SCHOOL OF PUBLIC HEALTH
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LEGON

ASSESSMENT OF THE STANDARD OPERATING PROCEDURES OF
SELECTED RESEARCH ETHICS COMMITTEES IN GHANA

BY
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LEGON, IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE
AWARD OF MASTERS IN PUBLIC HEALTH DEGREE

JULY 2019
DECLARATION

I declare that this dissertation is the result of my own original research work which has not been published or presented somewhere else for another degree. Published literature of other researchers cited in my work have been duly acknowledged by means of referencing.

Dr Evans Gyimah Boateng
(10703858)

Dr. Paulina Tindana
(Supervisor)

Signature:……………………

Date…………………………

Signature:……………………

Date…………………………
DEDICATION

I dedicate this dissertation to my wonderful children, Yaa, Ama, Abena and Kwabena.

You are my source of inspiration.
ACKNOWLEDGEMENT

I am most grateful to the Almighty God for bringing me this far in the pursuit of my MPH degree. My sincerest appreciation goes to my supervisor, Dr. Paulina Tindana for her guidance and ensuring that this dissertation was completed successfully. Also, I am grateful to Mr. Samuel Aseidu Afari, Dr. Joshua Kodom and Mr Samuel Amoah for their assistance.

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ABSTRACT

**Background:** Research involving human participants presents a number of key ethical challenges. In the context of health-related research, it is globally recognized that there is the need to protect human participants from the risks that may be posed by various research activities. These risks may be social, psychological, emotional, and physical. One of the key safeguards to protecting human participants from research-related risks is the role of Institutional Review Boards (IRBs) or research ethics committees (RECs).

**Aims:** This study assessed the Standard Operating Procedures of selected research ethics committees in Ghana by examining the composition and submission requirements of these committees, exploring key stakeholders’ views on Standard Operating Procedures of the Ethics Committees and identifying key challenges in the review process.

**Methods:** The study used an exploratory qualitative research approach to collect primary data from three Research Ethics Committees (REC)/Institutional Review Boards (IRB), namely; Ghana Health Service- Ethics Review Committee (GHS-ERC), the Institutional Review Board of the Kintampo Health Research Center (KHRC-IRB), and that of the Dodowa Health Research Center (DHRC-IRB). Documents including the Standard Operating Procedures (SOP) of these IRB/REC and the World Health Organization’s (WHO) Guidelines on Research Ethics with Human Participants were reviewed for this study. The study also used In-depth Interviews (IDI) to collect qualitative data from 32 respondents which included Heads of Institutions, the IRB/REC Administrators, the Chair, researchers and the members of the research ethics committee for the selected Research Ethics Committees (REC)/Institutional Review Boards (IRB). These respondents were purposively selected from these institutions for the study.

**Results:** From the study, one of the major challenges facing institutions in running the activities of research ethics committees is funding. These activities include, monitoring
approved protocols, proper or adequate motivation for committee members and providing frequent training programmes for committee members. Another important finding is that the institutions do not have a formal system to evaluate the activities of the research ethics committees. Also, committee members are overburdened with an increasing number of protocols despite their busy schedules. Other key challenges identified in this study include requirements for requirements for submitting several copies of the research protocol, delays in the review process and delays in communicating the outcome of the review process to researchers.

Most respondents of the study viewed the ethics committees as independent though the Heads of Institution were part of the review process contrary to WHO recommendations. Generally, the research ethics committees have diverse expertise, which makes them capable of reviewing all types of research protocols.

**Conclusion:** The standard operating procedures of the IRBs/RECs are closely aligned with the recommendations in the WHO SOPs. However, there are unique challenges that need to be addressed to improve the efficiency of the IRB/RECs’ operations.
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UNDP  United Nations Development Programme

WHO  World Health Organization
OPERATIONAL DEFINITIONS OF KEY TERMS

CONFIDENTIALITY: A protection of personal information.

ETHICS: A branch of knowledge that deals with moral principles.

GUIDELINES: A statement to determine a course of action.

HARMONIZATION: The process of minimizing redundant or conflicting standards which may have evolved independently.

INSTITUTIONAL REVIEW BOARDS: It is an administrative body that is established to protect the rights and wellbeing of research activities involving human participants that are carried out by the institution with which it is associated.

MULTICENTRIC: Having more than one center

PRIVACY: The ability of an individual or organization to seclude themselves or information about themselves thereby expressing themselves selectively.

REVIEW ETHICS COMMITTEES: A type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical.

STANDARD OPERATING PROCEDURE (SOP): A set of step by step instructions compiled by an organization to help workers carry out complex routine.
CHAPTER ONE

1.0 INTRODUCTION

1.1 Background of the Study

Ethics is broadly defined as a branch of philosophy that deals with the distinction between right and wrong- with moral consequence of human actions (John, 2001). Ethics is also defined as norms of conduct that distinguish between acceptable and unacceptable behavior for various professions (Shah, 2011). For example, medical ethics guides health professionals on how they ought to relate with their patients and colleagues and addresses issues related to patient autonomy, confidentiality and duty of care. In the context of health-related research, it is globally recognized that there is the need to protect human participants from the risks that may be posed by various research activities. These risks may be social, psychological, emotional, and physical. One of the key safeguards to protecting human participants from research-related risks is the role of Institutional Review Boards (IRBs) or research ethics committees (RECs).

Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) are established to review the ethical merits of research involving human participants. These institutions aim at safeguarding the welfare, dignity and safety of the participants and the community at large. They also ensure that all research involving human participants (living individuals about whom the investigator obtains information) are in line with approved protocols and also promote public confidence. The IRBs/RECs ensure that research activities involving human participants are carried out in a scientifically accepted manner. These aims are achieved through the following: prior review, observation, monitoring, resolution, premature termination, accountability and quality assurance (Guraya, et al., 2014).
Health research involving human participants may include epidemiological, biomedical, behavioral and social science. Since human participants need protection during research, there is the need for clear guidelines to facilitate the work of IRB/REC.

The history of medical research dates back to the early 19th century, the age of experimental medicine. However medical ethics has an already existing history which is almost 2000 years old. The difference is that in the early ages before Hippocrates, research ethics was least discussed. Research ethics was a quiet field, whereby codes of ethics were typically addressed as medical etiquette. Furthermore, experimentation was not too different from the practice itself (Valdez-Martinez et al., 2005).

The research ethics literature suggests that there are many treaties and declarations which emerged to address fundamental principles of ethical conduct in biomedical research. These include the Nuremberg Code, the Declaration of Helsinki, EU Convention on Human Rights and Biomedicine [Convention on Human Rights and Biomedicine (the Oviedo Convention)] (Guraya, et al., 2014).

The declaration of Helsinki was adopted in the year 1964 at the general assembly of the World Medical Association. It was published to introduce an authoritative attestation of the need for prior review of any kind of human research (Guraya, et al, 2014). The Declaration emphasized on providing guidance to physicians engaged in clinical research and its main focus was the responsibility of the researcher to protect research subjects.

In 1975 the declaration was reviewed and the shortcomings were assessed and rectified. This is because the previous declaration left the rights and safety of the research participants
with the individual investigator. However, with the revised version, biomedical research involving human subjects finally had been furnished with a firm system of internationally accepted norms and principles (Carlson, 2004). The field of medical research ethics has evolved as a vital aspect of protecting human participants. The requirements for such protections have also evolved because of historical traces of ethical violations against human participants in the name of scientific development (Becker, 2005; Chadwick 1997; Pressel, 2003)

Against this background several ethical values have been categorized into different national and international policy documents, which began in the 1970s with the Belmont Report (Beauchamp, 2004; Office of the Secretary 1979). In the academic field this regulatory framework has constituted a major shift and has raised various concerns about the style and variations of the ethical safeguards.

To ensure that research is conducted in an ethically accepted manner and for the development and protection of the rights and welfare of participants in research along with their communities, these guidance or codes should be adhered to. By this guidance, it implies that before any health-related research is conducted, the research ought to be subjected to review by a capable research ethics committee.

A study by Hoeyer et al. (2007), has suggested that the requirements of these institutionalized codes were stringent and posed a unique challenge for the researcher especially on research conducted in the healthcare setting. There is the need to also question the perceived adversarial relationship that has developed between researchers and IRBs/RECs. Implying that the reviews must be carefully assessed with the aim of exploring
the composition and submission requirements of research ethics committees, as well as key
stakeholders’ views on Standard Operating Procedures of selected ethics committees.

In Africa, especially in sub-Saharan Africa there is a growing need for research ethics
committees to develop appropriate standards and build capacity that can make them most
efficient and effective in reviewing research protocols.

1.2 Statement of Problem

Globally, there is a general recognition of the important role of RECs/IRBs in human
participant protection with many research institutions establishing systems that will support
ethics review. In many developing countries, however, the establishments of research ethics
committees were influenced by international research collaborations and requirements from
funders (Oguz, 2003). The competencies of these IRBs have however been called into
question as a result of an underdeveloped scientific culture coupled with the absence of
established ethical standards.

In Ghana, there are about eighteen (18) IRBs/RECs involved in reviewing research
proposals. These committees are established by various institutions including universities,
research organizations and the Ghana Health Service. There is no national body or authority
for ethics in Ghana, although the Ghana Health Service Ethics Review Committee, based at
the Research and Development Division often plays this role as well as being responsible
for the review of research conducted in Ghana Health Service facilities.

The absence of national research ethics guidelines provides for less protection of human
participant in health research. Because some international regulations like respect for
autonomy are not culturally sensitive according to Oguz (2003), it puts pressure on the country to have its own guidelines that will fit the settings of its people. A country like South Africa has a national policy guideline passed by their parliament that all research conducted in the country should conform to the national policy guideline. In Ghana, it is the Public Health Act that makes mention of research ethics review only in clinical trial.

One other challenge identified is that the standards of IRBs in Africa seem hard to achieve. For example, in Ghana, decisions and approvals of research protocols often vary from one IRB/REC to the other, particularly in international collaborative research which involves multiple reviews. These IRBs have developed specific standard operating procedures (SOPs) based on the World Health Organization’s Standard Operating Procedures. However, there has not been any assessment on how these standards are applied in practice in the review process.

1.3 Justification of the Study

The need to protect human participants in research is imperative and has become a global issue. As research increasingly becomes complex with advancements in sciences and technology, the operations of IRB/RECs need to be strengthened to make them more efficient and effective. The literature suggests that IRB/RECs face several challenges (Nyika et al 2009). In Ghana, some of the challenges that have been highlighted include inconsistencies in the review process by IRBs/RECs especially in the case of multiple reviews where a protocol needs to be reviewed by different IRBs/RECs. Also, currently, there is limited data especially on national ethical guidelines as well as a regulator for the eighteen IRBs/RECs in the country currently. To the best of my knowledge there is limited data on the current standard operating procedures of research ethics committees in Ghana
and it is unclear if the current standards are in line with the standards stipulated in international research ethics guidelines such as the WHO standard operating procedures. It is in line with these reasons that this study was conducted.

1.4 Objectives

The main aim of this study was to assess the Standard Operating Procedures of selected research ethics committees in Ghana.

1.4.1 Specific Objectives

1. To examine the composition of research ethics committees
2. To examine the submission requirement of research ethics committees
3. To explore key stakeholders’ views on current standards for ethics review in Ghana
4. To identify key challenges in the review process.

1.5 Research Questions

1. What is the composition of research ethics committees in Ghana?
2. What are the submission requirements of research ethics committees in Ghana?
3. What are the key stakeholders’ views on current standards for ethics review in Ghana?
4. What are the key challenges in the review process?
CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Health research is an ethically rich endeavour such that the concept of its delivery is inconceivable without an articulated ethical framework. Professionals and individuals hold differing views about the pertinent issues of ethics either based on factual knowledge, subjective experiences, or varying rational and religious presuppositions. In the light of these, it is common to draw different ethical conclusions regarding the appropriateness of a given approach to medical intervention, particularly in a more diverse society.

Owing to historic abuses committed against human participants during research, most research institutions, universities, community-based organizations, and research hospitals have made ethics review for research a requirement (Becker, 2005; Pressel, 2003; Beauchamp 2004). A formal collation of ethics was undertaken in the 1970s in various national and international policy documents which was perceived by researchers to be a major shift from professional ethics to the codification of ethics through regulatory frameworks and external review organizations (Guta et al., 2013). After 30-40 years, even the best known of the new approaches are yet to achieve a wide spread use by practitioners (Munro and Mingers, 2004; O’Brien 2011). Currently, there is the need to develop tools that will be applicable to the majority of researchers and professionals. The literature review reveals that some non-academic researchers tend to deal with ethical issues in an ad-hoc intuitive way in the context of a particular intervention.

2.2 The Development of Ethical Standards and Associated Challenges

To address the issue of ethics and its associated challenges in the past 50 years, two
developments have emerged - clinical ethics consultation and institutional ethics committee (Hook et al., 2013). According to the American Society for Bioethics and Humanities (Jonsen et al. 1982), clinical ethics consultation is “a set of services provided by an individual or a group in response to questions from patients, families, surrogates, health professionals, or other involved parties who seek to resolve uncertainty or conflict regarding value-laden concerns that emerge in health care.” The main objective of this consultation is to make available immediate access to individuals with the requisite skills and knowledge to aid patients and clinicians in addressing thought-provoking ethical questions and dilemmas. On the other hand, institutional ethics committees are responsible for the establishment of institutional policies and technical guidelines for certain aspects of care with considerable ethical components.

