biochemistry	☐Gastroenterology	☐Neurology	☐Psychiatry
☐Biomedical sciences	☐Haematology	☐Nuclear medicine	☐Psychology
☐Bioethics	☐Human genetics	☐Nursing	☐Pulmonologist
☐Biostatistics	☐Immunology	☐Nutrition	☐Radiation oncology
☐Cardiology	☐Infectious diseases	☐Occupational therapy	☐Radiodiagnosis
☐Clinical pharmacology	☐Internal medicine	☐Obstetrics & Gynaecology	☐Radiobiology
☐Community health	☐Legal expertise	☐Pathology	☐Rheumatology
☐Dermatology	☐Medical physics	☐Paediatrics and child health	☐Sports science
☐Emergency medicine	☐Medical virology	☐Physiotherapy	☐Surgery
☐Endocrinology	☐Molecular biology		

☐Other	*[Please specify/list below]*

Is there a community member on the REC?	☐Yes☐No	If so, how many?	

How are community members selected?*[Please describe below]*

What are each of their backgrounds?	
What is their role in the community?	
What is their education level?	

What issues related to diversity of membership are challenges in your REC?*[Please answer in the space below]*

What is the role and responsibility of the **Chairperson** on the REC?*[Please describe below]*

What are the roles and responsibilities of the **Vice-Chairperson**(s) on the REC?*[Please describe below]*

Section D: Financial and material resources

Does your REC receive funding/financial support?	☐Yes ☐No ☐ Don't know
If yes, which bodies/organizations fund your REC?*[Please describe below: info received will be kept confidential]*	
Does your REC receive institutional support (e.g. academic input from universities, legislative support from government, input from consultants, etc.)?	☐Yes ☐No ☐ Don't know
If yes, which institution/organisation gives support to your REC?*[Please describe below]*	
Are REC members paid?	☐Yes ☐No ☐ Don't know
If yes, how? (e.g. per diem, per meeting, salary, honorarium etc.) *[Please describe below]*	
Are there paid administrative and/or managerial staff supporting the REC?	☐Yes ☐No ☐ Don't know
If yes, what type and how many?*[Please describe below]*	
In your opinion, what are some of the infrastructural or material resources that your REC lacks for smooth running? *[Please list / describe below]*	

Section E: REC processes

How often does your REC meet for review of research studies?		
Does the REC meet in person or by phone/email or both?		
Does your REC use an electronic review system?	☐Yes☐ No	
If yes what system do you use and what is your perception on using the system		
What constitutes a quorum for an REC meeting?		
Is meeting a quorum at REC meetings a problem?	☐Yes☐ No☐ Sometimes	*[Please describe below]*
How many protocols (provide a range) does your committee review per meeting?		
What is the duration of time that your REC takes to review an application?		

What is discussed/voted on in the agenda at your REC meeting? *[Please select ALL that apply]*			
Applications for **new research**: ☐*More than minimal risk* research ☐*Minimal risk* research		Applications for **continuing review**: ☐Annual progress reports ☐Final reports	☐Amendments ☐Serious adverse events (SAEs)
☐Other	*[Please specify/list]*		
Does your REC do annual reviews of all applications?			☐Yes☐No
If Yes, how does this work? *[Please describe below]*			
If No, how often does your REC review ongoing research? *[Please describe below]*			
Does your REC have a separate review process (outside the meeting) for *minimal risk* research?			☐Yes☐No
If yes, please describe below i.e. how are minimal risk studies reviewed?			