With the issues of research misconduct and abuse, it was imperative to develop codes and principles that governed research work. This led to the subsequent emergence of Research Ethics committees or Institutional Review Boards being setup in developed countries in the early 1980’s (Thomson, 2012). However, in Africa, according to Kass et al., 2007 and Rwabihama et al., 2010, the oldest REC in Africa was established in 1967 at the University of Witwatersrand in South Africa. Soon after, in 1974, the Medical Research Council in Zimbabwe was established. This was followed in 1988 by the National Health Sciences Research Committee of Malawi (Henderson et al., 2007). In most of these emerging countries, research ethics committees were not established as a result of any public consciousness or recognition of some heart-breaking research studies but because of the duress which emanated from the Western scientific community (Karakaya & Oguz, 1993). The pressures from the Western scientific community emerged in three different forms. The first was that, major scientific periodicals required the endorsement of research ethics
committee. Without research ethics committee’s approval, studies by researchers were not published. Secondly, because multi-centric studies which involved developing countries was on the increase and that these studies followed some mutual protocols, most researchers were pressed to prove that their studies were carried out in an ethical manner. This was necessary for international collaboration (Cerrahpasa Faculty of Medicine, 1992). Lastly, researchers were required to have research ethics committee’s approval before they secured funding for their project which to most researchers was very crucial (Arda et al., 1999). Notwithstanding these pressures from the western world, in a survey conducted by Hyder et al., 2004, researchers in developing countries indicated that one third out of 15% of studies that were funded by the U.S did not undergo any form of review by an REC or health authority in these countries. With this backdrop, most developing countries saw the emergence of Research Ethics Committee (REC) without a formal understanding of the significance of ethics in research, as was in the scientific community. That is, the advent of Research Ethics Committee preceded the widespread understanding of the importance of ethics in some developing countries. These ethics committees lacked standards and regulations when they began to be operational. Secondly, beside the lack of standards and regulations for operation, research ethics committees from developing countries could not cope with the new international standards, as they were too high to be attained immediately. This was because, research procedures in the developed countries were determined within the confines of the scientific culture and norms at the time, which most developing countries did not have (Oguz, 2003). Developing countries needed the resources that are, human and capital resources to meet the international standards of ethical research. Hence, members of the research committees of the developing countries needed to interpret the international guidelines and standards in the context of their specific socio-economic and cultural conditions characterized by inequalities in education, technology and power among government and research funders. These challenges mentioned above were typical at the inception of the Research Ethics Committees in developing countries.
It is established that ethical endorsement alone does not necessarily ensure the practice of ethics during conduct of a study. Considering the plethora of evidence of abuse even after ethical approval in several studies of time past and the continuous existence of unethical behaviour during the conduct of studies, it has become imperative for the review to take into account and ensure the safety and welfare of research participants all the way through the research process. Hence, there is the need for approved research to be monitored continuously. Ethical review and monitoring require resources and training, which apparently are lacking in most African ethics committees. It involves the continuous follow up through visits to study site to check compliance to approved protocol, sometimes an interaction with participants and other major stakeholders. All these are ways to ensure that researcher comply with approved protocol. It often comes with an enormous cost to the research ethical committee. In developing countries, due to the financial constraints, such important actions of the review committee may not be done.

Although most African countries are stated to have some form of ethical review process in place, it was reported in 2001 by the WHO Regional Committee for Africa that, some research studies were not going through any form of ethics review (Kirigia, Wambebe, & Baba-Moussa, 2005). For studies that go through ethical review process, the operationalization of these processes is hindered by some interlocking factors which include inadequate resources, poor staffing, and lack of training for members. For instance, a study by Ikingura et al., (2007) carried out in Tanzania found that among 45 respondents who are part of the research ethics committee, about 49% of them did not have any training in health research ethics review. Similarly, a study by Milford et al., (2006) also reported that among 27 respondents, about 87% agreed to the fact that there was lack of general and sufficient ongoing training for members in health research ethics. A major and often-cited challenge
of Research Ethics Committee in developing countries is their capacity to review research proposals. The committee is vested with the authority to interpret the international ethics guidelines in specific socio-economic and cultural settings, but unfortunately some committees work in a complex environment which is characterized by power inequalities among government, funders, researchers or community.

Also, in the wake of increased workload, most committees report that they are overwhelmed by the number and complexity of studies to be reviewed (Hyder et al., 2013; Nyika et al., 2009). According to Ijsselmuiden et al., 2012 and Rivera & Ezcurra 2001, there is the need to improve ethics supervision and the review capacity of RECs/IRBs in Africa and other developing countries. This is to increase the protection of human participants in the wake of the rise in workload combined with the complexity especially with international collaborative biomedical research with human participants. Again, some scholars and experts have showed concerns that the increase in biomedical research happenings have not been accompanied by an increase in research ethics capacity advancement in developing countries (Bhutta, 2002; Silverman, Edwards, Shamoo, & Matar, 2013). All these play-out either individually or together to militate against the committee’s capacity to efficiently and effectively review research proposals. Also, reliance on the parent institution for funding may compromise the independence of the committee.

Another noteworthy challenge is the reliance on paper-based data management and archiving systems (Nyika et al., 2009). This system has the tendency to inhibit the committee’s ability to effectively follow up and monitor approved studies. Furthermore, most committees in the developing world lack dedicated office space to securely store their documents. These in effect work to compromise the confidentiality and the privacy of the...
committee’s work. As they may sometimes keep some of these documents at home or even on their personal computers. This makes it easier for others to gain access to classified files.

Another challenge is that, there is also the issue of high staff turn-over, which may affect the continuity of expertise (Nuffield council, 2002). Specifically, in sub-Sahara Africa, Nyika et al., (2015) found that membership for some Research Ethics Committees are problematic as some have as low as 3 members and others, 19 or more. Important contributory factors to this large variation in membership are the lack of compensation for the costs incurred in attending the committee’s meeting and potential members’ unwillingness to go beyond the committee’s normal duties (Nyika et al., 2015). Upon reflection of the challenges faced by the Research Ethics Committee, researchers, for instance, Nyika et al., (2015) suggest that members are trained before or upon joining the committee to help orient them on the standard operating procedures that are put in place and the specific ethical review procedures utilized by the particular committee. To ensure the independence of the research ethics committee, Nyika et al., (2009) suggest that the committee generate adequate funds in order to reduce its reliance on the parent institution and also employ from outside the parent institution in order to ensure their true independence in their operationalization. As part of a capacity building forum for research ethics committees by Nyika and his colleagues (2009), a software was procured and members were trained in its usage. The software, according to Nyika et al., (2009) provided an efficient means for data filing system and also facilitates follow-ups and the monitoring of approved studies while precluding the unauthorized access to the committee’s data system.
2.3 Standard Operating Procedures

To meet the obligations of the EU directive, Standard Operating Procedures (SOPs) were introduced in 2004. Researchers in the UK were required to register each application they consider onto research ethics committees (RECs) Research Ethics Database under the SOPs. Such applications are reviewed at REC meetings. (Nyika et al., 2009). Applicants are requested to attend, and while in attendance, they may well be invited to answer specific questions. The committee may additionally discuss in private any matters arising from the discussion, and then a decision is made.

2.4 WHO Standard Operating Procedures

In line with the introduction of the Standard Operating Procedures in 2004 as stated above, the World Health Organization (WHO) released a document to that effect. The document was developed for establishments which were involved in research in the health sector involving humans, comprising biomedical, behavioral, social and epidemiological research (WHO, 2011). The purpose is to provide guidance to research ethics committees in reviewing and overseeing the ethical aspects of research studies. The progression of this document commenced before the year 2000. However, during the special programme for research and training in Tropical Diseases by the UNDP/WORLD BANK/WHO, effective guiding principles for the committees that reviewed biomedical research in reaction to collaborative research throughout the world were published in the year 2000. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) under the World Health Organization (WHO) in 2006, acknowledged the essence of capacity building in the area of ethical review when undertaking research. It was also noted that plans are in place to strengthen clinical trials and the legislative framework of the emerging countries, especially in sub-Saharan Africa, together with the enhancement of the standards
in ethical review.

A consultative meeting was organized in Geneva by WHO in 2009 which brought together key international experts, made up of memberships as well as chairmen and chairpersons of various ethics committees, researchers, representatives of the international institutions, and ethicists to deliberate on the key guiding principles that should be required by RECs worldwide. The meeting concluded that member states may find the 2000 WHO publication very useful in setting standards for very high-quality decision making against which RECs might measure their own performance. Therefore, as a recommendation, members instructed WHO to coordinate the needed process to put together standards for RECs as well as review the 2000 operational guidelines that describe detailed measures that is needed in order to achieve these standards. The standard was to complement prevailing laws, regulations, and practices and to serve as a guide in developing specific dos and don’ts as well as procedures for IRBs/RECs. As such, its aim was neither to substitute the local and national guidelines for ethical review of research nor to supplant legislation of any nation.

There are 10 standards that were documented as outlined below.

2.4.1. Responsibility for Establishing Research Ethics Review System

In the WHO SOP, research that deals with human participants is presumably subjected to RECs oversight. The review committees are responsible for giving approval for various research activities. In recent times, obtaining a biomedical Research Ethics Committee (REC) or Institutional Review Board (IRB) approval is the conventional way of documentation for a researcher who has taken the necessary steps to ensure the research subjects’ safety. It is considered as an element of misconduct if a researcher fails to do so
for whatever reason. This element of misconduct should not be rewarded by approval for publication. However, it has been indicated in a literature published by Riaz Agha that the frequency of ethics review board permission amongst surgical RCTs is low (Agha et al., 2007).

Again, according to the document, the RECs are seen to be a portion of bigger research participant protection programmes, which also include training of REC members and researchers as well as the mechanisms to make sure that RECs work effectively. As such, the processes are there to guarantee clear and effective communication, coordination of standards, interaction and operation between the national committee at the various levels where applicable (WHO, 2011). Therefore, to make certain that the activities of RECs harmonize with national regulatory authorities, these several mechanisms must exist. The mechanisms are in place for obtaining community input into ethics review system, and by that a system existing for registration of RECs that operate in a particular country (WHO, 2011).

2.4.2. Research Ethics Committees’ Composition

This standard talks about how and who should be chosen as part of the REC. The members chosen have the primary role of sharing their insight patterning societies, where research respondents will probably be chosen from. To have the right composition, ordinary people without health background are appointed in appropriate proportion so that they will feel at ease when airing their views. Also, members who are not affiliated with sponsoring and funding or conducting research review by REC are to be included in the attempt to make sure that several viewpoints are brought to bear during discussions. (WHO, 2011). However, it should be noted that in recruiting members of any REC, serious consideration should be
given to individuals’ sensitivity to an array of traditional and different conceptions of harm, risk, and vulnerability, (Guta et al., 2010).

2.4.3 Research Committee Resources

A third standard in the WHO SOP is for IRB/RECs to be adequately resourced. A study by Guta et al. (2010) reported that some participants were of the opinion that their REB/IRBs had developed, but this was mostly from a part-time to a full-time position or the addition of a limited number of staff members. This implies that, a handful of people are employed to manage the reviews at major institutions. This however puts undue pressure on the few staff that are expected to meet the demands of reviewing and approving protocols in a timely manner. Again, the study showed the effect of economic instability on the staffing of the board. That is, the staff strength is cut down with the economic downturn, which adversely affects the operational activities of the committee.

Even though it is clear that the low staff strength is associated with increased work pressure, it is also obvious that the use of time saving technology could be a major remedy. The staff must therefore be well supported to ensure that they are adequate in number. The training of the IRB/REC on various time saving technologies would also empower the IRB/REC to undertake its technical and administrative duties. There must be sufficient resources for the staff to efficiently and effectively carry out their functions. This includes access to suitable space for committee meetings; suitable means for members to communicate between meetings, and sufficient financial resource to enable the committee deliver a very good work with high standards. To motivate IRB/REC members, there is also the need for them to be remunerated unless they are being rewarded through other resources for their time and effort on the REC (WHO, 2011).
2.4.4. Independence of Research Ethics Committee

The WHO SOP spells out the independence of the research ethics committee under this section. According to the recent SOPs of the United Kingdom (UK) Health Research Authority (HRA), it is imperative for the Research Ethics Committee to operate without interference in matters concerning ethical review of research and training of its members. This should be provided separately by the IRB/RECs with the support of the National Research Ethics Advisers’ Panel. It was specified that the procedures to be adhered to in the SOPs in communicating decisions agreed upon during meetings, demanding additional information from applicants and, issuing views of members should not in any way coerce the independence of the IRB/REC in assessing the ethics of individual research applications and deciding whether or not to give a favorable opinion. IRB/REC must have one person who is not affiliated with the organization sponsoring or conducting the research under review. Researchers, sponsors and funders may be present at the meetings to answer questions regarding their research protocols. Senior decision makers of the entity establishing the IRB/REC need not function as members or chair of the IRB/REC. Organizations that establish the IRB/REC must ensure the protection of its members from intimidation (WHO, 2011).

2.4.5. Research Committee Training

This WHO SOP stresses on training the IRB/REC to be able to work excellently on the role and responsibilities and other relevant activities based on international recommendations. The trainings are done on the ethical aspects of research involving human participants, how to apply ethical considerations to different types of research, and how the reviews of research are conducted by the REC. This training is delivered to REC members when they join the committee and intermittently during their time served on the committee. Training
may be carried out either directly by the employing body or through agreements with other REC's and/or establishments that provide education on research ethics (WHO, 2011).