Does your REC have a separate review process for *continuing review* submissions?	☐Yes☐No
If yes, please describe below e.g. What happens with amendments, progress reports and SAEs submitted to this REC? How are they reviewed?	
Does your REC have documentation such as Standard operating procedures (SOPs), a manual of operations, guidelines, application submission forms, review criteria etc.?	☐Yes☐No
If yes, where and how can they be assessed?	
[Please list the documentation and explain below]	
Does your REC keep minutes?	☐Yes☐No
How often does your REC bring in a consultant to provide scientific/other expertise for review of a protocol?	
What types of conflicts of interest arise in REC members' review of proposals?*[Please describe below]*	
Please indicate whether you consider the following as challenges to the ethical review process in your REC?	
Lack of a national accreditation mechanism for RECs	☐Agree☐Disagree
Lack of national standards for composition of RECs	☐Agree☐Disagree
Lack of national standards for operation of RECs	☐Agree☐Disagree
Lack of a national audit mechanism for RECs	☐Agree☐Disagree

Variable procedures, across RECs, for review of protocols.	☐Agree☐Disagree
Meeting a quorum at REC meetings	☐Agree☐Disagree
Other challenges to the ethical review process in your REC *[Please specify below]*	
What is your perception of the functioning of your REC?	

Section F: Types of research reviewed by REC

What types of research does your REC review? *[Please select ALL that apply]*		
☐Social science research ☐Health systems research	☐Implementation research ☐Product and intervention research	☐Laboratory research ☐Public health research
☐Other	*[Please specify/list below]*	

Does your REC review clinical trials?	☐Yes☐No
If yes, what types of clinical trials? *[Please describe below]*	
Is your REC involved in ethical review of any vaccine trials in Malawi?	☐Yes☐No
If yes, what types of vaccine trials? *[Please select ALL that apply]*	

☐TB vaccine trials	☐Malaria vaccine trials	☐HIV vaccine trial
☐Other	*[Please specify/list below]*	

If no, why not?*[Please describe below]*

Section G: Guidelines used by REC

Does Malawi have specific ethical guidelines for research?	☐Yes☐No☐Don't know
If Yes, please specify the guidelines used below	
Which international ethical guidelines does your REC use to review biomedical/ health research?	
CIOMS (Council for International Organizations of Medical Sciences)	☐Yes☐No☐Don't know
Declaration of Helsinki (2013)	☐Yes☐No☐Don't know
Belmont Report (1979)	☐Yes☐No☐Don't know
UNAIDS (2000) Ethical Considerations for HIV Preventive Vaccine Trials	☐Yes☐No☐Don't know
Singapore Statement	☐Yes☐No☐Don't know
ICH Good Clinical Practice (GCP) guidelines	☐Yes☐No☐Don't know
Other	*[Please specify/list below]*

How appropriate are the international ethical guidelines for use in Malawi?				
[*Please rate by marking the appropriate space. Please mark NA (not applicable) where the guidelines are not employed in Malawi]*	**Very Appropriate**	**Appropriate**	**Not appropriate**	**Not applicable**
CIOMS (Council for International Organizations of Medical Sciences)	☐	☐	☐	☐
Declaration of Helsinki (2013)	☐	☐	☐	☐
Belmont Report (1979)	☐	☐	☐	☐
UNAIDS (2000) Ethical Considerations for HIV Preventive Vaccine Trials	☐	☐	☐	☐
Singapore Statement	☐	☐	☐	☐
ICH Good Clinical Practice (GCP) guidelines	☐	☐	☐	☐
Other	*[Please specify/list below]*			

Which of the following are challenges to the use of ethical guidelines in Malawi?	
The need to develop appropriate national ethical guidelines	☐Yes☐No☐Don't know

Variable use of ethical guidelines across REC within the country	☐Yes☐No☐Don't know
Lack of sensitivity to local socio-political-economic-cultural context	☐Yes☐No☐Don't know
Difficulties in adapting international guidelines to local conditions	☐Yes☐No☐Don't know
Other	*[Please specify/list below]*
Does your REC use an ethics framework (e.g. Emanuel et al (2004).Benchmarkds for ethical research) when reviewing and discussing research? If yes, please state which framework.	
What do you understand by the benchmark of social value?	
Does your REC benchmark social value when reviewing new research application	☐Yes☐No☐Don't know
If yes how is the benchmark of social value applied during reviews and during REC meetings?	