2.4.6. Accountability, Transparency and Quality of the Research Ethics Committee

The standards for transparency, accountability and quality of the Research Ethics Committee require that knowledgeable and unbiased people on the IRB/REC conduct evaluations periodically using a pre-defined design; and supplementary independent external appraisals to be preceded by internal assessments. The organization establishing the IRB/REC is to be dedicated to think through and, when suitable, track the findings and recommendations made by internal and external evaluations. The evaluation outcomes are to be such that they can help the IRB/REC revise its way of doing things and measure performance at the same time promising the community that research is being done with regards to conventional ethics (WHO, 2011). However, based on this standard, there is a knowledge gap on transparency of the IRB/RECs. This goes a long way to affect the independence of these committees.

2.4.7 Decision-Making Process

According to the WHO standard operating procedures, there are ethical principles upon which research ethics committee make their decisions. This is done by utilizing a check list that guarantees that all pertinent criteria are well-thought-out during review. In general, similar protocols are treated together. The IRB/RECs provide very clear justification for a change in position if an approach taken in the past on an ethical issue is no longer valid. The key areas on the check list include scientific design and conduct of the study, informed consent process, community considerations, privacy and confidentiality, risk and potential benefits. The rest are selection of population and recruitment of research participants,
inducement, financial benefits, and financial cost. The IRBs/RECs expounds its analysis of any major ethical issues that arose during the review process by communicating the results to researchers (WHO, 2011).

2.4.8. Research Ethics Committee’s Decision-Making Procedures

Discussions that will elicit concerns and views related to research protocols are documented and considered by member participants during IRB/RECs meetings under the research protocols consideration. Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) recognizes the limits to their knowledge and seeks external ideas when required, voting or consensus is used to arrive at a decision (WHO, 2011). In the latest SOPs released from the United Kingdom Health Research Authority (UK HRA), the conduct of business meeting and decision was well spelt out. The chair leads and steers the committees meeting such that they reach agreement on all matters. The vice-chair normally chairs meetings in the absence of the chair. In the absence of the vice chair an alternate vice chair presides over the meeting. In the absence of all the three officers, IRBs/RECs appointing authority should be invited to appoint a member of the committee or a co-opted member as a temporary vice-chair at the meeting (HRA, 2018).

2.4.9. Written Policies and Procedures

The strategies and processes that spell out the authority, the terms, and the conditions of appointment of the IRBs/RECs are considered under this standard. The standard also defines how the offices of the IRBs/RECs are instituted. It spells out situations which warrant or require an independent consultant to provide special documentation required for the review procedure to facilitate decision making. (WHO, 2011). An enquiry suggests that, for a particular application, institutionalizing the IRB/RECs as the moral authority serves to
legitimize and authorize a specific opinion. However, the IRB/RECs do so through organizational structure and the social positioning of the parties to the process. This is not to imply that IRBs/RECs decision-making has no inherent moral standing; IRBs/RECs derive claims to moral standing from the selection and training of IRBs/RECs members, through the guidelines and norms of the IRBs/RECs community (even if these are not explicitly referred to), through the care and thoroughness with which they scrutinize applications, and more recently, through their engagement with researchers who attend meetings and may help to ‘‘co-produce’’ letters (Dixon-Woods, 2007).

The requirements for submitting an application for review are specified in IRBs/RECs policies and procedures, including the forms to be completed and the documents to be submitted. Institutional Review Boards (IRBs) or Research Ethics Committees’ (RECs) letters in this context shows key features of the practice of ‘‘giving reasons’’ (Tilly, 2006). In IRBs/RECs review, giving reasons implies not only that the recipients are entitled to reasons but the justifications need to be such that both parties can identify it as good bases. Many cases of misunderstanding between IRBs/RECs and applicants result from the failure to agree on ethical issues. In practice, if IRBs/RECs find some features of a proposal on ethical issue, it is only a brave researcher who would dispute or challenge their prescriptions, unless the researcher is very sure of his or her ground (Dixon-Woods, 2007).

2.4.10. Researchers’ Responsibilities

A proposal of the principles of ethics of proposed health-related research is submitted by a researcher qualified to undertake the particular study. Students submitting their applications are requested to do so under the responsibility of a qualified advisor or a faculty member who has an overview or preview of the student’s work or the student’s name is co-signed
by a qualified faculty supervisor. All information including disclosures about researchers’ conflicting interests, if any is submitted. This is required for a comprehensive and a complete review of the ethics of the proposed research. The research is conducted according to, and in compliance with the approved protocol by the IRBs/RECs. Prior approval of the IRB/REC is needed if there is a deviation in following the approved protocol or when changes are made to it, except in situations where instant action is required to avoid harm to research participants. In such instances, the IRB/REC is quickly notified of the changes or deviations made, and the rationale for doing so. The IRB/REC is informed of any changes at the research site like closure of a health facility at the research site or barriers to accessing healthcare that was originally available that may significantly affect the conduct of the research, and/or lessen the protection, increase the risk or decrease the benefits provided to participants (WHO, 2011).

3.5 Summary of Chapter

This chapter is a reviewed literature on some of the challenges faced by RECs/IRBs in developing countries especially in Africa. It also describes the ten standard guidelines developed by WHO, which serves as guide for RECs/IRBs’. The WHO Standard Guidelines is a very useful tool that facilitates the work of the IRB/REC. However, there is very limited literature on how these international standards are informing the operations of IRB/RECs, particularly in Africa.
CHAPTER THREE

3.0 METHODS

3.1 Introduction

This chapter outlines the methodology for this study. It looks at the sample techniques employed as well as ethical considerations for this study. The data collection procedures and how these data were analyzed are also presented.

3.2 Study Design

Having an appropriate defined statement of goals and justification from the beginning of a research project significantly enhances its success. This makes the identification and organization of the chronological steps needed for the writing of a research project simplified and easy (Congdon and Dunham, 1994). This can only be achieved by a study design that has been well detailed and explained. Hakim (1987), states that “design deals mainly with aim, purposes, motives and plans within the practical constraints of location, time, money and availability of staff.

For the purpose of this study, Exploratory Qualitative Research approach was used to collect primary data and it involved the review of documents, which included Standard Operating Procedures (SOP) of selected Ethics Committees/Institutional Review Boards (IRB) in Ghana and the World Health Organization’s (WHO) current guidelines on research ethics with human participants as well as In-depth Interviews (IDI) using the Office of Human Research Protections (OHRP) Quality Improvement Self-Assessment Tool; the Tangwa (2017) and the Research Ethics Committee Toolkit (RECAT). Qualitative research methods provide the researcher with an outlook of respondents through involvement into their culture or life experiences (Afari-Asiedu, 2018). According to Afari-Asiedu et al, (2018), it helps
the researcher to understand and explore the meanings people attribute to social phenomena and to reveal the mental processes underlying behaviors.

In-depth interviews explore the subtle distinction of what people think, feel, and experience. In-depth interviews are appropriate where personal, sensitive or confidential information cannot be obtained from the public domain. In-depth interviews are also ideal for researching people who due to their busy schedules will be unavailable for a Focus Group Discussions (FGD). The challenge with this method is that respondents may feel like they are under scrutiny and may be reluctant to open up. Nonetheless, it still remains an important data collection tool.

3.3 Study Area

The Study was conducted in three selected locations with Research Ethics Committees/Institutional Review Board (IRB) across the nation representing the Middle and Coastal Belt of Ghana; namely Ghana Health Service - Ethics Review Committee (GHS-ERC), Accra; the Institutional Review Board of the Kintampo Health Research Center(KHRC-IRB), Kintampo; and the Institutional Review Board of the Dodowa Health Research Center(DHRC-IRB), Dodowa. The three selected Research Ethics Committees/Institutional Review Boards (IRB) are under the Ghana Health Service.

Ghana Health Service Research Ethics Committee(GHS-ERC)

The Research division of the Ghana Health Service established the Ethics Review Committee in 2003 to review research protocols that are carried out at their facilities throughout the country. It has over 15 years of experience. Any research carried out at a Ghana Health Service facility needs approval from the GHS-ERC. It is also responsible for
reviewing protocols of research that are carried out by Ghana Health Service. The GHS-ERC is made up of 11 members, 5 females 6 males. Two of the committee members are non-scientific (2) people come from the Community. The committee members have diverse background raging from medical doctors to renowned researchers. The committee meets on the last Friday of every month and does not undertake expedited review.

Kintampo Health Research Centre Institutional Review Board (KHRC-IRB)

The Kintampo Health Research Center is located in the Kintampo North district of the newly created Bono East Region. It has been responsible for conducting several research activities in the region over the last 20 years. The KHRC-IRB was established by the Kintampo Health Research Center in the year 2004 with the mandate of ensuring that human participants involved in research in the communities in and around the middle belt are protected from harm. Donors insisted that before funding a project it needed to pass through an ethics committee and therefore the Center saw the need to have one established. The IRB has a membership of about 13 which include (8) from the Kintampo Research Center and five (5) from outside the Center. It is made up of five (5) females and eight (8) males. The committee members have diverse background raging from medical doctors to renowned researchers. The committee sits on the third Tuesday of every month with room for expedited review.

Dodowa Health Research Centre- Institutional Review Board(DHRC-IRB)

The Dodowa Health Research Center is located in the Shai-Osu-Doku District of the Greater Accra Region. It has been in existence for about eight (8) years. It conducts research activities in communities in and around the district. The Dodowa IRB was established in 2011 to help protect human participants involved in research. The IRB has a membership
of about 7 which include 2 from the Dodowa Research Center and 5 from the community. It is made up of 4 females and 3 males. The committee members have diverse background ranging from medical doctors to renowned researchers. The committee meets once every month subject to the availability of protocols and also allows for expedited review.

3.4 The Study Population/Target Respondents

The target respondents were purposively selected from the three Research Ethics Committees (RECs)/Institutional Review Boards (IRBs). A mapping of all research ethics committees in Ghana was done by asking key stakeholders and this resulted in 18 IRBs/REC being identified. Three (3) Research Ethics Committees out of the eighteen (18) ethics committees in Ghana were chosen for the study. The Ghana Health Service (GHS) has four (4) research ethics committees out of the eighteen IRBs/RECs in Ghana. These are the GHS - Ethics Review Committee, The Dodowa Health Research Center-IRB, The Navrongo Health Research Center-IRB and the Kintampo Health Research Center-IRB. Three of these committees were purposively selected for this study.

Merriam (1986) states that, “purposive sampling is based on the assumption that the investigator wants to discover, understand and gain insight and therefore must select the sample from which most can be learned”. Purposive sampling method was used for this study due to the fact that, the selected respondents had the required characteristics that could best help answer the research questions of this study.

Thirty-Two (32) In-depth Interviews (IDI) were conducted targeting the Head of Institutions, the Administrators, the Chair, Researchers and the Members of the Research Ethics Committee. Table 3.1 shows the targeted respondents for the study.
Table 3.1: Targeted Respondents for the Study

<table>
<thead>
<tr>
<th>IRB</th>
<th>Administrator</th>
<th>Chair</th>
<th>Institutions</th>
<th>Member</th>
<th>Researcher</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHS-REC</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>KHRC-IRB</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>DHRC-IRB</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>11</td>
</tr>
</tbody>
</table>

Source: Author (2019)

3.5 Data Collection and Instruments

The study employed different approaches in data collection. This included review of Standard Operating Procedures (SOP) of the selected IRBs/RECs as well as the use of semi-structured interview guide to collect information from selected respondents by conducting in-depth Interviews (IDI).

The document review involved the collection and review of SOPs of the selected IRBs/RECs and the World Health Organization’s (WHO) current guidelines on research ethics with human participants, focusing on (but not limiting to) the composition, terms of reference and requirements for ethics review.

3.6 Semi-structured Interviews

The interview guides were adopted from existing tools for assessing research ethics committees across the globe. These included the Pan-African Bioethics Initiative (PABIN) Survey of Ethical Review Committees; the African Malaria Network Trust (AMANET)

The guides included questions about membership, training, submission and review process, resources and administrative efficiency. Themes identified through this analysis was also explored through the in-depth interviews with key stakeholders (members of ethics committees, researchers, Heads of institutions, IRB Chairs and Administrators) on what should count as good ethical practice. The interviews lasted for an average of Thirty (30) minutes.

3.7 Data Processing and Management.

All the interviews were audio-recorded, transcribed verbatim into word, verified and uploaded unto the qualitative analysis software Nvivo11. Major themes of interest were developed taking into consideration the objectives of the study. Themes were developed according to preexisting or a priori themes to guide the coding process. The data were coded according to themes and summarized. These themes were guided by the key elements of the WHO standard operating procedures which include composition, decision making submission requirements. The analysis was also inductive focusing on emerging themes on stakeholders’ views and challenges in the review process.
3.8 Ethical Considerations

Ethical clearance for the study was obtained from the Ghana Health Service Ethics Review Committee (GHS-ERC057/02/19). Permission was obtained from the Head of institutions and Chairs of the various IRBs and the School of Public Health, Legon before the research was conducted.

Each participant was taken through the informed consent process where the purpose of the research was explained to them. They were made aware that participation was voluntary and that there was no penalty for refusing to participate. Participants were duly informed about the risk and benefits associated with the study and also made aware that no compensation would be given. The research study had the benefit of improving the ethics review system in the country (see consent form attached in appendix 2). During the consenting process participants were made aware that they were digitally recorded. The recording device was only turned on once consent was given.

The participants were assured that information provided would be kept confidential. As such, throughout the study, information provided remained confidential and was only used for its intended purpose. Soft copies of information were password protected and hard copies kept under lock and key. Only the PI and those involved in the research had access to it. Participants were also assured of anonymity. Data were analyzed in such a manner that anonymity of all respondents was strictly maintained. Besides, all research participants were duly informed of their right to decline participation in the study and also had the right to withdraw from the study anytime they so desired.
3.8.1 Conflicts of Interest

There is no potential conflict of interest with regards to the study on the part of the researcher.

3.8.2. Funding

The fieldwork for this study was funded by supervisor’s UG Book and Research Allowance (UG BRA)

3.9 Quality Control

All audio interviews were carried out by the researcher and transcription done by professional transcribers there by maintaining confidentiality.

3.10 Inclusion Criteria

1. All committee members of the selected IRBs/RECs involved in the study are included

2. All committee members of the selected IRBs/RECs involved in the study who give consent

3.11 Exclusion Criteria

1. Members of Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) who refuse to give consent
CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter presents the results of the in-depth interviews (IDI) carried out among key stakeholders involved in the ethical review process. The categories interviewed include three (3) IRB/REC Administrators, three (3) Heads of institutions, nine (9) Researchers, three (3) Chairpersons and fifteen (15) members of the various IRB/RECs.

The results are presented as narratives with quotes or responses from the various respondents to support findings and summarized in a table. The results are presented under the following theme below.
Figure 4.1: A Mind Map of the Study

Source: Authors (2019), Using Nvivo
### Table 4.1: Overview of SOP

<table>
<thead>
<tr>
<th>WHO SOP</th>
<th>GHS-ERC</th>
<th>KHRC-IRB</th>
<th>DHRC-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibility for Establishing Research Ethics Review System</strong></td>
<td>Institutional</td>
<td>Institutional</td>
<td>Institutional</td>
</tr>
<tr>
<td><strong>RECs Composition</strong></td>
<td>11</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Research Committee Resources</td>
<td>Inadequate</td>
<td>Adequate</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Independence of REC</td>
<td>independent</td>
<td>Independent</td>
<td>independent</td>
</tr>
<tr>
<td>Research Committee Training</td>
<td>inadequate</td>
<td>Inadequate</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Accountability, Transparency and Quality of REC</td>
<td>Transparent and Quality</td>
<td>Transparent and Quality</td>
<td>Transparent and Quality</td>
</tr>
<tr>
<td>Decision-Making Process</td>
<td>Checklist used</td>
<td>Checklist used</td>
<td>Checklist used</td>
</tr>
<tr>
<td>REC’s Decision-Making Procedures</td>
<td>Consensus or voting</td>
<td>Consensus or voting</td>
<td>Consensus or voting</td>
</tr>
<tr>
<td>Written Policies and Procedures</td>
<td>SOP exist</td>
<td>SOP exist</td>
<td>SOP exist</td>
</tr>
<tr>
<td>Researchers’ Responsibilities</td>
<td>Needs improvement</td>
<td>Needs Improvement</td>
<td>Needs improvement</td>
</tr>
</tbody>
</table>

*Source: Authors (2019)*

#### 4.2 Composition of Research Ethics Committee

According to the World Health Organization (WHO), a minimum of 5 members is required to form a quorum. These five members must include a community representative.
Table 4.2: Summary of Composition of IRB/REC

<table>
<thead>
<tr>
<th>COMPOSITION</th>
<th>GHS-ERC</th>
<th>KHRC-IRB</th>
<th>DHRC-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of committee members</td>
<td>11</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Scientific members</td>
<td>9</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Non-scientific members</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Expertise</td>
<td>Bioethicist, epidemiologist, religious authority, gender specialist, pharmacist, clinicians, Health economist</td>
<td>Public Health specialist, Traditional Authority, gender specialist, Entomologist, clinicians, Social scientist, Health tutors</td>
<td>Religious Authority, Clinicians, Biostatistician, Nutrition and medical anthropologist, Pharmacist</td>
</tr>
</tbody>
</table>

Source: Authors (2019)

Generally, in the various research institutions, IRB/RECs included in this research, membership ranged from seven (7) to thirteen (13) with an average membership of ten (10) members. The committees have the scientific and non-scientific members or lay members as required by the WHO SOPs. The background or expertise on the selected committees included, medical doctors/clinicians, pharmacist, social scientist, epidemiologist, biostatisticians, entomologists, religious leaders, women and children activist, traditional authorities and public health specialist. Despite the diverse background represented on these committees, the respondents indicated that these are not exhaustive and some boards invite other people with specific backgrounds and expertise to complement its membership when the need arises. An IRB committee member in an IDI had this to say:

“...I can say that with regards to one particular vaccine trial or something in relation to pharmaceutical; it has to do with drug. We didn’t really have much background but we knew that there was really something that we needed to really seek higher attention. We refer such people and such questions to the FDA who came on board to really check to see the safety of it before those protocols were reviewed” (Committee Member#7 at an IDI)
The composition of the Committees was similar and they all lacked one vital expertise which one IDI participant highlighted as captured in the quote below:

“Well, from the SOP I read we could have lawyers and others but unfortunately we don’t have Lawyers living in our research setting here. The people we have in Kintampo are those they have recruited. We are alright, but there could be room for improvement” (committee member#8 at an IDI)

In terms of the number of community representatives on the committee, findings of the study indicated that, the community representatives could be increased on the IRBs. This can be seen from some of the responses below:

“To me they (Institution) should have still added more because just one from the community will not speak the mind of the community” (committee member#9 at an IDI).

“Yes, but I wish there could be more committee members on board” (Administrator#1 at an IDI).

However, this view was not shared by a respondent who indicated that, community representation on the committee is adequate since some of the members of the committee are also part of the community. As the response below illustrate;

“... Since, we have the key people in the community who make decisions as part of the ethics committees, I think that it is appropriate” (committee member#10 at an IDI).

Study respondents reported that the consideration that goes into the selection of members onto the committee is by need or expertise. It is also by recommendation of the ethics administrator to the Heads of the institutions. Participants in the IDI had these to say:
Table 4.3: Consideration for Selection

“With the selection, well I was invited and informed that they would like me to be a member of the ethics committee since I am working with the general public within my district and they wanted a woman to be a committee member. A woman to defend issues affecting women within my district or the community where I live and where the institution also does its research’” (Committee member#7 at an IDI).

“Well, Dr XXX called me and said they’ve seen me advocating at the district assembly and they appreciated my thoughts and my comments and so they would wish if I would join them. So they officially wrote a letter to me to join and I’ve been on it since then” (Committee member#8 at an IDI)

“That is how people get selected on the committee. They look at your background, your training, your expertise and how useful you will be to the committee so that’s how come the management suggested that I joined the committee” (Committee member#6 at an IDI)

“Ok, so normally what we do is that, the center or the management of the center will recommend so maybe we write a letter to an institution for instance maybe social welfare and ask for somebody they deem appropriate or can contribute to be selected by them to serve on the board. So, when we send the letter then they will select somebody for us to serve on the board but within the institution, I sometimes recommend to my Boss that this person can contribute then, management can think about it and decide” (Administrator#1 at an IDI)
The chairpersons from the various ethics committees do not play a role in the recommendations and selection of members onto the committee. A participant in the IDI had these to say:

“This is an interesting question, the chairperson of the ethics committee, well is good that as a chairperson you would know who is on the committee but when it comes to selection of people probably it could be maybe a blind selection if that is the right term so we can say we are looking for a woman who has interest in this area or who lives in the jurisdiction that kind of thing but not to say it should be Mrs. A or madam B that kind of thing, so that much the chair should be involved but I think when it comes to who the person is then is not very important” (Chair#2 at an IDI)

Participants of the in-depth interview are of the view that the committee is gender balanced. This view was shared by all the participants as indicated in the responses below;

“Gender balanced yes. I think in the IRB we have about four ladies and the backgrounds to is just interspersed. One lady from social and nutrition background, one from public health and then gender reproductive health and then education and then of the sciences” (Committee member#10 at an IDI)

Well, we tried from the beginning trying to go strictly by what the WHO standard says but some of these things, in reality it’s difficult. So I would say yeah, it is because we have now 7 board members, one who we call on when there is the need for expertise but I will say we have 3 males, 4 females (Administrator#1 at an IDI)

Generally, almost all the respondents indicated that the various ethics committees are capable of reviewing any protocol from epidemiological studies to clinical trials. However, there are others who shared different opinions. The responses below substantiate this finding:

“Yes, as at now they are capable. May be last year I wouldn’t say they were capable of reviewing clinical trials but we just had a training this year so I would say they are capable to review any kind of study” (Administrator#1 at an IDI).
"For our sector here, we have not looked at the clinical study which I think is beyond the centre. I think it’s beyond the center because we haven’t looked at clinical trial studies but other studies, we are capable of handling" (Committee member#2 at an IDI).

"Yeah, I would say yes. Because we have people from the public health background Qualitative methods and quantitative, we have the social sciences, we have the medics and I think generally yeah" (Committee member#10 at an IDI).

One thing that is consistent with the various ethics committees is the fact that the Heads of institutions are members of the board. They don’t have voting right but they are co-opted members or conveners who assume the role of an observer. This can be seen in the following quotes:

‘’He is… I think he’s a co-opted member, not a full member’’ (Committee member#2 at an IDI)

“He is not a voting member. I think he is just a convener” (Committee member#14 at an IDI)

“Yes, as the director of the institution I am an ex officio member meaning that I can sit in board meetings but I don’t have a vote” (Head #1 at an IDI)

“I am a member of the committee, am a non-voting member” (Head #1 at an IDI)

An IRB administrator however, indicated that the Head of institution does not sit on the committee as highlighted in the response below:
“We avoid having heads of institutions sit in the meeting so for some time now since this current director came in, we have not even thought about it” (Administrator #1 at an IDI)

“He doesn’t sit in our meetings” (Chair #2 at an IDI)

Generally, respondents of the study were of the view that the presence of the Head of institution does not affect the independence of the committee. This view was contrary to what another respondent indicated:

“It is yes and no. Yes, because he sitting there certainly especially research work coming from the health institution usually is able to influence the decision making when he explains it is difficult to argue much. No because he is a non-voting member, he doesn’t take part and anything that involves him he goes out, he doesn’t participate in decision making” (Chair #1 at an IDI)

4.3 Submission Requirement of Research Ethics Committee

The IRB/ERC secretariats demand researchers to meet specific requirement before their proposals pass for review by the committee members. The IRB/ERC provides a checklist on their website that contains all the necessary documentation needed as indicated by some participants:

“Okay, so the ethics committees they have a website. For instance, there are instructions on the website to tell investigators or researchers of their requirements” (Researcher# 5 at an IDI)

“When you go to their website, you just look at what the requirements are” (Researcher# 1 at an IDI)

The different committees have different requirements as outlined in the quote below:

“Well, different ethics committees have different requirements” (Researcher# 5 at an IDI)
The common requirements for submitting research protocols for ethics review includes an application form, updated curriculum vitae (CV) of principal investigators (PI), executive summary, study budget, data collection tools, protocols of proposed research, informed consent form and for students, the CV’s of their supervisors. This can be seen in the following quotes:

“Mostly, they require us to submit our CV’s, copies of our protocols which should contain the informed consent the budget, the data collection tools, fill a form among others”” (Researcher #8 at an IDI)

“We provide researchers with a checklist that contains all needed requirements for submission in addition to a protocol submission form and for the students we require that they provide the CV of their supervisors” (Administrator #1 at an IDI)

The findings of the study revealed that among the three IRBs/RECs included in the study, it is only KHRC-IRB which makes scientific review a prerequisite to IRB/REC review. This finding is supported by the quote below:

“As part of submission requirements, researchers are required to seek scientific approval from the scientific research committee before they can submit an application for ethical approval even with the student protocols” (Administrator #2 at an IDI)

Also, from the study because researchers work in the institutions housing these IRBs, they have access to them except in circumstances where they have to take it to other committees outside their institution such as GHS-ERC. Some researchers believe that the submission requirements are very clear and easy to understand. Others however did not share this opinion as they indicated that the submission requirement is not clear. This can be found in the quotes below:
“Well, different ethics committees have different requirements. So, for some, their requirements are clear, for others it’s a bit cumbersome” (Researcher# 5 at an IDI)

“Okay, largely, it’s clear as to the documents we have to submit and they usually make sense to you to submit” (Researcher# 6 at an IDI)

“There are some that are not very clear like I said if it’s the first time, you struggle” (Researcher# 1 at an IDI).

“Oh, I think it is straightforward from my perspective. It’s easy to fill those form, like it’s easy to understand and fill, it’s not anything complicated” (Researcher# 3 at an IDI)

Some participants are familiar with submission requirements while others are not due to the fact that things keep on changing from time to time. This is what some participants had to say:

“I can’t say I am fully familiar because at almost, I know the basic documents that should go into a proposal. But at almost, every time we have to do that or I have to do that, I speak to the ethics later to be sure that the documents are set. More so, you know things keep changing but the ethics administrator keeps updating us anytime we want to be sure” (Researcher# 6 at an IDI).