Section H: Laws regulating research in Malawi

Is it possible to conduct health research without any ethics approval in Malawi?	☐Yes☐No☐Don't know
If yes, under what circumstances/conditions would that be?*[Please describe below]*	
Does Malawi have certain laws that govern ethical review of health research?	☐Yes☐No☐Don't know
If yes, specify some of the laws*[Please describe below]*	
Are there any laws dedicated to the protection of research participants in Malawi?	☐Yes☐ No ☐Don't know
If yes, please list / specify these laws*[Please describe below]*	
Are there laws stating that a participant must give their informed consent before participating in any research in Malawi?	☐Yes☐ No ☐Don't know
If yes, please list / specify these laws*[Please describe below]*	
Is health research with human participants reviewed for scientific quality by an authority/central regulatory body in Malawi?	☐Yes☐ No ☐Don't know
If yes, please name the regulatory body(ies)*[Please describe below]*	
Are there any laws that regulate how the national research agenda is set?	☐Yes☐ No ☐Don't know
If yes, please list / specify these laws*[Please describe below]*	
Do researchers have to register with a professional body?	☐Yes☐ No ☐Don't know
If yes, please name the professional body(ies) where they register*[Please describe below]*	

If yes, does this body have the powers to discipline members who infringe ethical codes?	☐Yes☐No☐Don't know
Do research ethics committees have to register with a professional/ national regulatory body?	☐Yes ☐No ☐ Don't know

Section I: REC training

In your own view, is there any need for training REC members to review health research protocols?	☐Yes☐No
If yes, what are some of the training needs required? *[Please describe below]*	
Please indicate whether training on the following aspects are/might be important for your REC *[Please select ALL that apply]*	
☐Scientific design issues in health research ☐The use of placebo controlled trials ☐The interpretation of pre-clinical studies ☐Determinations to run phases (I, II, III) in a country ☐Determination of potential risks of research ☐Provision of appropriate risk reduction interventions ☐Assessment of anticipated benefits ☐Incentives for participation	☐Community participation ☐Assessment of understanding informed consent ☐Assessment of cultural sensitivity of research ☐Privacy and confidentiality ☐Social and behavioral studies ☐Monitoring and oversight ☐Post-trial access to successful treatment ☐Post trial care ☐Other *[please specify below]*
☐Other	*[Please specify/list below]*

Thank you for your support and assistance by completing this questionnaire

Appendix 2: Information leaflet and informed consent

___/___/ 2017

Title of the Study: **The Composition and Functioning of Research Ethics Committees Reviewing Health Research in Malawi**

Introduction

My name is Nicholas Phiri. I am a student, pursuing a Master of Social Science Degree in Health Research Ethics at the University of KwaZulu-Natal, School of Applied Human Science in the Department of Psychology in South Africa. In partial fulfilment of the requirement for the award of the Master's degree, I am conducting a research study on **The Composition and Functioning of Research Ethics Committees Reviewing Health Research in Malawi**.

You are being invited to consider participating in this study. This consent form explains the research study you are being asked to join. Please, read it carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study. If you agree to participate, you will complete a self-administered questionnaire. The questionnaire will be anonymised and nobody except the researchers will know what you said. If we report on this study, we may use one of your sentences or responses but even if we do that we will not put your name; nobody will know that it was you who said it.

Purpose of the study

The aim and purpose of this research is to describe the roles and responsibilities, composition, and capacity of Malawi's two health research ethics committees (RECs), including their perceived needs for capacity building; the types of research reviewed by RECs in Malawi; and to explore whether and how the benchmark of (local) social value is applied when reviewing research.

Participants

The study is expected to enrol a minimal of 30 participants. At least 16 participants from the National Health Sciences Research Committee (NHSRC) and 14 from the College of Medicine Research and Ethics Committee (COMREC) are expected to be enrolled in the study. The study targets REC members, Chairpersons, Vice Chairpersons and Secretariat staff of the two committees. All 30participants in this study will be requested to complete a self-administered questionnaire.

Risks/Discomforts

There are no physical risks/discomforts involved in this study. However, you might feel upset or worried to reveal your private information when answering some of the questions. To minimize this, please, feel free to choose not to answer any questions you do not want to answer. The self-administered questionnaire may take approximately 25 to 30 minutes of your time to complete

Anticipated Benefits

The results generated from the study will not provide any direct benefits to you but may help to highlight the needs of RECs in the country. The highlighted needs and challenges may help to facilitate the establishment and implementation of solutions or lead to further investigation/studies that may help enhance and/or improve the functioning of RECs in Malawi.

Confidentiality

We will keep what you answer in the questionnaire and what you say to us in the interview strictly confidential. The REC you belong to will also be kept anonymous. The reputation of the REC will be maintained and ensured by disassociating the responses with the identities of specific RECs in the report. You and the REC you belong to will be assigned a unique identification number and letter respectively. We will only refer to the number and letter in future and not to your name or your REC's name. This implies that you and your REC will also not be identified as a participant and a specific REC involved respectively in any publication that can come from this study. The information collected will be kept in restricted access offices and on password-secured computers. The in-depth interviews will be audio recorded to

enable transcription and analysis. All audio-recordings will be stored safely and securely in a password protected computer for 5 years after which they will be destroyed.

Independent review

This study has been reviewed and approved by the University of KwaZulu-Natal (UKZN) Biomedical Research Ethics Committee in South Africa (ethics approval number BE090/17). It has also received ethics approval from the National Health Sciences Research committee (ethics approval number**1766**).

Voluntariness and the right to withdraw

Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving any reason. If a question makes you uncomfortable and you don't want to answer it, then you don't have to. If during the administration of the questionnaire or at a later date you have second thoughts, then please feel free to withdraw from the study. If you withdraw your participation, you will not incur any penalty or loss of benefit to which you are normally entitled.

Compensation

No costs will be incurred for your participation in this study. Since data collection will be done during your REC meeting, the student investigator will provide some soft drinks and snacks as a token of appreciation for your time.

Contact Information

In the event of any problems or concerns/questions you may contact me on +265 (0) 999 201 649 at anytime or through my email address at nicho_phiri@yahoo.com. You may also contact my supervisor and co-supervisor through email addressesnbarsdorf@sun.ac.za and fmasiye@sun.ac.zarespectively. If you have concerns about your rights as a participant in this study, you may contact either the UKZN Biomedical Research Ethics Committee or the National Health Sciences Research Committee

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001
Durban
4000

KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

or

National Health Sciences Research Committee

Ministry of Health
P.O.Box 30377
Lilongwe 3
Tel: +265 1 726 422/418

Email: mohdoccentre@gmail.com

Statement/declaration by the Study Participant

- I .....confirm that Nicholas Phiri, who is asking for my consent to take part in his study has told me about the nature, process, risks, discomforts and benefits of the research entitled: **"Mapping the Composition and Functioning of Research Ethics Committees Reviewing Health Research in Malawi"**

- I have received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study.
- I am aware that the results of the study, including personal details, will be anonymously processed into research reports.

- I declare that my participation in this study is entirely voluntary and that I may withdraw from the study at any time without affecting my job, reputation, any treatment or care that I would usually be entitled to me.

- I have had time to ask questions and have no objection to participate in the study.

- I understand that there is no penalty should I wish to stop my participation and my withdrawal will not affect me in any way.

- If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher through his cell-phone number or email address at nicho_phiri@yahoo.com or on +265999201649 or his supervisors as indicated in the information leaflet provided.

- If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

THE BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

Or

National Health Sciences Research Committee

Ministry of Health
P.O.Box 30377
Lilongwe 3
Tel: +265 1 726 422/418
Email: mohdoccentre@gmail.com

Participant Signature……Date…../……./……

Name of Study Participant ……

Student Investigator Statement

I confirm that the study participant has understood the information and voluntarily agreed to participate in the study.

Signature……..….Date…….