“Yes, it’s because I’ve applied several times” (Researcher# 1 at an IDI)

Researchers submit various types of studies to the IRB ranging from the social sciences, to epidemiological studies and behavioral studies. The frequency may depend on which institution the researcher works with. Some researchers submit every year and others submit once awhile.
All researchers involved in the study indicated that, they were obliged by their institutions to submit all their research work to the REC for ethical approval since it is an institutional requirement. This is supported by the responses below:

“Yes, it’s mandatory. You cannot conduct any research without having ethical approval first.” (Researcher# 5 at an IDI)

“Yes, it’s an institutional requirement” (Researcher# 6 at an IDI)

“Yeah, it’s a requirement here at the university of Ghana that if you are doing any research, if it’s being funded by the university or anywhere else, you need ethical approval.” (Researcher# 7 at an IDI)

From the findings of the study, researchers were of the view that it was important to seek ethical clearance to protect the people who took part in research studies. This is what a participant had to say:

“Yeah, yeah yeah. I think it’s necessary, I think it’s very important because research is for the benefit of humanity and science should not be at the expense of human rights or safety issues so the ethics committees are very important to make sure that we safeguard the safety involving of people who volunteer to be part of studies” (Researcher# 5 at an IDI)
4.4 Key Stakeholders’ Views on Current Standards for Ethics Review in Ghana

The stakeholders interviewed included the Chair of the IRB/ERC, Heads of Institutions, IRB/ERC Administrators and Committee Members. The IDI sought to explore their views on the standard operating procedures for their IRBs/ERCs including the key elements of the WHO SOPs and how these are applied in the review process. These are some of the responses from selected participants of the study:

“...So, I wouldn’t say it [WHO SOP] is the ultimate, I wouldn’t say it’s the final one. It’s good, it serves as a guide, it serves as the basis when you don’t have especially like Ghana, we don’t have any national regulatory or whatever. It serves as a basic guide to help in running the IRB in terms of protecting human subject but it’s not the ultimate” (Administrator #1 at an IDI).

“I think it[WHO SOP] is okay but we need to also take into consideration other guidelines. Now it’s like everything is about WHO, but we also need to consider other guidelines. But so far, I think the WHO one is okay.” (Administrator #3 at an IDI).

“Well, it[WHO SOP] is universal. They are universal guidelines that take into consideration all the various declarations in the various conventions, etc. they can be applied anywhere. I think usually WHO does their guidelines considering all the international standards so they are good. But of course, it is important that each country will look at their own context and then do some modification because what is pertaining in Asia could be different from what is pertaining in Africa. Even within the African context, there are different issues, gender issues are different, and cultural issues are different. So, it is still important that we adopt them, adapt them to our context to make them relevant and operational” (Chair# 1 at an IDI)

“Well the WHO SOP is a general guide, general operating procedure that you can look at and look at your circumstances and adopt it to suite ours, because, it a general thing so you will need to adopt it to suite your particular situation”(Chair# 2 at an IDI)
Committee members are of the view that since the various aspects of the research protocols are considered during the review process, the review process adds to or enhances the study to be undertaken. This is supported by the quotes below;

“Yes the review process we try to address, there are time that we make recommendations even concerning the sciences, concerning the methods, concerning the feasibility of the studies itself and some of the researchers agree with us and then they go back and modify so we do contribute and of course you know that for some journals without the research, without the ethical review process if you have not gotten ethics clearance they will not publish your paper so we do contribute to better research” (Chair#1 at an IDI)

“It protects the rights of participants. It makes sure that scientists do the right thing. It makes sure that scientists conduct a research in a way and manner that will be beneficial for the scientific committee but also protecting the rights of participants who engage in the research themselves”. (Committee member#6 at an IDI)

The committee members indicated that the deliberations on the committee are very rigorous, very good and healthy whereby decision making in the review process is by either a consensus or by voting. A Participant had this to say;

“...So usually whatever decision we arrive at is a team decision. It’s not one person imposing their minds on somebody but we agree. Sometimes we vote If we feel that they are descending views sometimes we have to vote in order to arrive at a decision. So sometimes that is how vigorous the review procedure is done” (Committee member#6 at an IDI)

“Very independent, I mean people coming from different perspective, if you forget about something someone will bring it up, I think its engaging, the deliberations are usually really vigorous .There are times that we disagree we have to debate with sound reasoning to be able to agree. So I think that the review process is very independent and we don’t consider who we know, we try to look at what is available to us. This has been the guidelines, the code etc”. (Chair#1 at an IDI)
“Oh very good and healthy because there are always divergence views and it all helps putting up our comments so that the work is carried out in the best interest of the research participants who for me are always there, key people that as a committee we need to get” (Committee member#14 at an IDI)

Researchers who participated in the in-depth interviews were of the opinion that, their research proposals are enhanced by the comments received on their protocol in the review process; this is indicated in the quotations below;

“Yes, for most of the research proposals that were submitted. Especially internally the comments have been helpful and sometimes though they are even looking at just ethics, they end up giving further suggestions in terms of scientific approach” (Researcher#6 at an IDI).

“Yeah, some comments are helpful; they improve the quality of the protocol” (Researcher#5 at an IDI).

4.5 Key Challenges in the Ethics Review Process

Generally, the challenges in the review process are the same for the various IRB/ERC included in this research except for one IRB where a participant was of the view that, the lay members on the committee felt intimidated. As outlined in the quote below:

“... the non-scientific members or the lay members are sometimes or most at times feel intimidated and are not able to contribute as you expect them to. They are most of the time laid back and it’s like they are there to represent the community. But they end up not really contributing as they expected like voicing out the moral aspect as in studying the context of their community. I feel they are a bit laid back.” (Administrator#1 at an IDI).

A committee member was of the view that, sometimes they receive protocols that should not have been passed through because they fall short of the submission requirement but however they find their way through the system and this puts undue stress on the committee
members. This participant had this to say;

“for me if someone submit a protocol or a proposal you should be able to check to be sure that even sometimes some of the things that you expect like let’s say informed consent there are certain statements that should be clear but where people don’t have the information, the consent form doesn’t have information sheets, straight away that thing should not even cross to come to a board member, that thing straight away should be dealt with madam or please sir can you get information sheet as part of it, these are some of the things that I expect shouldn’t cross, so you double check with it before it comes to the board but when it comes to the board member and these things are not there is like they want to kill you. You become like this is clear the person should get it fixed before sending it” (Committee Member #5 at an IDI)

The other key challenges which ran through all the committees include competing commitments of members, limited training opportunities, inadequate compensation, undue pressure and influence from researchers, as highlighted in the quotes from respondents below:

Table 4. 5: Key Challenges by Committee Members

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<th>Key Challenges</th>
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<td>“We have lecturers among us, we have health workers amongst us, so if the meeting comes at a time all these people with other commitments have to attend to their core responsibilities, they excuse themselves and once that happens we are unable to meet because we are unable to form a quorum” (Committee member #06 at an IDI)</td>
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<td>“The last time training was organized face-to-face was I think 2 years ago” (Administrator #2 at an IDI)</td>
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<td>“We encounter sometimes the researchers attempting to influence, we try to look at undue influence on the subjects. Some of the proposals are purely technical and sometimes we may need external support to review. The people in the community, their background in the sciences is not so good so they don’t even touch there. There are times that we have to review too many proposals at a sitting, so it doesn’t allow for quality work” (Chair #1 at an IDI)</td>
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<td>“Compensation is woefully inadequate it is not even the amount even sometimes it doesn’t even come” (committee member #5 at an IDI)</td>
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<td>“The greatest challenge is like when the tenure of members expires, the replacement of experts in the country is not quite large. So, it is difficult to get replacement for the experienced ones who are leaving. That’s the challenge I see” (Committee member #12 at an IDI)</td>
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The study revealed a challenge that was peculiar to one IRB/REC. A committee member indicated that, supervisors are not doing enough to help their students by not reading through their work. This finding is supported by the quote below;

“... one serious thing is that it looks as if the supervisors are not doing enough to help especially the students and all that. the supervisors are not doing enough even to go through their work, so you see we are not just going through ethics sometimes we are going through grammar and English and all that, for me that is one of the serious aspect of this thing so if you are not able to finish and bring it, it looks as if you don’t have interest but you have to read through the whole thing and if you write that correct your mistakes and all that some people don’t take it easily, especially the students protocol the supervisors are not helping us at all” (Committee member #11 at an IDI)

The various IRB/ERC administrators are also faced with a lot of challenges in the review process which includes late submission of protocols and the lack of understanding of submission requirements. This is indicated in the quotes below:

“Then, even when the people come, some of them you see that the protocol, the requirement, they don’t stick to the requirement and One is the late submission” (Administrator#3 at an IDI)

“The fact that the center is not allocating enough resources like finance and personnel to support the work of the IRB “(Administrator#1 at an IDI)

“...the issue of researchers not understanding, having issues with some of the comments that comes” (Chair#2 at an IDI)

An administrator reported not being given the needed recognition as supported in the interview below”
“I will say the issue of not recognizing my role as an administrator and being made to feel like your role as administrator is not really a job” (Administrator#1 at an IDI)

Committee members agreed on common challenges facing administrative staff in the review process and this included material and financial resources. Participants had this to say:

“We have to depend on the research institution for funding and I don’t think that is enough” (Committee member#6 at an IDI)

“These days there’s a challenge in this our printer papers and things like that. It delays work because there is this internal regulation of printing and things like that. So, I think that they have a machine but it’s faulty and we don’t get things done when you want them as to when you want them so it causes some delay” (Committee member#6 at an IDI)

“Getting proposals to all the members on time is a problem” (Chair#1 at an IDI)

Challenges faced by the committee members as seen by the Heads of the institution included inadequate compensation for time, scheduling of meetings and poorly written proposals. As outlined in the quotes below:

“And then also as I’ve said adequate compensation for their time” (Head#1 at an IDI)

“I think the major one is sometimes time, sometimes finding the time to review the proposals is a major one, so sometimes you call a meeting and people can’t come and so on” (Head#1 at an IDI)

“Some researchers will write very poor proposals they haven’t thought through things well. Sometimes bad language, grammatical typographical errors, and it frustrates the board” (Head#1 at an IDI)

The Heads of institutions see financial constraints as one of the major key challenges to administrative staff in the review process. This is what a participant said:
“Well, I think the major one is sometimes they will complain that they need transport to move around, they don’t have a dedicated pay of course and basically because IRB is not funded, they need to lobby a little to get what they need” (Head#1 at an IDI).

“One, they face the challenge of delay of sending protocols to the committee members. Because it’s manual, when we get the protocols, we have to send to them, sometimes the transport, sometimes traffic and all these things, does that make it easy for us to send the protocols to them early. So that’s why I said if we can digitize it, people submit just online you send to the reviewers it will be easier but for now it is not like that. People have to bring paper and you have to find transport and send, sometimes they are not in their houses, they have to come back, you call and they don’t pick so sometimes they delay. When they get the protocols, they don’t have enough time to work on them” (Head#2 at an IDI)

The key challenges faced by researchers identified were commonly shared across all the various committees. This was what participants in the in-depth interview had to say

“So, the major challenge is the transporting of these documents. Then also sometimes there is a gap in communication. When you submit the document and may be, you forgot to add some important documents, if you don’t make follow-ups, you will not hear from them” (Researcher#6 at an IDI).

“There is delay in getting feedback from the Board” (Researcher #2 at an IDI).

From the perspectives of the Heads of institutions, researchers face challenges that range from undue delays in the review process and a perceived lack of understanding from the committee members on what they intend doing as outlined below:

“Very often researchers get frustrated by some of the posturing of the IRB. The IRB often stands behind that bad sciences, bad ethics so a lot of the IRB go and stand behind that and say if the science is not good then its bad ethics then they will be dragging people and sometimes you know so much time ends up been lost because you are going back and forth” (Head#1 at an IDI)
“...so why don’t you do a qualitative study instead of a quantitative study so sometimes just frustrating people on scientific technical issue rather than ethical issues themselves” (Head#1 at an IDI)

A participant indicated that they had to travel irrespective of where they are to show their work to an administrator and that too much power was given to the administrator of the ethics committee such that in her absence nothing can be done for researchers even though there were others in her office. The participant had this to say;

“...what we do is that we put everything together and then we take it there for the administrator to crosscheck if we have done the arrangement well and then we bring it back to do it right. But you see I am in Accra I am thinking about somebody who is in let us say in Tamale or Kintampo how are they able to get the administrator? And I think that when it happens that way it is as if too much power is put in the administrator because I can tell you for a fact if she is not there, they will not get anything done for you, I mean even people around who kind of like are also in the office will not make any attempt at doing something if she is not there. And I don’t think it is right. It should, I mean everybody there should be able to attend to you because again if it is the standard thing that is done then everybody should know what the standards are” (Researcher#8 at an IDI).

4.6 Recommendations by Stakeholders

From the study some participants are of the opinion that researchers should make adequate funds available for ethical review in their funded projects. Also, a participant indicated that research ethics committees should consider digitizing their process and review the terms of office of committee members. Participants had these to say;

“...I think the way forward is for the proposals which are properly funded needs to have adequate provision for ethical review”(Head#1 at an IDI)

“I want one, digitization of the process. Two, the terms of office of the committee members”(Head#2 at an IDI)
A participant recommended that, in doing research, Researchers should not allow sponsors to just come and collect their data without benefit to the people. Participant had this to say;

“...In the same way if we are doing research, we should think about the people, we shouldn’t allow our sponsors to just come and collect their data and go and get their PHDs and their professorships and go, what is in it for the people we should make sure that for example, if you do a research and some group are comparism and some are intervention and then something good comes out of it, at least the minimum is the people who served as the comparism, you should do something for them, so as researchers we should also be thinking about that.” (Head#1 at an IDI)

Another recommendation made by a participant from the interview is the fact that government or the country needs a portal to showcase all approved and completed research with their respective evaluation as well as grading of all the research ethics committee. Also participants indicated that there should be effective communication between researchers and research ethics committees. This is supported with the responses below;

“I think there should be a national portal that will show all the studies that has been approved and not only approved but a rating of all the research that has been done and that should be on the national portal and then there should be a rating of the ethics committees.” (Head#3 at an IDI)

“...So I think there should be a good line of communication between the ethics committees and the researchers and then as we apply the principles, we apply the principles in context of the study that is being undertaken. It shouldn’t be as though because some atrocities were conducted in terms of research in the past so many years and so ethics committee members always view every research as in quote bad or researchers taking advantage of research participants. We need science; we need advanced science to improve the lives of people. So if committee members have that mindset so that we all work hand in hand” (Researcher#5 at an IDI)
A participant recommended periodic training for both old and new members. This is indicated in the quote below;

“I think there should be training for the new members because some have come, and have served on it for a while but they have not had any formal training and I think there should be periodic training.” (Committee Member #8 at an IDI)

From the study, respondents indicated that, the country needs a national policy on ethics that will determine how research should be conducted in the country. These findings are supported with the quotes below:

“I think so we need. We need a national policy. Because when that happens we can situate the ethics committee properly and that will have a stronger muscle and a biting power.” (Head #3 at an IDI)

“Yes, I think a national policy on research ethics is something that has been missing for a very long time and I know people have tried all kinds of things, am aware that a lot of efforts have been put in but nothing has come out so far.” (Head #1 at an IDI)

“That will be good if we have a national policy document on ethics because we review proposal from different ethics committee in the same country and sometimes the things that we see as ethical others may view them as they have difficulties with them, other things that they see as ethical and so sometimes the researcher has to be going up and down so I think that having a policy document on research ethics and then national SOPs that will guide all of us will be good to avoid all these moving up and down by the researches” (Chair #2 at an IDI)

“In Ghana I think is long overdue. We should have a policy document governing research ethics, something that guides all the ethics committees in Ghana. we should have one, a focus something that we all hold on to and it gives something common for us, it’s long overdue.” (Chair #1 at an IDI)

Participants also indicated from the study that, there was the need for a national ethics committee as outlined in the responses below:
“I expect the ethics committee to be governed by having a national level committee. Kind of national level policy group such that when the ethics committee reviews a proposal and there researcher is not satisfied, there is another level that the person can go for arbitration or redress if the person is not satisfied. But currently as it stands, once this ethics committee says no, I will reject the proposal you have nobody to go to” (Head # 3 at an IDI)

“I think we should have a national ethics committee, a mother body that will give us all some focus, I think I have looked at the other ethics committee in Ghana some of them I have an idea and I think they are doing very very well, I compare them to other ethics committees in other countries, some countries have such a body so we should also have something like that a mother body, a national ethics committee that will guide us” (Chair # 1 at an IDI)
CHAPTER FIVE

5.0 DISCUSSION

5.1 Introduction

The motivation to carry out this study was the fact that despite the number of research activities being conducted in Ghana and the increase in the number of research ethics committees in the country, very few empirical studies have explored the role and functions of research ethics committees in protecting human research participants. This section discusses the results obtained from the various in-depth interviews.

5.2 Composition of Research Ethics Committee

The WHO standard operating procedures, which were developed in 2011, stipulate that a research ethics committee should have a minimum of five [5] members. A survey by Nyika et al. (2015), found that membership for some research ethics committees were as low as 3 members and others 19 or more which was consistent with the findings of this study that all the ethics committees were found to have 7 - 13 members. From the data collected for this current study, Dodowa has seven (7) research ethics committee members, Kintampo has 13 and Ghana Health Service has 11 committee members. This indicates that all the ethics committees were compliant with WHOs standard guideline of the least number of committee members that a research ethics committee can have.

Although, it is not clearly stated in the WHO SOP about the membership of the administrator of the IRB/REC, a participant interviewed in this study counted the administrator and the deputy administrator as part of its membership. Also, some committees counted their institutional head as members.
The study found that the consideration that goes into the selection of committee members was by need or expertise and also by recommendations by the ethics administrator to the Heads of institutions. This is not consistent with the findings of Guta et al. (2010) which gives serious consideration to individuals’ understanding of a range of traditional and different notions of harm, risk and vulnerability.

In terms of gender, all the research ethics committee members indicated that, their committees were gender balanced and adequately diverse. This finding is in contrast to the findings from a study carried out by Moodley & Myer, 2007 where female members were found to be under represented. The Dodowa Research Centre had 4 women as against 3 men and in Kintampo, out of 13 members on the committee, 5 women were found on the committee. Also, with Ghana health Service, 5 women were found on an 11-member committee. To form a quorum the WHO recommends that the committee should have five members including one lay member. Currently, it takes 5 committee members to form a quorum on the DHRC-IRB and seven (7) to form a quorum on both the GHS-ERC and the KHRC-IRB. From the interview with respondents, it was found that every gender had equal opportunity to become members of the committee. This shows that these committees were compliant with the WHO requirement of ensuring that the composition of the research ethics committee is gender balanced and adequately diverse.

From all the IRBs/RECs interviewed, it was found that none of these committees had expertise in legal matters. Also, in terms of expertise in matters of ethics and law, only GHS committee had a member with expertise in ethics and law with the other two IRB/RECs not having expertise in ethics or law. This is in contradiction with WHO SOP which states that every IRB/REC should have either an expert in legal or ethics as part of the committee. The
findings of this study also go to buttress the finding of another study carried out by Milford et al 2016, where 1% of a survey of 35 RECs were made up of ethicists. This shows that it is difficult for these committees to get an expert with legal or ethical background as part of the committee. From the above, it can be seen that having a person with either legal or ethical background is very important to the committee. However, due to the unavailability of these experts from the community, the various IRBs/RECs have been formed without them.

All the IRB/RECs had a community representative on the committee whose contributions were seen to be valuable by the scientific members of the committee. Committee members agreed that members from the community brought a different perspective to the review process. Kintampo IRB/REC and GHS-ERC have Two (2) and Three (3) members respectively from the community. However, Dodowa IRB/REC has only one member from the community contrary to the findings of a study carried out by Moodley & Myer, 2007 where only 8% were community representatives. A respondent was of the opinion that the lay persons on the committee were laid back and felt intimidated by the scientific members of the committee and this is in agreement with WHO SOP 2 which states that insufficient lay people on the committee may make them uncomfortable to voice their views.

The study also found that, all the committees have the Heads of institutions or divisional Heads being part of the IRB/RECs. This contradicts WHO SOP 4 which states that senior decision-makers of the entity creating the IRB/REC do not serve as members of the IRB/REC. Even though majority of the committee members were of the view that the Institutional Head’s presence on the committee does not affect the independence and decision making of the ethics review process, because he or she doesn’t vote on the
committee, other members disagreed to this notion. Majority of the committee members are of the view that the committees are capable of reviewing all types of protocols. This is in similar to the findings of Abdel-Aal et al., 2013 which concluded that medical research ethics committees has increased their capacity to conduct ethical review of medical research since 2005.

Generally, there was a fairly low membership turnover by the three-research ethics committee in contrast to the Nuffield council, (2002) findings which saw a high turnover of staff may affect the continuity of expertise on the ethics committee. For example, although the institutional SOPs that were reviewed stated that members should serve a maximum of eight (8) years, some of the members had served for over ten (10) years.

5.3 Submission Requirement of Research Ethics Committee

The study also found that submission instructions were very clear, even though different committees had different submission instructions which at some point have similarities. The submission instructions changed with some types of research and this is also true for the submission requirement.

From the study, all the IRBs/RECs have similar requirements for submitting research protocols for ethics review. Some submission requirements include an application form, updated curriculum vitae (CV) of principal investigators(PI),executive summary, study budget, data collection tools, protocols of proposed research, informed consent form. For students it is mandatory that, they submit their applications under the obligation of a qualified advisor /faculty member involved in the oversight of the student’s work or in the student’s name, co-signed by the qualified faculty supervisor. This in line with the WHO
SOP Ten (10) which talks about the responsibility of the researcher in submitting an application for ethics review. The study also revealed the fact that ethics review is preceded by a mandatory scientific review by the scientific review committee at the KHRC-IRB.

The study also found that, the more research protocol submitted, the more familiar researchers were with the submission requirements. However, some of the requirement changed over time explaining why some researchers were not familiar with the submission requirement. From the study, it was an institutional requirement for all researchers to submit their research proposals to the REC. These researchers were of the opinion that it was necessary to protect participant involved in research studies. This finding is contrary to the findings of a study carried out by Matar & Silverman, 2013 where 7 out of 13 respondents indicated that it was mandatory in their institution to submit to the REC. From the study conducted by Matar & Silverman, 2013, researchers did not bother to submit to the REC all research work done for promotion.

5.4 Key Stakeholders’ Views on Current Standards for Ethics Review in Ghana

From the responses, most stakeholders indicated that the SOPs were not the ultimate but it is a good guide to help in running IRB/RECs in terms of protecting human participants and these guidelines take into consideration the various declarations in the various conventions. Some committee members believe that because of its generality, each country should look at their own context and do some modifications that will depend on the country’s context. This is in agreement with findings from Oguz (2003) which suggested that some international regulatory rules like respect for autonomy are not culturally sensitive. Different continents will have different contexts and even within continents different countries will have different issues such as gender and cultural issues. In other to make
WHO SOP relevant and operational, it should be adopted to fit our context or suit particular situations. Most members felt that the current SOPs that their committees were using were adequate but needed review.

The IRB/RECs mostly consider all aspects of a proposal during the review processes. Members are not restricted to certain portions of the protocol, for example to focus on the ethics alone or the science aspect alone. Committee members look at the protocol in its entity. This is in line with the WHO standard guidelines seven which talks about the considerations made by ethics committees in decision making using a checklist that covers the entire protocol. Committee members are able to improve the quality of the protocol once researchers make the necessary corrections or work on their comments.

From the study research ethics committees arrive at decisions through either consensus or voting when the need arises. This conforms to the WHO standard guideline eight (8) which talks about the decision making procedures of the REC. This finding is similar to that of a study carried out by Matar & Silverman, 2013 where majority of the REC involved in the study used consensus in arriving at a decision, with others using voting or both.

Generally, the deliberations on the committees were good, vigorous and healthy. All committee members have equal opportunity to make meaningful contributions to the protocol under review.

5.5 Key Challenges in the Review Process

Findings from the study revealed that all the IRB/REC have similar challenges. These challenges range from lack of training to lack of resources among others.
Generally, there is a lack of periodic training for new and old members. Some IRB/RECs had training for their members two years ago. Some new members of the committee were yet to receive any training whatsoever. Apart from the fact that funding issues made it difficult to organize training for committee members, getting all committee members together at the same time for training was also difficult. This is in agreement with the study conducted by Milford et al, (2006) which stated the fact that there was lack of general and sufficient ongoing training for members in health research ethics. This is also contrary to the WHO standard guideline Five (5) which talks about training of IRB/REC members when they join and periodically on SOP and the roles and responsibility of IRB/REC.

There was an expression of intimidation by an administrator with regards to the lay people on the committee. The intimidation felt by these lay members of the IRB/REC could affect the decisions of the committee. Since they feel intimidated, they may not be able to voice out which could therefore affect the decision of the committee. This is in agreement to the findings of Matar & Silverman, 2013, where several respondents, were of the view that Junior staff is not intimidated by the senior staff and they are not scared to voice their concerns or their reservations during meetings.

It is also difficult forming a quorum since committee members are mostly busy attending to their regular work schedule contrary to the study carried out by Kass et al, 2007 in which meeting a quorum in general was not difficult. This is coupled with having to review too many proposals at a sitting that compromises the quality of work. Also, some proposals are purely technical and may need external support or expertise to review. This may delay the review of protocols. These findings from the study is in line with the findings from the University of Ghana http://ugspace.ug.edu.gh
studies carried out by Hyder et al, 2013 and Nyika et al, 2009 where committee members were overwhelmed by the number and complexity of studies to be reviewed.

According to some committee members, researchers do not have an understanding of comment requested. Again, some committee members are of the opinion that some researchers sometimes have issues with some of the comments that come to them. Researchers are sometimes seen to be attempting to influence subjects or participants unduly.

All the committee members agree that the sitting allowances they receive are woefully inadequate, and even though some complain, others feel that it’s a sacrificial work or service to God and country. This is in contrast to the research carries out by Matar & Silverman, 2013, where all the respondents had varied perspective on the compensation for ethics committee members. Committee members believe that administrative staffs have challenges in getting proposals to members on time as well as funding and material resources like printers and papers.

However, a committee member from a research ethics committee was of view that because administrative staff were overwhelmed by their work due to understaffing, such that they allow certain protocols to cross to committee members which should have been rejected in the first place. This contravenes the WHO standard guideline three(3) which talks about the resources of the committee including support staff, which should be adequate in number and training to enable the committee carry out its technical and administrative responsibilities. This challenge is peculiar to that research ethics committee and a bother to committee members.
From the perspective of the administrators, some researchers do not stick to the requirements while others are always late in submitting their protocols. Some other administrators also believe that they are not allocated enough resources like finance and personnel to support the work that they do. This is contrary to the findings of Nyika et al., (2009) which suggested that, to ensure the independence of the research ethics committees, RECs should generate adequate funds in order to reduce its reliance on the parent institution. They also feel that they are not given the needed recognition as administrators and made to feel that their role as an administrator is not really a job similar to the findings of Sleem et al., 2010, which suggests that, the dearth of support for administrative workforce has been a challenge to the effective operations of RECs.

The Heads of institutions were of the view that committee members are not adequately compensated for their time and also finding time to review proposals. A Head of Institution indicated that, a major challenge committee members faced was to do with poorly written proposals, sometimes bad language and other times proposals with grammatical and typographical errors that may frustrate them. This goes against the WHO standard guideline ten (10) which talks about the responsibility of the researcher in the conduct of research which may also affect the decision making negatively as spelt out in The WHO standard seven (7). The Heads of institutions also believe that lack of funding makes it difficult for committee members to monitor approved protocols to see if they are going according to the laid down procedure. IRBs/RECs who fail to monitor approved protocols due to lack of funds are not able to meet the WHO standard guideline nine(9).This is also in agreement with the findings of Kass et al, 2007 where all trainees said that funding was a challenge for the research ethics committees. Heads of institution again indicated that, researchers also
perceive a lack of understanding on what they intend doing by committee members and undue delays caused by the comments and posturing of some committee members as major challenges faced by them. The Heads of institutions also see financial constraints as one of the key challenges facing administrative staff.