Name of Student Investigator……

Appendix 3: Ethics approval letters and support document

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

26 April 2017

Mr N Phiri (216074139)
Discipline of Psychology
School of Applied Human Sciences
Humanities
nchlsphiri@yahoo.co.uk

Dear Mr Phiri

Protocol: Mapping the composition and functioning of Research Ethics Committee reviewing Health Research in Malawi.
Degree: MSocSc
BREC reference number: BE090/17

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 22 February 2017.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 12 April 2017 to BREC letter dated 07 March 2017 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given **full ethics approval** and may begin as from 26 April 2017. **Please forward outstanding ethics approval and gatekeeper permission letters to BREC as soon as available.**

This approval is valid for one year from **26 April 2017.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

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

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

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

The sub-committee's decision will be **RATIFIED** by a full Committee at its next meeting taking place on **09 May 2017.**

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

Yours sincerely

Professor Joyce Tsoka-Gwegweni
Chair: Biomedical Research Ethics Committee

cc supervisor: nbarsdorf@sun.ac.za
cc postgraduate administrator: khcnvillet@ukzn.ac.za

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Telephone: +27 (0) 31 260 2486 **Facsimile:** +27 (0) 31 260 4609 **Email:** brec@ukzn.ac.za

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI
RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

02 August 2017

Mr N Phiri (216074139)
Discipline of Psychology
School of Applied Human Sciences
Humanities
nchlsphiri@yahoo.co.uk

Dear Mr Phiri

PROTOCOL: Mapping the composition and functioning of Research Ethics Committee reviewing Health Research in Malawi. Degree: MSocSc
BREC reference number: BE090/17

NEW TITLE: The composition and functioning of Research Ethics Committee reviewing Health Research in Malawi

We wish to advise you that correspondence received on 17 July 2017 submitting an Application for Amendments to change the title to the above, change in study design and addition of questions in the questionnaire for the above study has been **noted and approved** by a sub-committee of the Biomedical Research Ethics Committee.

This approval will be **ratified** by the full committee at its next meeting taking place on **12 September 2017.**

Yours sincerely

Mrs A Marimuthu
Senior Admin Officer: Biomedical Research Ethics Committee

Telephone: + 265 789 400
Facsimile: + 265 789 431

All Communications should be addressed to:

The Secretary for Health and Population

In reply please quote No.

.....

MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
LILONGWE 3
MALAWI

8th May, 2017

Nicholas Phiri
University of KwaZulu Natal/KCH
Lilongwe

Dear Madam,

RE: PROTOCOL # 1766: MAPPING THE COMPOSITION AND FUNCTIONING OF RESEARCH ETHICS COMMITTEES REVIEWING HEALTH RESEARCH IN MALAWI

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER : 1766**
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE : 08/05/2017**
- **EXPIRATION DATE**
  This approval expires on **07/05/2018.** After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on phone number *+265 888 344 443* or by email on mohdoccentre@gmail.com.
- **OTHER**: Please be reminded to send in copies of your final research results for our records (Health Research Database).

Kind regards from the NHSRC Secretariat.

SECRETARY FOR HEALTH
2017 -05- 08
P.O. BOX 30377, CAPITAL CITY, LILONGWE 3

.....

For: **CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE**
Promoting Ethical Conduct of Research

Telephone: +265 789 400
Facsimile: +265 789 431

All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
LILONGWE 3
MALAWI

14th July, 2017

Nicholas Phiri
Kamuzu Central Hospital
Lilongwe

Dear Sir/Madam,

RE: PROTOCOL # 1766: THE COMPOSITION AND FUNCTIONING OF RESEARCH ETHICS COMMITTEES REVIEWING HEALTH RESEARCH IN MALAWI

Thank you for the above titled proposal for amendment dated 29 June, 2017 that you submitted to the National Health Sciences Research Committee (NHSRC) for review.

The Committee reviewed and **approved** the following changes:

1. Change of title from "*Mapping the Composition and Functioning of Research Ethics Committees Reviewing Health Research in Malawi*" to "*the Composition and Functioning of Research Ethics Committees Reviewing Health Research in Malawi*"
2. Change in the study design from Mixed Research Method to Descriptive Cross-sectional survey
3. Addition of questions in the original questionnaire

Kind regards from the Secretariat.

SECRETARY FOR HEALTH
2017 -07- 14
P.O BOX 30377, CAPITAL CITY, LILONGWE 3

FOR: CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

NATIONAL COMMISSION FOR SCIENCE & TECHNOLOGY

Lingadzi House
Robert Mugabe Crescent
P/Bag B303
City Centre
Lilongwe

Tel: +265 1 771 550
+265 1 774 189
+265 1 774 869
Fax: +265 1772 431
Email:directorgeneral@ncst.mw
Website:http://www.ncst.mw

All communication should be directed to the Director General

REF.NO.NCST/RTT/2/6 **21st July, 2016**

The Director
Biomedical Research Ethics Administration
Research Office
Westville Campus
Govan Mbeki Building
Private Bag X54001
Durban 4000

TO WHOM IT MAY CONCERN

Mr Nicholas Phiri, who is a student at University of Kwazulu-Natal **(Reg. No.216074139)** has presented himself to the National Commission for Science and Technology in Malawi to find out if it is necessary to contact the administration and members of local research ethics committees as would be research participants for his study to seek their prior consent in waiting for obtaining ethics approval.

This office which is responsible for national regulatory affairs for the conduct of research in Malawi, would like to state that there are no such regulatory requirements in force. What is in force, among others, is that any researcher be it a student or not must first obtain a local research ethics committee approval for the study to be conducted in Malawi. For a student affiliated to a university outside Malawi, it is a regulatory requirement for such a student to first obtain a research ethics approval from a research ethics committee of the university to which the student is affiliated. Once this is obtained, the student/researcher is required to submit an application package to the local ethics committee (in Malawi) with the approval letter from a foreign research ethics committee of the country/institution of origin of the study. Once the local research ethics committee is obtained, the researcher is free by law to contact and access any would be research

participants for purposes of implementing the approved research at which level the researcher would now obtain an individual consent from a targeted would be participant.

Please assist the student accordingly so that he should obtain the ethics committee approval in Malawi without further delay.

Yours Sincerely

Mike G Kachedwa
CHIEF RESEARCH SERVICES OFFICER & HEAD OF HEALTH, SOCIAL SCIENCES AND HUMANITIES DIVISION, ETHICS AND REGULATORY AFFAIRS

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

14th March, 2017

Nicholas Phiri
University of KwaZulu Natal
RSA

Dear Nicholas,

RE: PERMISSION TO CONDUCT ACADEMIC RESEARCH AT THE NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE (NHSRC) SECRETARIAT

I write to advise that permission will be granted for you conduct your study at the NHSRC Secretariat when your proposal has been given ethical approval by University of KwaZulu Natal and one local ethics committee in Malawi.

Yours sincerely,

SECRETARY FOR HEALTH
2017 -03- 14
P.O BOX 30377, CAPITAL CITY, LILONGWE 3

Dr D. Kathyola
DIRECTOR OF RESEARCH

COLLEGE OF MEDICINE

Principal
M. H. C. Mipando MSc PhD

Our Ref:

Your Ref:

College of Medicine
Private Bag 360
Chichiri
Blanytre 3
Malawi
Telephone: 01 871911
01 874107
Fax: 01 874 700

Dear Nicholas Phiri,

Re: Permission to conduct academic research at University of Malawi – College of Medicine Research and Ethics committee members (COMREC).

I write to advise that permission will be granted for you to conduct your study with COMREC members, after your proposal has received ethical approval from your academic institution and one local ethics committee in Malawi

The permission is granted for administering questionnaires to College of Medicine Research and Ethics Committee members.

Yours Sincerely,

Dr Lucinda Manda-Taylor (PhD)
COMREC Administrator