Researchers in their view are faced with the challenge of printing a lot of copies of protocols as a requirement by ethics committee. Also, other major challenge researchers faced were the transportation of research documents to the research ethics committees as well as gap in communication between them and the ethics committee. This gap in communication causes a delay in the feedback from the committee to researchers. The intervals at which the committees met was also a challenge.

WHO recommends that, institutions establishing IRBs/RECs should put in measures to evaluate the activities of the IRB/REC at regular intervals both internally and externally. This is to ensure that the IRBs/RECs are operating according to set down policies and guidelines. However, none of the IRB/REC has a formal system of evaluating performance to know the quality of committee review process.

5.6 Recommendations by Stakeholders

Generally, researchers made recommendations on the reduction of the number of hard copies that were needed by the research ethics committee. There were also recommendations on the improvement of communication between the ethics committee and the researchers. On the issues of funding participants recommended payment of realistic charges for the review of protocols and the provision of adequate funding for ethical review in sponsored projects.
Some respondent spoke about the need for the country to have a national research ethics committee that will oversee the activities of all ethics committee. This national research ethics committee will also serve as an avenue for researchers to seek redress. This finding from the study is similar to a study conducted by Kirigia et al 2005, where 10 out of 28 countries lacked RECs at a national level.

Also, respondents were of the view that the country lacked a national policy on research ethics which was long overdue. A national policy on research ethics which they indicated will help improve the functioning of RECs and guide all the research carried out in the country. This finding is similar to a study by Abdel-Aal et al., 2013 which cited the lack of national ethics guidelines in some countries which was also a challenge for the effective functioning of some RECs.
CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Introduction

This chapter concludes on the entire study and makes recommendations based on the findings.

6.2 Conclusion

According to the findings of this study, funding is a major challenge facing institutions in carrying out the activities of research ethics committees. Owing to lack of funds the Research Ethics Committees are not able to carry out certain functions such as monitoring approved protocols, providing appropriate remuneration to motivate committee members and train new and old members. Another important finding is that the institutions do not have a system for evaluating activities of the research ethics committees. Also, there is an increasing number of protocols that committee numbers have to deal with despite their busy schedules.

From the study, researchers have to deal with sending a lot of copies of their protocols to the research ethics committees coupled with delays in the review process. There is also a communication gap contributing to delays in providing feedback between the committees and the researchers. Most respondents of the study viewed the ethics committees as independent even though the Heads of Institution were part of the review process contrary to WHO recommendations.

Overall, the research ethics committees are composed of people with diverse expertise. The diverse background of committee members makes them capable of reviewing all types of
6.3 Recommendations

The general recommendations from the study are as follows:

1. The Research and Development Division of the Ghana Health Service should facilitate the development of national research ethics guidelines.

2. Research Institutions should reconsider the membership of the Heads of Institutions on the board since this could affect the independence of the IRB/RECs.

3. The IRB/REC of the Ghana Health Service should include more lay persons from the community to the committee to ensure that the lay persons on the committee become comfortable to air their views

4. IRBs/RECs should try and get people with expertise in Ethics or Legal matters to serve on the committee

5. Research institutions should facilitate periodic training and retraining of committee members and researchers on standard operating procedures and also on the current trends in the biomedical field

6. IRB/REC should adopt a digital system of protocol submissions to reduce costs and to streamline the review process. An online platform would also enable the IRB/REC to track the progress of approved research projects.

7. Institutions under the Ghana Health Service should develop a formal system for evaluating the activities of the ethics committees

8. Institutions under the Ghana Health Service should find innovative ways of resourcing research ethics committees to effectively undertake monitoring, administrative duties and also to adequately compensate committee members for their time.
9. There should be a national ethics committee that will oversee the activities of all research ethics committees and accredit research ethics committees.

6.4 Limitations of the study

Due to time constraint and limited funding, IRB/RECs outside the Ghana Health Service were not included in the Study.

6.5 Future research

Future research should include all the 18 IRB/RECs in Ghana
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APPENDICES

Appendix 1: Participant Information Sheet

Participants Information Sheet

The Information Sheet provides information about the research for participants to make an informed decision of whether to participate in the study or not. It outlines the nature of the research, what the research involves, risks, benefits, compensation (if there is none, this should be stated).

Title of Study: “Assessment of Standard Operating Procedures of Research Ethics Committees in Ghana”

Introduction: I am Dr. Evans Gyimah Boateng, a Master of Public Health (MPH) student at the School of Public Health of the University of Ghana, Legon. My email address is gyimahboateng2015@gmail.com and my telephone number is 0203456534. I am conducting a research on the topic “assessment of the standard operating procedures of research ethics committees in Ghana”.

Background and Purpose of research: Research with human participants present several ethical challenges. There is a need to protect human participants from the risks that maybe posed by various research. IRBs/RECs are independent national or institutional ethics committee responsible for reviewing research protocols. Their aim is to safeguard the dignity, rights, safety and wellbeing of research participants and the community. Before starting any health-related research, it should be subjected to ethical review by a competent ethics committee. There are specific guidelines that spell out the key standards for research ethics review. These include the composition, the independence, resources, training and ethical decision-making. It is however unclear if the standard operating procedures of current research ethics committees meet these international standards.
**Nature of research:** This is an explorative study to assess the standard operating procedure of research ethics committees in Ghana. Three selected research ethics committees from a total of 18 IRBs/RECs that we have in Ghana will be involved in this research. In-depth interviews will be held using a semi-structured interview guide. The interview will be audio recorded and your permission is needed to audio tape the interview. I am targeting the chair, the administrator, members of the ethics committees, head of the research institution and also researchers who submit their protocols to these committees.

**Participants involvement:** I would like to invite you to participate in this study because you are either a researcher/a member of an ethics committee/the head of a research institution/administrator of an ethics committee. I believe that you can help me answer my research objective by sharing your experiences on being on the research ethics committee/the head of institution that established IRB/ you are a researcher, regarding your experience with the committee or experience submitting your research protocol to the ethics committee. I will also like you to share with me your general perceptions about the ethics review process.

**Duration /what is involved:** If you are interested in participating in this study, we will conduct an in-depth interview with you. The interview is about your experiences either being on the committees or as a researcher. It will take about 30 minutes, and will be audio recorded. If you do not want the interview to be audio recorded, alternatively you may consent for a written report. The interview will be held at a time and place that provides sufficient privacy, and is agreed upon by you and me.

**Potential Risks:** This is a minimal risk study and you will not be harmed by participating. However, some of the information you provide may be confidential and you may feel uncomfortable talking about it. You do not have to answer any question you do not feel comfortable with. You do not have to give us any reason for not responding to any question.
or for refusing to take part in the interview.

**Benefits:** Although there will not be any direct benefit for you, your participation is likely to contribute towards the improvement of the standards of research ethics review in Ghana.

**Costs:** Participation in this study will not cost you any money. You will also not receive any money/incentives for participating in this research.

**Compensation:** You will not be compensated for your participation and loss of time

**Confidentiality:** Your information will be kept strictly confidential, and will not be shared with people outside the research group. The results of this study will only be available for its intended purpose. The audio recordings will be safely stored and will not be identified with you. Soft copies of information shall be password protected and hard copies kept under lock and key. Only the PI and those involved in the research will have access to it.

**Voluntary participation/withdrawal:** Participation is voluntary. You are free to choose if you want to take part in this study. Also, you can withdraw your consent at any time without further explanation, and without any adverse consequences.

**Outcome and Feedback:** Data gathered will help to improve the ethical review process in Ghana.

**Feedback to participant:** No feedback will be given to you as an individual but a report will be given to the various IRBs/RECs and the research institutions that manage the research ethics committees.

**Sharing of participants Information/Data:** Data gathered will be kept in my possession and will not be shared with any other organization(s) or individuals. It will be solely mine.

**Storage of samples:** Data will be stored safely, and will be destroyed 5 years after the interview. Clearance will be sought from the ERC before any future use of stored data.

**Provision of Information and Consent for participants** You will be given copy of the Information sheet and Consent form will be given to you after it has been signed or thumb-
printed to keep.

**Who to Contact for Further Clarification/Questions:**

If you have a concern about any aspect of this research, please contact Dr. Evans Gyimah Boateng, at The School of Public Health, Legon or speak to me on tel. no 0244676897/020345653. For further clarification on ethical issues please contact Madam Hannah Frimpong, the administrator at the Ghana Health Service Ethics Review Committee on Tel 0507041223.
Appendix 2: Participant Consent Form

Consent Form

Title of Study: “Assessment of Standard Operating Procedures of Research Ethics Committees in Ghana”

Participants’ Statement

I acknowledge that I have read or have had the purpose and contents of the Participants’ Information Sheet read and satisfactorily explained to me in a language I understand (English). I fully understand the contents and any potential implications as well as my right to change my mind (i.e., withdraw from the research) even after I have signed this form. I voluntarily agree to be part of this research.

Name or Initials of Participant…………………………..   ID Code ………………………………..

Participants’ Signature ……… …………………..OR Mark (Please specify)………….

Date:…………………………………..

I consent with audio recording (tick what applies): Yes ☐ No ☐

Investigator Statement and Signature

I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher’s name……………………………………………….

Signature …………………………………………………..

Date…………………………………………………………..

Appendix 3: Interview Guide for Head of Institution

Study Title: Assessment of Standard Operating procedure of selected research ethics
committees in Ghana.

Introduction

Welcome the participant and briefly describe objectives of the project

Review Study Info Sheet & provide copy of Consent Form for signature

Outline the format of interview

1. Could you please tell me a bit about yourself? I.e. Your background and training/position? No names

2. How long have you been the head of the institution?

3. What is the history of the REC at this institution?

4. What considerations went into the formation of the REC?

5. How important do you view the role of the REC within the institution now?
   - What kinds of resources does the institution make available to the REC?

6. In your view, are these resources adequate? Why or why not?
   - What do you think the REC is doing really well?

7. What do you think are some of the challenges REC members experience in fulfilling the work of the committee?

8. What do you think are some of the challenges REC administrative staff experience in fulfilling the work of the office?

9. What do you think are some of the challenges researchers experience in their interactions with the REC?

10. What are some things you think the institution could do to improve the quality and efficiency of the REC?

11. First, what do you think you could do to improve the QUALITY of the REC?

12. Now, what are some things you think the institution could do to improve the efficiency of the REC?
What changes would you like to see happen with respect to the REC?

13. What would the REC need to make these changes happen?

14. Is there anything else that I haven’t asked about that you would like say about research ethics committee review at your institution?

Thank you very much for your time and insightful inputs to this project
Appendix 4: Interview Guide for Researchers

Study Title: Assessment of Standard Operating Procedure of Selected Research Ethics Committees in Ghana.

Introduction

1. Welcome the participant and briefly describe objectives of the project
2. Review Study Info Sheet & provide copy of Consent Form for signature

Outline the format of interview

1. Could you please tell me a bit about yourself? No name\ i.e. your background and training?
2. How long have you been working as a researcher? which institution
3. Is there other anything you would want to add?
4. Thank you very much
5. Tell me about your interaction with the REC?
6. Are you mandated to submit protocols to REC? if Yes Why? ...........
7. (e.g. institutional requirement, funder requirement, personal motivation)? Is it necessary?
8. Do you ever consult the REC about a study before submitting an application?
9. How frequently do you submit research protocols to the REC?
10. What kinds of protocols do you submit?
11. How do you know whether it is required to submit an REC application for your research projects? Please explain
12. Are you familiar with submission requirements?
13. How clear do you find the submission instructions?
14. How did you find out what you needed to submit?
15. What kinds of research ethics training have you received?
16. Are you familiar with institutional policies and/or guidelines about research with human participants?

17. Where do you look for guidance when preparing your application?

18. What kinds of challenges, if any, did you experience in the submission process?

19. What kind of comments and requested changes have you received on your protocols?

20. Did you understand the comments/feedback? If no did contact them for clarification?

21. Did they seem well justified?

22. Did you think they were helpful and/or enhanced the quality of the study?

23. In your experience, approximately how long has it taken from the time you submit an application to the time you receive a decision from the REC?

24. What changes to the REC guidelines or operations would you recommend to improve the quality and efficiency of ethics review at your institution?

25. First, what recommendations do you have to improve the QUALITY of ethics review? How valuable are the comments to enhance the protocol?

26. Now, what recommendations do you have to improve the EFFICIENCY of ethics review? eg too many documents, unclear instructions

27. Is there anything else that you would like to say about the REC or research at your institution that I haven’t asked about?

   Thank you very much for your insightful inputs to this project
Appendix 5: Interview Guide for Administrator

Study Title: Assessment of Standard Operating procedure of selected research ethics committees in Ghana.

Introduction

1. Welcome the participant and briefly describe objectives of the project
2. Review Study Info Sheet & provide copy of Consent Form for signature
3. Outline the format of interview

Background of interviewee

1. Could you please tell me a bit about yourself? No name i.e. your background and training?
2. How long have you been the Administrator of the research ethics committee/institutional review board?
3. Have you received any training on administrative responsibility? Long term/short term
4. Have you received any training on research Ethics?
5. How many training sessions have you received since you became the chair?
6. When/where was the last training?
7. Which institution conducted the training (FDA, individual resource persons etc)
8. Did your training include certification?
9. What kinds of resources does the institution make available to the REC?
10. In your view, are these resources adequate? Why or why not?
11. What do you think the REC is doing really well?
12. Is there any other thing you want to add?

Composition of IRB

13. How are members selected to the committee? Explain process
14. What are the different expertise on the IRB?

15. Is the IRB capable of reviewing any type of research proposal? E.g., clinical drug trial, psycho-social study, interventional study, etc…. Do you think IRB membership is adequately diverse?

16. Where, if anywhere, is content-area expertise lacking in the committees?

17. Who is/are the community representative(s) on your IRB?

18. Is community representation on the IRB valuable? Do you think the IRB has appropriate community representation? How does the IRB recruit community representatives?

19. Do you think the IRB has enough members? Too many?

20. How is IRB membership ‘turnover”? What are the common causes?

21. Is the head of institution part of the IRB?

22. How does his/her membership affect the WHO standard e.g. Decision making, independence, review process.

Experiences with reviewing Protocols

23. What are the processes involved in your institutional ethics review?

24. -is it documented?

25. -What are the types of research often reviewed by your ethics committee? (probe for clinical trials, genetic/genomic research)

26. -Is the review process different for all other types of research?

27. What ethical issues does the ethics committee normally encounter/ 

28. What is the ethical consideration that informs the committee’s decisions on protocols?

29. Is there any other thing you want to add?
Ethics/Governance Issues

30. What is the standard operating procedure for your committee?

31. How were these SOPs developed?

32. Did the WHO SOPs influence the development of these SOPs?

33. What are your views on WHO standard guidelines on Ethics?

34. What’s your take on having a policy document governing research ethics in Ghana?

35. -on clinical trials, data sharing, consent process, use of human participants etc

36. What are some of the challenges you face as the administrator of the ethics committee?

37. Probe for standards like Independence, decision making process, composition.

Closing Remarks

38. Based on our discussions, what recommendations would you give for addressing the challenges related to Ethics?

39. Is there anything that we haven’t covered that you’d like to mention?

Thank you very much for your insightful inputs to this project
Appendix 6: Interview Guide for Chair

Study Title: Assessment of Standard Operating procedure of selected research ethics committees in Ghana.

Introduction

1. Welcome the participant and briefly describe objectives of the project
2. Review Study Info Sheet & provide copy of Consent Form for signature
3. Outline the format of interview

Background of interviewee

1. Please tell me a bit about yourself? No name i.e. your background and training?
2. How long have you been a member of the research ethics committee/institutional review board?
3. Have you received any training on research Ethic?
4. How many training sessions have you received since you became a member?
5. When/where was the last training?
6. Which institution conducted the training (FDA, individual resource persons etc)
7. Did your training include certification?
8. Is there any other thing you want to add?
9. Thank you

Experiences with reviewing Protocols

10. What are the processes involved in your institutional ethics review?
11. -is it documented?
12. -What are the types of research often reviewed by your ethics committee? (probe for clinical trials, genetic/genomic research)
13. -Is the review process different for all other types of research?
14. What ethical issues does the ethics committee normally encounter/
15. What is the ethical consideration that informs the committees decisions on protocols?

16. Is there any other thing you want to add?

**IRB Composition**

17. How were you selected to the IRB?

18. Is the IRB capable of reviewing any type of research proposal? E.g., clinical drug trial, psycho-social study, interventional study, etc…. Do you think IRB membership is adequately diverse?

19. Where, if anywhere, is content-area expertise lacking in the committees?

20. Who is/are the community representatives(s) on the IRB?

21. Is community representation on the IRB valuable? Do you think the IRB has appropriate community representation? How does the IRB recruit community representatives?

22. Do you think the IRB has enough members? Too many?

23. What role do you play in selection of members? If no, do you think you should and why?

24. How is IRB membership ‘turnover”? What are the common causes?

25. Is the head of institution part of the IRB?

26. How does his/her membership affect the WHO standard e.g. Decision making, independence, review process.

**Ethics/Governance Issues**

27. What is the standard operating procedure for your committee?

28. What are your views on WHO standard guidelines on Ethics?
29. What is your take on having a policy document governing research ethics in Ghana?
   - On clinical trials, data sharing, consent process, use of human participants etc.

30. How should the governance of research Ethics be managed?

31. Who should be involved? Probe for Ethics committee, data access committee

32. What framework should be adapted to data access and control?

33. What are some of the challenges you face as the chair of the ethics committee?

34. Probe for standards like Independence, decision making process, composition.

Closing Remarks

35. Based on our discussions, what recommendations would you give for addressing the challenges related to Ethics?

36. Is there anything that we haven’t covered that you’d like to mention?

*Thank you very much for your insightful inputs to this project*
Appendix 7: Interview Guide for Committee Members

Study Title: Assessment of Standard Operating Procedure of Selected Research Ethics Committees in Ghana

Introduction

1. Welcome the participant and briefly describe objectives of the project
2. Review Study Info Sheet & provide copy of Consent Form for signature
3. Outline the format of interview

Background

1. How long have you been a member on the IRB?
2. First, what do you feel are the roles of the REC? Do you think it serves its function(s)? Why/why not?
3. Do you think the written IRB policies and procedures (e.g. Standard Operating Procedures) are adequate? Are there any that you would change?
4. What is your committee’s relationship with other committee(s), if any others exist? Does anyone sit on more than one of the committees?
5. What major changes has the IRB seen in the past two years? What caused those changes?
6. How independent do you think the committee’s decisions are from the influence of outsiders (e.g. high-ranking institutional officials, well-known researchers, etc.)?

IRB Composition

7. How were you selected to the IRB?
8. Is the IRB capable of reviewing any type of research proposal? E.g., clinical drug trial, psycho-social study, interventional study, etc. ....
9. Do you think IRB membership is adequately diverse?
10. Where, if anywhere, is content-area expertise lacking in the committees?

11. Who is/are the community representatives(s) on the IRB?

12. Is community representation on the IRB valuable? Do you think the IRB has appropriate community representation? How does the IRB recruit community representatives?

13. Do you think the IRB has enough members? Too many?

14. How is IRB membership ‘turnover”? What are the common causes?

15. Is the head of institution part of the IRB?

16. How does his/her membership affect the WHO standard e.g. Decision making, independence, review process.

Quality and Efficiency of IRB Review

17. I’d like to hear any thoughts you might have on the quality of IRB review. Do you feel like the review process adds something to the research being conducted? If yes, what does it add? If no, what is missing?

18. How would you describe the deliberations of the committee? Do you think everyone has an opportunity to contribute? Are interactions generally thoughtful and respectful?

19. During an average protocol review, what does the IRB spend most of its time reviewing? (E.g. science, ethics, budget, researcher qualifications, etc. …) Why are certain things emphasized over others?

20. How efficient do you feel the REC’s administrative processes are? What are some obstacles to administrative efficiency?
IRB Resources

21. Do you think the IRB has adequate resources to do its work? What does it need and why?
   a. Material resources?
   b. Support staff?
   c. Compensation for time?

Researchers

22. How would you describe the IRB’s relationship with researchers?

23. Do you think researchers have a good understanding of what the IRB does?

24. Do you think that researchers know what they need to submit to the IRB, how to submit it and when to submit it? How would a researcher learn this information?

25. Do you think that most research proposals that should be submitted to the IRB are indeed submitted to the IRB? Are there any reasons why you think researchers might be hesitant to submit proposals to the IRB?

26. Could you tell me a little about the quality of the materials that are submitted by researchers to the IRB? Are there parts of the submissions that are typically of lower quality (e.g., informed consent documents), and parts that are typically of higher quality (e.g., research methods)? Does the quality differ by the type/area of research?

Ethics Training

27. Have you received any training on research Ethics?

28. How many training sessions have you had since joining the IRB?

29. When/where was the last training?

30. Which institution conducted the training (FDA, individual resource persons etc.)

31. Did your training include certification?
32. What sort of experiences have you had in the past with ethics training? Did those training experiences focus on things that facilitated your ability to conduct ethics review?

33. What additional training might help increase your ability to conduct IRB review?

34. Does the IRB help train researchers in research ethics? If so, how?

**Perception of Strengths/Challenges**

35. If you could ask the institution [GHS/KHRC/DHRC] to do one thing to improve the IRB’s ability to operate, what would that be?

36. What do you see as the committee’s greatest strength?

37. What do you see as the committee’s greatest challenges moving forward?

38. Is there anything else that you would like to say about the REC or research at your institution that I haven’t asked about?

*Thank you very much for your insightful inputs to this project*
### Appendix 8: List of IRBs/RECs in Ghana

<table>
<thead>
<tr>
<th>Name of IRB/ERC/REB</th>
<th>Location</th>
<th>Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. University of Ghana, Central Ethics Review Office</td>
<td>ORID and NMIMR</td>
<td>Ms. Helena Baidoo/HBaidoo@noguchi.ug.edu.gh</td>
</tr>
<tr>
<td>2. University of Ghana, Noguchi Memorial Institute for Medical Research</td>
<td>NMIMR, College of Health Sciences University of Ghana, Legon</td>
<td>Ms. Dorcas Opai-Tetteh/Dopai-tetteh@ug.edu.gh</td>
</tr>
<tr>
<td>Institutional Review Board (NMIMR-IRB)</td>
<td></td>
<td>Tel: 0244736513/0209376258</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ms. Celestine Sappor/csappor@noguchi.ug.edu.gh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel: 0208994549</td>
</tr>
<tr>
<td>3. Kintampo Health Research Center Institutional Ethics Committee (KHRCIEC)</td>
<td>Kintampo Brong Ahafo</td>
<td>Fred Kanyoke</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:fred.kanyoke@kintampo-hrc.org">fred.kanyoke@kintampo-hrc.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel No: 0246954713</td>
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<tr>
<td>4. Navrongo Health Research Center Ethics Research Committee (NHRCERC)</td>
<td>Navrongo</td>
<td>Cletus Tindana</td>
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<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:Tindana@navrongo-hrc.org">Tindana@navrongo-hrc.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel No: 0244712474</td>
</tr>
<tr>
<td>5. Committee on Human Research Publications &amp; Ethics School of Medical Sciences</td>
<td>Kumasi Ashanti Region</td>
<td>Peter Agetinga</td>
</tr>
<tr>
<td>Komfo Anokye Teaching Hospital (KATH/KNUST)</td>
<td></td>
<td>Email: <a href="mailto:Chrpe.knust.kath@gmail.com">Chrpe.knust.kath@gmail.com</a></td>
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<tr>
<td></td>
<td></td>
<td>Tel No: 0207185564</td>
</tr>
<tr>
<td>6. Ethical and Protocol Review Committee</td>
<td>College of Health Sciences, Korle-Bu Accra</td>
<td>Mr. Mr. Daniel Abankwah</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:Daniel_jnr@hotmail.com">Daniel_jnr@hotmail.com</a></td>
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<td></td>
<td>Tel No: 0243534022</td>
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<td>7</td>
<td>Ghana Health Service Ethical Review Committee (GHSERC)</td>
<td>Adabraka, Accra</td>
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<td>8</td>
<td>University of Ghana, Ethics Committee for Humanities (UG-ECH)</td>
<td>College of Humanities, University of Ghana, Legon</td>
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<td>9</td>
<td>Ghana Atomic Energy Commission Ethical Review Committee (ERC)</td>
<td>Ghana Atomic Energy, Accra</td>
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<td>10</td>
<td>University of Cape Coast IRB (UCC-IRB)</td>
<td>Cape Coast, Central Region</td>
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<td>11</td>
<td>Centre for Scientific &amp; Industrial Research Institutional Review Board (CSIR IRB)</td>
<td>Airport, Accra</td>
</tr>
<tr>
<td>12</td>
<td>Dodowa Health Research Center Research Ethics Committee(ERC)</td>
<td>Dodowa, Accra</td>
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<tr>
<td>13</td>
<td>37 Military Hospital Institutional Review Board (IRB)</td>
<td>37 Military Hospital, Accra</td>
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<td>14</td>
<td>University of Ghana, Ethical Committee for Basic and Applied Sciences (ECBAS)</td>
<td>College of Basic and Applied Sciences, University of Ghana, Legon</td>
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<tr>
<td>15</td>
<td>Centre for Plant Medicine Research Ethics Committee</td>
<td>Mampong, Eastern Region</td>
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<tr>
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<tr>
<td>17.</td>
<td>UHAS Research Ethics Committee</td>
<td>University of Health and Allied Sciences</td>
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<tr>
<td>18.</td>
<td>University of Development Studies Ethic Committee</td>
<td>Tamale, Northern Region</td>
</tr>
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</table>
Appendix 9: Ethical Approval

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

My Ref. GHS/RDD/ERC/Admin/App 19/16/2
Your Ref. No.

Evans Gyinah Boateng
University of Ghana
P.O. Box TS 185
Teshie-Accra

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

<table>
<thead>
<tr>
<th>GHS-ERC Number</th>
<th>GHS-ERC057/02/19</th>
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<tbody>
<tr>
<td>Project Title</td>
<td>Assessment of the Standard Operating Procedures of Research Ethics Committees in Ghana</td>
</tr>
<tr>
<td>Approval Date</td>
<td>19th February, 2019</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>18th February, 2020</td>
</tr>
<tr>
<td>GHS-ERC Decision</td>
<td>Approved</td>
</tr>
</tbody>
</table>

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.
- Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED........................................

PROFESSOR MOSES AIKINS
(GHS-ERC VICES CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra