ACTIVE HEALTH RESEARCH MONITORING IN TANZANIA: PERSPECTIVES FROM MEMBERS OF INSTITUTIONAL REVIEW BOARDS

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October, 2017

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By

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A dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of Masters of Science (Bioethics) of the

Muhimbili University of Health and Allied Sciences
October, 2017

CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled *"**Active Health Research Monitoring in Tanzania: Perspectives from Members of Institutional Review Boards"*** in (partial) fulfillment of the requirement for the degree of Master of Science (Bioethics) of Muhimbili University of Health and Allied Sciences.

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Prof. Evaristi Magoti Cornelli

(Supervisor)

Date: _____

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ACKNOWLEDGEMENT

I give every praise to the Lord Almighty, for His enduring guidance, strength and wisdom in guiding me to fulfill this important mission. Glory be to His Mighty Name!!!

The accomplishment of this dissertation would not have been possible without support from various individuals who in one way or another stood by my side. I am grateful to the Fogarty Global Health program in collaboration with the Muhimbili University of Health and Allied Science (MUHAS), department of Bioethics and Health Professionalism for the financial and administrative support through the Dartmouth/MUHAS Research Ethics Training (DMRET) Project Number: 5R25TW007693-07.

I am highly indebted to my supervisor Prof. Evaristi Magoti Cornelli for his tireless efforts in reading my work timely, academic guidance, constructive criticism and patience during my dissertation period. I would also like to thank Ms. Daima Bukini for her encouragement. This dissertation would not have been possible without their immense role.

I thank the National Institute for Medical Research (NIMR) management for giving me time off from work for the whole study period. I also thank my colleagues from NIMR for their support, without forgetting my classmates of MSc. Bioethics 2015/2017, for their companionship.

I am grateful to my lecturers and staff at the School of Public Health, Department of Bioethics and Health Professionalism at MUHAS for their support and guidance. I thank all the staff and members of the four Institutional Review Boards (IRBs) visited for their time and participation in this study.

Finally, I am deeply grateful to my loving family and all my friends for their emotional support, love and endless encouragement. I request the Lord to highly reward them.

DEDICATION

I dedicate this work to my loving family for all their support, love, encouragement and faith in me. May The Almighty God bless them.

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ABSTRACT

Background

Ethical approval for research involving human subjects began in Europe due to gross abuse and unethical practices that occurred during the Second World War. In Africa, the ethical approval and active research monitoring of human research arose due to concern of possible ethical misconducts and exploitation on vulnerable population. In Tanzania, the National Health Research Ethics Committee (NatHREC) was established in 2002 to oversee all health research activities. To widen its scope, NatHREC accredited institutional review boards (IRBs) to review, approve and actively monitor research conducted by local investigators with non-foreign collaboration at institution level. However, available evidence indicates that active research monitoring is scarce. Lack of available guidelines, competent personal and funds has been mentioned as factors that constrain or enable the conduct of active research monitoring in other countries. A knowledge gap remains on understanding the conduct of active research monitoring with perspectives from members of IRBs in Tanzania.

Objective

The main objective of this research was to explore active health research monitoring in Tanzania with perspectives from members of institutional review boards.

Methodology

A mixed method research that employed quantitative and qualitative research techniques for data collection and analysis was carried out between June-July in 2017. IRB documents such as annual report, proposals, active monitoring SOPs and were reviewed and analysed manually. In-depth interviews were conducted among 11 key informants purposively selected from four IRBs in Dar es Salaam, Tanzania. Interviews were recorded, transcribed and translated before being analysed using content analysis technique with NVivo software version 10 software.

Results

Active research monitoring was preserved to be an important obligation for IRB members, however it was not being conducted regularly. Some of the IRB members felt that they were less involved in the decision-making on the conduct of active monitoring. Factors noted to constrain active monitoring included; financial resources, training, members' availability, lack of guidelines and tools, lack of prioritization and difficult to monitor research in remote areas. Factors that had enabled active monitoring included; institutional support and sense of obligation, alarming reports from passive monitoring, available SOPs and tools, proposal submission fees and the use of heads of departments.

Conclusion and recommendations

The study findings revealed that active research monitoring at the IRBs was perceived to be inadequate. Inadequate financial support, training among IRB members, devoted time from members, lack of full time secretariat staff, lack of specific guidelines and tools for active monitoring as well as the lack of regular supervision and mentorship were described to hinder its implementation. Strategies considered to be important in addressing these challenges included; reinforcement of existing SOPs and guidelines from national level, IRB members to be more pro-active to prioritize its need during review meetings, consider IRB specific means in rising financial support for active monitoring e.g. through submission fee and subcontracting qualified individuals at regional, district and department level when required.

LIST OF ABBREVIATIONS

AHRM	Active Health Research Monitoring
CIOMS	Council for International Organizations of Medical Sciences
DRP	Directorate for research and publication
DSMB	Data Safety Monitoring Board
EAC	East African Community
IRBs	Institutional Review Boards
IHI	Ifakara Health Institute
MRCC	Medical Research Committee Council
MUHAS	Muhimbili University of Health and Allied Sciences
NatHREC	National Health Research Ethics Committee
NIMR	National Institute for Medical Research
PHRM	Passive Health Research Monitoring
SAEs	Serious Adverse Events
SOPs	Standard Operational Procedures
T/FDA	Tanzania Food and Drug Authority
WHO	World Health Organization

OPERATIONAL DEFINITIONS

The following key terms were used:

1. Active health research monitoring (AHRM) - the act where committee members, secretariat staff or delegated committee, go physically to the research study site to assert researchers' compliance to all study elements and assess participants safety of approved proposals (Rivera 2008).

2. Institutional review boards (IRBs) - are committees based at universities, hospitals or research institutions that review and oversee human health research studies (Rivera 2008). May also be referred to as institutional research ethics committees.

3. Passive Health Research Monitoring (PHRM) – the act where IRBs review relevant documents such as study progress reports to evaluate whether or not an approved study is implemented in accordance to approval criteria of ethics committee with no deviation (Kruger et al. 2014**).**

4. Vulnerable population – individuals who are relatively or absolutely incapable of protecting their own interest e.g. children, pregnant women, prisoners and elders' mentally ill e.t.c. (WHO 2002).

Note: The term active research monitoring in various literature has also been referred to as oversight, post-approval monitoring or on-site monitoring thus has been interchangeably referred to in this study.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Health research is beneficial to prevent and manage diseases, though can be exploitative if not well monitored (Morse, 2001). Exploitation from health research could be prevented by regulatory authorities like research ethics committees which review, approve and actively monitor the conduct of research (Kruger et al. 2014). In the United States, institutional review boards (IRBs) and food and drug authority (FDA) were initially established to review and approve human research before implementation. This was a response to several scandals associated with historical exploitative medical research practices upon vulnerable populations during and after World War II. Such scandals include; the Nazi scientists' experiments on prisoners, (Weindling, 1996), Thalidomide trial on pregnant women (Kim & Scialli, 2011) and Tuskegee Syphilis trial on Afro-American men (Kruger et al., 2014).

The vulnerable population also termed 'research subjects' had little or no understanding on the nature of the research (Oakes, 2002). These scandals laid the foundation of the Nuremberg Code of 1946 which latter gave birth to three basic ethical principles, namely respect for person (autonomy), beneficence and justice (Belmont report, 1979). Subsequently other international guidelines were formulated including; i) the Human Right Charter of 1948; ii) the Declaration of Helsinki of 1964; iii) the Belmont report of 1979; and several versions of iv) the Council for International Organization of Medical Sciences (CIOMS) i.e. of 1982 and 2000 (WHO, 2002). The IRBs were considered to be important organs to approve health research thus prevent research misconduct as they ensure protection of participants and society from physical, emotional or social risks that may otherwise go unreported (Klitzman, 2011; Kruger et al., 2014). Based on these developments, many other countries developed national guidelines to facilitate ethical procedures and research monitoring (Kruger et al. 2014).

Research monitoring is referred to as a method of actively or passively evaluating whether research projects are implemented according to proposals approved by IRBs (Kruger et al. 2014). The need for actively monitoring human research became alarming with increase in clinical trial research approvals. In the 60's, Beecher published an article on 22 cases of misconducts in the New England Journal of Medicine which also raised the necessity for active research monitoring (Emanuel & Grady, 2006). Monitoring research involves five steps that include i) monitoring of consent process, ii) periodic monitoring of research practice, iii) data integrity; and iv) site-visits (Kruger et al., 2014). According to Emanuel (2006) active health research monitoring has evolved through four paradigms with different emphasis since 60's from i) Research paternalism-emphasizing on researchers' judgments, ii) Regulatory protectionism focus on IRB review process and informed consent, iii) Participant access driven by AIDS pandemic and individual autonomy, and iv) Community partnership driven by genetics research and community collaboration (Emanuel & Grady, 2006).

The increase of pressure from scientific journals for researchers requirement to seek ethical approval before publication, led most developing countries to adopt the IRBs system in 1960's (Arda 2000; Ikingura et al., 2007). In Tanzania, the East African Community (EAC) initially regulated health research until its collapse in 1977. The National Institute for Medical Research (NIMR) established in 1979 was then mandated by the government to promote, coordinate, monitor and evaluate health research through its Medical Research Coordinating Committee in Tanzania (MRCC) (URT, 1979). The MRCC further established a sub-committee, the National Health Research Ethics Committee (NatHREC) in 2002, to help oversee and conduct both passive and active health research monitoring (Ikingura et al, 2007).

Active health research monitoring in Tanzania is structured at two main levels, the national level (NatHREC) and zonal or institution level (IRBs) (NIMR, 2009). The IRBs are mandated to review, approve and actively monitor non-clinical research with non-foreign collaboration conducted by local investigators (URT, 1997), while international collaborations and clinical trials are actively monitored by NatHREC, TFDA (Tanzania Food and Drug Authority) and Data Safety Monitoring Boards (DSMB) (Tanzania Food and Drug Authority, 2009; NIMR

2009). The NatHREC has so far accredited thirteen IRBs at zonal and institutional levels. These include i) Kilimanjaro Christian Medical College (KCMCollege)-IRB; ii) Mbeya Referral Hospital-IRB; iii) Lake Zone-IRB; iv) Central Zone-IRB and v) the University of Nelson Mandela-IRB (Ikingura J. & Temu, 2014). The eight IRBs in Dar es Salaam include i) Ifakara Health Institute (IHI)-IRB; ii) Muhimbili University of Health and Allied Sciences (MUHAS)-IRB; iii) African Research and Medical Foundation (AMREF)-IRB; iv) Muhimbili National Hospital (MNH)-IRB; v) Aga Khan University (AKU)-IRB; vi) Hubert Kairuki Memorial University (HKMU)-IRB; vii) University of Dar es Salaam (UDSM)-IRB and viii) Open University-IRB (Ikingura J. & Temu, 2014).

The distribution of IRBs is important to support NatHRECs' functioning role, as they are closer to the research community and local researchers. The IRBs are expected to provide regular feedback to NatHREC on research that they approve and monitor (Kruger et al. 2014; Saver, 2009; NIMR, 2009). Despite its relevance, active health research monitoring by IRBs is often noted not to be conducted (Kilama 2005; Ikingura J. & Temu 2014). Therefore, this study was focused to find out factors that shape such conduct of active health research monitoring in Tanzania with perspectives from members of institutional review boards taking into consideration that the initial research monitoring system in the country was more on passive monitoring (NIMR, 2009).

1.2 Problem statement

For effective active research monitoring of health research, IRBs are expected to observe the informed consent documents and procedure, enrollment process, participants' welfare, potential risks, research team capacity, data and material documentation and handling of approved health research at institution level (NIMR, 2009; Purdue University, 2012).

So far, only a few research misconducts have been documented in Tanzania, mostly through whistle blows that trigger ad-hoc instead of regular monitoring visits (Kilama, 2005). It is likely that more reports on research misconducts in Tanzania might be available in the absence

of active health research monitoring by IRBs in the country (Kilama, 2005; Ikingura J. & Temu, 2014). Most IRBs do not conduct active health research monitoring on researches they approve with regular feedback to the NatHREC as required. Failure to do so may expose research subjects to exploitation and impend IRBs' institutional supportive role to NatHREC in overseeing health research (Mashalla et al., 2009).

Lessons from other countries suggest that various factors may influence IRBs to conduct active health research monitoring. Such factors have been related to structural, procedural and performance issues (Emanuel et al., 2004); and high cost and lack of training (Ochieng et al., 2013). In Tanzania studies on IRBs have assessed the "Review process and need of IRBs establishment" (Ikingura et al., 2007) as well as the "Composition and training needs…'in clinical trials settings (Nyika et al., 2009) only to mention a few.

However, there is scarce information on aspects which influence active health research monitoring for both clinical and non-clinical trial research in the country (Ikingura J. & Temu, 2014). Despite existing IRBs, active monitoring remains a challenge at both IRB and national level. It was important to address issues surrounding the enabling environment, challenges and possible strategies to ensure optimal conduct of active health research monitoring by IRBs. Hence, this research aimed at exploring active health research monitoring in Tanzania with perspectives from members of institutional review boards on factors that enable and constrain its implementation.

1.3 Justification of the study

The study findings may contribute to generate information to the limited literature on active health research monitoring by IRBs, and thus understanding of factors that enable and/or constrain its implementation in Tanzania. The information provided may also enable NatHREC to develop supplementary guidelines for effective active monitoring of approved proposals at IRBs level. The study might also be an eye opener to illustrate gaps on active

research monitoring that may provide additional insights required by others interested in a similar research area in the future.

1.4 Research questions

1. What is the adequacy of active health research monitoring at IRBs?
2. What are the factors that constrain active health research monitoring by IRBs?
3. What are the factors that enable active health research monitoring by IRBs?
4. What strategies are required to address challenges of active health research monitoring by IRBs?

1.5 Study objectives

1.5.1 Main objective

To explore active health research monitoring with perspectives from members of institutional review boards in Tanzania.

1.5.2 Specific objectives

1. To conduct document review on the adequacy of active health research monitoring at IRBs.

2. To explore factors that constrains active health research monitoring by IRBs.

3. To examine factors that enable active health research monitoring by IRBs.

4. To document strategies to address challenges in active health research monitoring by IRBs.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Adequacy of active health research monitoring at IRBs

Various studies have tried to explain the complex process of active health research monitoring by IRBs. At the global level, active research monitoring practice or oversight of approved research involving human subjects has been perceived to be inadequate (i.e. scarcely conducted or not conducted at all) despite its emphasis and importance (Shamoo & Katzel, 2007; Emanuel et al., 2004; WHO, 2002). Emanuel (2004) points out that most literature do not clearly provide standards metrics for what constitutes adequacy in protecting human subjects (Emanuel et al., 2004).

In view of this discrepancy, the appropriate meaning addressed to adequacy in active health research monitoring for this study was derived from Rivera (2008), which requires IRB members or delegated authorities to conduct routine post-approval monitoring through site visits to check if the approved proposals was implemented accordingly and well documented (Rivera, 2008). This definition is considered to be appropriate for this study because based on routine obligates, the IRB should conduct at least one initial site visit of the research study it approves regularly.

Research subjects often place their trust toward study investigators to safeguard their interests when involved in a study (Enfield & Truwit, 2008). However, this is not always the case. For instance, while over 20 million research subjects in the US who participate in health research, a significant number of them have been described to be involved in unregulated or unmonitored research (Shamoo & Katzel, 2007). Reportedly, more than half of the 25 IRBs surveyed in Latin America (59%) were found to lack active health research monitoring mechanisms in place (Caniza et al, 2006). Most of them failed to conduct active health research monitoring on the approved studies due to lack of standard guidelines.

According to the Council for International Organizations of Medical Sciences, sponsors and clinical investigators are ethically obliged to support the establishment of capacity for active health research monitoring in countries which lack appropriate resources (WHO, 2002). However, most developing countries in sub-Saharan Africa's IRBs still have inadequate or no active health research monitoring systems in place, despite the volume of health research they approve (Nyika et al., 2009; Noor, 2009).

A survey conducted in Uganda revealed inadequate active health research monitoring practice among IRBs. This was associated with regulatory violation in terms of informed consent violation, rights to participants' welfare, unreported event reports such as progress reports and serious adverse events (SAEs) reports (Ochieng et al., 2013).

Despite the increase of research activities in Tanzania, the number of active health research monitoring visits are seemingly low, mostly being triggered by alarming reports or whistle blowing that necessitate ad-hoc visits (Mashalla et al., 2009). This is the case both at the national level (NatHREC) and zonal or institutional level (IRBs). The NatHREC Standard Operational Procedures (SOPs) requires that the secretariat (which consists of the Secretary, deputy Secretary, Legal officer, Administrative officer, and several research scientists) to initiate active monitoring through regular meeting. The secretariat is to budget, plan and conduct active monitoring of approved research studies in collaboration with committee members and other delegated individuals if need arises (NIMR, 2009).

The above-mentioned studies support the argument that active health research monitoring is inadequate at IRBs. However, these studies have focused more on clinical trial researches. The question remains is on how IRB members perceive the adequacy of active health research monitoring of both non-clinical and clinical trial research approved at local level? Hence, this study focused to find out the perceived adequacy of active research monitoring from IRB members on non-clinical and clinical research at institutional level. The next section scrutinizes literature on factors that constrain and enable active research monitoring by IRBs.

2.2 Factors that constrain active research monitoring by IRBs

It has been noted that active health research monitoring at IRBs and availability of funds have been closely related to one another; as IRBs that don't not allocate enough budget to conduct active health research monitoring are more likely not to conduct regular monitoring compared to IRBs which allocate budget for this activity (Weijer, 2001).

Implementation of active health research monitoring is also thought to be constrained by possible problems grouped into three categories that may occur with institutional structure, review procedures and performance assessment that measures IRB performance and dissemination of clinical trial data (Emanuel et al., 2004). However, again these problems have been noted at the international level and more pronounced with clinical trial research even with well-established IRB system.

A case reports from various African research ethics committees showed that most African countries have ethical review systems in place. However, active research monitoring is mostly conducted as ad-hoc and on only few clinical trial researches possibly due to constraints such as inadequate fund allocation, human resource capacity guidelines and tools in conducting monitoring, training, inaccessible study sites, as well as communication breakdown among and between IRB members and national regulatory authorities (Kruger et al., 2014).

The presents of standard operational guidelines for conducting active research monitoring has also been perceived to an important role in determining the frequency and quality of active research monitoring activities (Caniza et al., 2006). For Tanzania, factors that constrain active health research monitoring by IRBs have not been systematically studied. It is important to understand such factors to facilitate active monitoring of both clinical and non-clinical research that involves human subjects (Schatz, 2004).

2.3 Factors that enable active research monitoring by IRBs

Factors that enable active monitoring of approved health research by IRBs have been referred to be more country or IRB specific rather than universal. For example, some IRBs are

government funded while other IRBs utilize the specific fees from submitted proposals to cover associated active monitoring costs enable implementation of routine active health research monitoring in Canada (Weijer, 2001).

In Africa, there has been an attempt to develop and implement active monitoring of health research. For example, a research team in Uganda developed a community based and contextual model/tool for conducting active health research monitoring (Ochieng et al., 2013). The tool highlights several areas of focus when conducting active monitoring. These areas include overseeing; regulatory documents, site facility, informed consent process, participate welfare, passive reports, study related training, committee work practice and debriefing by communicating findings with team and institutions for feedback. These factors have worked as a guide to enabled IRBs conduct regulate and less costly active health research monitoring activities on approved research (Ochieng et al., 2013).

The review on Research Ethics in Africa also revealed mechanisms that possibly enabled IRB members to conduct active monitoring. These include; IRB members dedicated time, developing necessary tools and working with stakeholders to implement active research monitoring. These stakeholders include; empowering research community members, Data Safety Management Board (DSMB), the Community Advisory Board (CAB) and other delegated individuals (when a need arises) to ensure that post-approval active health research monitoring is conducted (Kruger et al., 2014).

Having drawn from the literature of various factors on active monitoring of health research from other countries, the question remains on what are the possible factors that have enabled known active monitoring activities of approved health research at some IRBs in Tanzania?

The literature has focused on the adequacy of active health research monitoring and factors that constrain and enable its implementation by IRBs. These factors were seen to relate to ethical regulations, finance, availability in personnel and training of IRB members.

2.5 Theoretical framework

The “Deontological Theory” formed the philosophical ground that helped to guide this study. According to its German pioneer Immanuel Kant, the morally right way, “is to act from a person’s duty rather than from the consequences of the act” (Tordjman, 2013). This theory provides a framework that explains morality as doing the right thing if done in accordance to the rules or principles, which are perceived to be paramount and thus ought to be followed by everyone. Kant further categorized the theory to ‘categorical imperative’ basing on three assumptions that are, i) to act as if the will were also a universal law, ii) to respect people as rational beings and iii) to treat people as ends in themselves and not as a means to achieving an end (Tordjman, 2013).

For the purpose of this study, focus was made on the assumptions drawn from the categorical imperative to further investigate on the factors that influence active health research monitoring by IRBs in Tanzania. In research ethics, active health research monitoring of approved health research is seen as an obligation (or universal law) of the approving authorities such as RECs, IRBs, TFDA or DSMB. Whereby, active monitoring aids to ensure protection of research subjects (by respecting their rights and autonomy as rational beings and not using them as a means to an end of the research goal) (Kruger et al., 2014). Emphasis was made on IRB members and researchers to act in accordance to their research obligations and adhere to the ethical principles of respect for person, beneficence and justice when conducting health research (Emanuel & Grady, 2006).

Therefore, the concept from this theory was used to refer active research monitoring as a duty that needed to be carried out by research approving authority which in this case were the IRBs which ought to review and actively monitor approved proposals conducted by local researchers at institutional level no matter the consequence (Schüklenk, 2000; Tordjman, 2013).

2.6 Conceptual framework

The conceptual framework has adapted its concepts from Kant's first categorical imperative with assumption that requires one to "act as if the will were also a universal law" (Tordjman, 2013). The main purpose of this framework was to illustrate the concepts explored and their relationship originating from various reasons found in literature from other countries associated with factors that influenced active health research monitoring. These concepts have been categorized into three main groups for the purpose of this study: personnel, regulations and finance (Emanuel et al., 2004; Ochieng et al., 2013).

The concepts described may either be well utilized or underutilized to maximum a given good in the process of fulfilling ones' duty in this case conducting active research monitoring of approved health research proposals at IRBs, as illustrated in Figure No. 1 below.

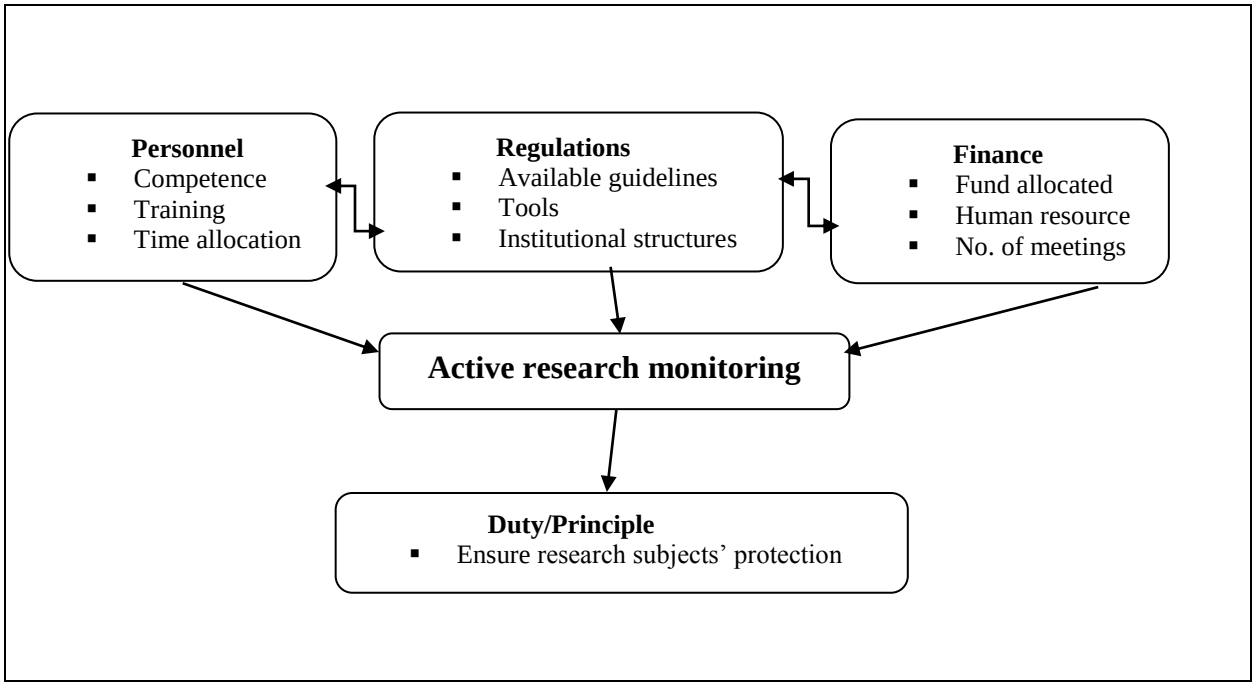

Figure 1: Conceptual framework on factors that influence active health research monitoring of approved health research at IRB. *Source: Emanuel Ezekiel with researcher's modification*

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

A cross-sectional exploratory study that employed mixed methods of quantitative and qualitative data collection and analytical methods was used. This design was chosen because according to Creswell it ensures in-depth understanding of a particular research phenomenon which in this case is active research monitoring. In addition the quantitative method was used in the studied to capture quantifiable information from the document review (Creswell, 2002).

3.2 Study duration

The research study was carried out in June and July 2017.

3.3 Study area

The study was conducted in Dar es Salaam, a city with several research and academic institutions. The study focused on IRBs mainly established at academic institutions, research institutions and referral hospitals of both public and private origin. Dar es Salaam having a total of eight accredited IRBs with mixed categorization made it a suitable study area.

Specifically, the study involved five IRBs in Dar es Salaam. The reason for selecting the five IRBs was that they had been accredited by NatHREC and were fully functioning at the time this study was conducted. The five IRBs selected for this study include; i) The Muhimbili University of Health and Allied Sciences - IRB a public academic institution; ii) The Ifakara Health Institute - IRB a private research institution; iii) The AMREF - IRB a private research institution; iv) The Muhimbili National Hospital - IRB a National hospital; and v) Aga Khan University - IRB a private academic institution. However, Aga Khan University – IRB was not available and thus not included in the study and remained with only four IRBs.

3.4 Study population

The study population included IRB Chairperson, Secretary or deputies and members of the four IRBs. The key informants were purposively selected due to their decision-making position and experience in coordinating committee activities. Specifically, the study population included the following three categories of key informant indicated in the (Table 1) below.

Table 1. IRBs key informants selected and reasons for their selection

No.	Key Informant	Reason for Selection
1.	Chairperson	An appointed member among the committee members who chairs committee meetings and guides decisions arising from the meetings which include when and how active health research monitoring should be done for approved proposals. S/he is normally not affiliated to the institution to avoid any conflict of interest.
2.	Secretary	A member of the committee and head of Secretariat unit (the ware house of the committee) with regards to proposal submissions, reviews, clearance and monitoring. S/he is an employee of the host institution and coordinates daily communication between researchers and committee members dealing with active research monitoring logistics and reports.
3.	Member	A member of the committee. S/he may be but not always affiliated to the institution. They are responsible for reviewing research proposals and other IRB activities that include active monitoring.

3.4.1 Eligibility criteria

3.4.1.1 Inclusion criteria

The IRB members served on committee for over one-year willing and consented for interviews.

3.4.1.2 Exclusion criteria

The IRB members served on the committee for over one year but who have not attended IRB meetings.

3.5 Sample size

Two levels of sample size were used to sample for key informants and IRB sites. A total number of 15 key informants, at least 3 from each IRB were purposively selected to participate in this study. However, the saturation was determined at the field, thus a total of 11 key informants were included in the study (Fusch & Ness 2015). The total accredited and functioning IRBs in Dar es Salaam were five. However, only four had agreed to participate and thus were included in this study. The Aga Khan University IRB was not included in the study due to their engagement in academic and institutional affairs, despite the researchers' contact efforts with several emails, phone calls and physical visits. There was no other substitute IRB due to the fact that only 5 IRBs were accredited and functioning in Dar es Salaam during the time the study was conducted.

3.6 Sampling procedure

A non-random sampling method was used to select participants from the four IRBs, based on features such as their position and experience in the committee. This gave them a more likelihood to respond to the research phenomena (Marshall, 1996). Normally known the IRB members range from a total of 5 to 15 members of different professional background (NIMR, 2009). Therefore, a purposive sampling technique was used to recruit participants with experience including the Chairperson and Secretary. However, in there absents, other members from the four IRBs were selected to participate in the study.

3.7 Data collection methods and tools

An in-depth interview guide was used to gather face-to-face information from participants. In-depth interviews are useful when research participants cannot be directly observed as it

provides historical information on research problem and a chance for further clarification through probing during the interview process (Creswell, 2002). This method was selected due to its flexibility to investigate detailed information from the individuals' perspectives.

An English in-depth interview guide (Appendix 1) was composed of various questions and probes on study phenomena. The guide was translated to Kiswahili (Appendix 2), language in which some of the interviews were conducted. The interview guide captured information on the adequacy and factors that influence active health research monitoring by IRBs in Tanzania. Review of various documents was also done by using a document review guide (Appendix 3) to back-up information from the in-depth interviews.

3.8 Training of research assistant

The researcher being an employee at NIMR and student at MUHAS declared conflict of interest with her host University MUHAS - IRB due to the fact that some of the committee members were her lectures and with other IRBs. For this reason, one research assistant a degree holder with non - MUHAS affiliation, assisted with note taking transcription, translation and coding. Two-days were used to orient the research assistant on the study objectives, method and information required from in-depth interview guide and document review guide. On the second day, the researcher and assistant pre-tested the data collection tools on IRB members at the national level before refining and finalizing the tools. Moreover, the researcher worked in close collaboration with the research assistant throughout the data collection process to ensure the quality of data collection and handling.

3.9 Data collection procedure

In-depth interviews were conducted at the respective IRBs with participants' place of choice i.e. in a private space or room. Appointments were initially made before each interview so as not to interfere with participants' daily activities. Interviews were thus conducted and recorded by the researcher assisted by the assistant after participants' permission.

A list of the required document to be reviewed was provided to the secretariat member at each IRB visited. The list included the proposal register (book or electronic copy), the SOPs, monitoring tool and reports on active health research monitoring that were available for the past year i.e. January – December 2016. The documents were reviewed in search of the number of proposals submitted and granted approval within the reporting period of one year as well as the number of active monitoring conducted and reports provided. The SOPs were also reviewed to identify the description on active monitoring activities and the tools to describe the issued to be assisted in conducting active monitoring.

3.9.1 Data reliability and validity

Data reliability and validity was guaranteed through various steps during study design, data collection and data interpretation phase (Fusch & Ness, 2015).

Validity of data was obtained through pre-testing the research tools with participants from the National Health Research Ethics Committee (NatHREC) to assess how the questions were asked and responses of both the key informant interview guide and the document review guide. The questions were then modified to strengthen the tools with valid questions (Golafshani, 2003).

For data reliability, the researcher employed one research assistant who assisted in note taking to ensure not to miss out any information and have a second observer. Likewise, during the data coding process, the research assistant and one other colleague read through the transcripts and themes to ensure soundness of data collected and avoid single researcher bias (Krefting, 2017).

3.10 Data management and analysis

During study implementation, daily debriefing was done to check for clarity and quality of data collected from digital audio recordings. Data from audio recording was uploaded on the researchers' computer which was kept with a password under the researchers' own custodian at her office locker. At least two interviews were conducted and listened to on a daily base so

as to determine saturation of information gathered. Saturation point was finally reached upon the 10th interview.

Qualitative data analysis began with transcription, editing and translation of the in-depth interviews conducted in both Kiswahili and English that were further coded in vivo within the text. The researcher listened to the audio recordings several times so as to be familiarized with the data. Coding was done in relation of data within and among the contents. Phrases from the transcript wordings were segmented, transcribed and translated to identify important points described in forms of quotes. The coding process was continuing back and forth so as not to miss out important issues.

Data was then categorized into nodes which were created with relevance to the emerging themes that were used for content analysis with NVivo 10, a computer assisted qualitative data analysis software (CAQDAS) (Burnard P et al., 2008). The NVivo software program was designed only to organize and analyze interviews and field notes. Transcripts were reviewed several times to capture the intended message compared with the audio recordings.

Different concepts were identified and grouped into categories and sub-categories for discussion. Information from the document review guides was contextually described to enrich the interview information on active research monitoring with perspectives from members of IRBs in Tanzania.

3.11 Ethical considerations

The study dealt with qualitative data collection and analysis techniques that were sensitive information; hence it was important to observe ethical regulations. For this matter, individual written informed consents were administered to each participant before interviews (Appendix 4 or 5). Upon agreeing to participate in the study and having their interviews recorded (Creswell, 2002). The ethical issues considered included participants' confidentiality, protection from any harm related to their work position, free willingness to participate, their right to withdrawal at any point in time and right to privacy (Belmont report, 1979). Therefore,

the researchers clearly elaborated (Appendix 4 or 5) the purpose of the study to all participants and give them room for clarity before they willingly decided to/not to participate in the study. Permission to record the interviews was sought from participants who agreed to participate.

Nevertheless, the researcher tried as much as possible to keep the information confidential with privacy. Number codes were used to assure anonymity instead of the actual names of participants. Interviews were conducted in private rooms and participants were assured that the information they provided would not be used to affect their job to avoid possible psychological work-related harm.

Ethical approval was sorted from the MUHAS Directorate for Research and Publication (DRP) Committee and permission to conduct the study was sorted from Secretaries of each IRBs.

CHAPTER FOUR

4.0 RESULTS

4.1 Overview

This section provides general description and analysis of the information gathered through the in-depth interview and document review guides. The general objective of the study was to explore active health research monitoring in Tanzania with perspectives from members of IRBs.

4.2 Demographic characteristics of respondents

Data in (Table 2.) below illustrates the demographic characteristics of eleven study respondents who were recruited from four IRBs in Dar es Salaam. The study recruited eleven (11) IRB members that included three (3) Chairpersons, three (3) Secretaries and five (5) Members at four (4) IRBs in Dar es Salaam. The age of respondents ranged from 40 to 61 years while most of them were men 7(63.6). More than half of the respondents had attained their higher education of PhDs 6 (54.5%). Most respondents 8 (72.7%) had certificate training in ethics mostly conducted through short courses or workshops. However, none of the respondents had reported to be trained on active health research monitoring. Three respondents 3 (27.2%) had the experience of serving on the IRB for more than ten years.

Table 2. Respondents demographic characteristics

Demographic characteristics	Total 11= n (%)
Age	
40-49	6 (54.5)
50-59	4 (36.3)
60 >	1 (09.0)
Sex	
Male	7 (63.6)
Female	4 (36.3)
Highest education level	
Masters	5 (45.4)
PhDs	6 (54.5)
Ethics training	
Certificate	8 (72.7)
Diploma	2 (18.1)
Masters	1 (09.0)
Length at IRB in years	
1 - 5	7 (63.6)
6 - 10	1 (09.0)
11 – 15	3 (27.2)

4.3 General characteristics of the IRBs

The four IRBs visited were all within Dar es Salaam and had been accredited by the NatHREC. The IRBs were diversely mixed with representation in type of service and ownership i.e. public, private and service provision i.e. academic, research and referral hospital IRBs. The IRBs had been established not less than three years ago while only two IRBs had existed for more than 10 years. The members ranged from 20 to 11 per IRB while the secretariat members with the main role of day-to-day activities ranged from 3 to 1 per IRB composed of Chairperson, Secretary and Admin. All IRBs mentioned to have been

conducting passive research monitoring on approved proposals, while only one IRB reported to conduct active research monitoring after approval as illustrated on (Table 3.) below.

Table 3. Characteristics of IRBs

1	IRB	**MUHAS**	**IHI**	**AMREF**	**MNH**
2	Year established	2003	2005	2014	2014
3	Ownership	Public	Private	Private	Public
4	Service provision	Academic Institution	Research Institution	Research Institution	National Referral Hospital
5	No. of secretariat members	3	2	1	1
6	Secretariat composition	Chair, Admin & personal secretary	Secretary & Admin	Secretary	Secretary
7	No. of IRB members	20	15	11	19
8	If received passive monitoring reports	Yes	Yes	Yes	Yes
9	Presence of active monitoring reports	No	Yes	No	No

4.4 Document review guide findings

Information from document review guide was gathered so as to support the interview responses on information of the IRB monitoring activities during a period of one year (January-December 2016). All four IRBs visited, were found to be actively functionally with review and approval of research proposals in place. The number of proposals reviewed and approved during the one-year period ranged from 3 to 29 proposals. One IRB was found to have been reviewing and monitoring both clinical and non-clinical trial proposals.

Table 4. Document review guide on IRB active monitoring activities (Jan. to Dec. 2016)

Name of IRB	**MUHAS**	**IHI**	**AMREF**	**MNH**
No. of research submissions and approvals granted	29 *NCTs 6 **CTs	29 NCT	3 NCT	16 NCTs
No. of active research monitoring reports	0	1	0	1
IRB SOPs in place	Yes	Yes	Yes	Yes
If SOPs indicate active monitoring	Yes	Yes	Yes	Yes
Description of AHRM as per SOPs;	The IRB may decide to carry out surprise checks of research sites and facilities to provide assurance of compliance to the approved protocol.	IRB members should physically visit research projects in the field to assess if projects are conducted as per approval. -Ideally each approved study should be actively monitored	The IRB is responsible for not only approval of research proposals received, but also monitoring on-going research.	The IRB may decide to carry out surprise checks of research sites and facilities to obtain assurance of compliance to the approved protocol.
SOPs establishment	Revised in 2015	2010	2012	2013
Monitoring tools in place	***None	Yes	None	None
Monitoring tool developed	None	2010	None	None
Description of monitoring tools included;	None	IRB members are to use a tool to ensure appropriate issues are assessed during oversights.	None	None

Key: *NCT: Non-clinical trial ** CT: Clinical trial *** None: Not found at IRB

4.5 In-depth interview findings

With the qualitative in-depth interview content analysis, several issues emerged from the interviews. However, six (6) major categories from the interviews were taken in consideration in relation to the main study objectives. In this section, the qualitative findings have been

grouped into various categories, sub-categories and quotes that evolved from the in-depth interviews. The categories and related quotes are presented in (Table 5.) below. All the quotes were assigned special numbers so as to maintain respondents' confidentiality.

Table 5. Emerging categories sub-categories and respondents' quotes

Category	Sub-categories	Respondents' quotes
Members perceived active research monitoring to be very important	-Active monitoring is essential after approval -It is required to protect research participants.	*"Active research monitoring is very important after the approval" (6)* *"In violation of ethical principles, human beings can be victims if research is done by a Clinicians, Sociologists, or anybody" (9)*
Members were concerned with the adequacy of active monitoring at IRB level	-Active monitoring is not adequate	*"In general, it is not adequate. This is a very weak area." (8)* *"We do not monitor even student proposals" (6)*
Members felt less involved in active monitoring decisions	-Not involved in decisions on doing active monitoring	*"I have not been involved in any active research monitoring and I don't know how it operates." (5)*
Factors perceived to constrain implementation of active monitoring at IRBs	-Financial resources -Members time devoted for monitoring -Lack of guidelines and tools for monitoring -Prioritization for active monitoring -Tanzania is a big country -Lack in training on how to conduct active monitoring	*"The money we receive is not only for site visits but also to run the IRBs and secretariat as well." (1)* *"When you plan, you may find only few are ready to go to the field for site visits" (2)* *"We do not have guidelines, SOPs or tools on when and how to do it..." (6)* *"…if you only prioritize in reviewing protocols you will end up doing only that." (9)* *"… We are in Dar, if people are doing research in Rukwa or Katavi (remote areas), it is difficult to do monitoring..." (8)* *"...I would love a little bit more training in terms of how to do active monitoring." (3)*
Factors perceived by IRB members to enabled active research monitoring	-Sense of IRB obligation to conduct active monitoring - Institutional support -Passive monitoring report alerts	*"We are to have oversight on whatever is being done as we have provided clearance (6)* *'The IRB reports directly to the director, this gives us more independence, power and credit" (2)* *"Support from management is very important because if they do not approve we cannot go anywhere." (1)* *"…a yellow flag like reports from the site…" (1)*

	- Available SOPs and tools	*"The SOPs document guides us to do active monitoring." (7)*
	- Use of proposal submission fee	*"We depend on proposal submission fees to conduct monitoring." (2)*
	- Use of Heads of departments	*"We have empowered heads of departments who are made aware of approved research in their departments." (10)*
Several strategies were required for implementation of active monitoring at IRBs	-Strengthen IRB capacity	*"Members need to be trained at least every two years." (2)*
	-Strengthen regional and district	*"Strengthen regional structures e.g. RMOs and RHMT to own research in their area." (8)*
	- Prioritize active monitoring	*"Members need to push for active monitoring as they hold the voice to raise concern." (9)*
	-Charge submission fee	*"To increase amount of application fee." (2)*
	-IRB accreditation and supervision	*"NatHREC needs to oversee the local IRBs." (2)*
		"*NIMR needs to mentor IRBs to a level that they can do things properly." (8)*
	-To have SOPs for monitoring	*"We need an SOP for active monitoring that needs to be followed." (5)*
	- Subcontract people to do it.	*"You can subcontract somebody to do it." (9)*
		"If you have well-structured guidelines, any qualified person may do active monitoring.' (6)
	-IRB own initiatives	*"IRB members need to be proactive in doing oversight visit or else this is just a usual song." (9)*

4.5.1 Members perceived active research monitoring to be very important

Respondents perceived active research monitoring to be an important role for the IRB. They reported that their obligation as members of the IRBs who review and approve health research proposals was also to ensure that research was conducted accordingly as to approve proposal as illustrated below by one respondent:

> "*Active research monitoring is very important because researcher can take advantage of a weak IRB, knowing that there is no follow-up after approval. So, they can submit*

something else and they can implement something different. It helps to make sure that what has been approved is what is being implemented in the field" (Respondent. 3)

However, another respondent was in the view that active research monitoring was not given as much importance compared to other activates at the IRB and said:

"Active monitoring is very important as ethics is concerned. Those who are at the decision-making position have to take it as priority number one. If you house an IRB, make sure among other things active monitoring is done for non-clinical trials, however clinical trials should be priority number one." (Respondent. 1)

Respondents acknowledged the important role of NatHREC to conduct active research monitoring of the approved proposals especially for those with foreign researchers and of clinical trials at the national level. For example, one respondent said:

"The higher authority like NatHREC, have the mandate to actively oversee health research and other IRBs in the country, thus should be done so." (Respondent. 3)

Another respondent emphasized on the need to conduct active research monitoring despite the different discipline or type of research involved as illustrated below:

"Active monitoring is important for all types of research done on human regardless of the discipline, because when it comes to violation of the ethical principles, anybody can be a victim of violation whether the research is done by a Medical Doctor, Sociologists, or anybody." (Respondent. 9)

4.5.2 Members concern on adequacy of active research monitoring at IRB

Respondents reported that active research monitoring was not adequate i.e. not conducted on regular basis. This was further emphasized to be for both clinical and non-clinical research as expressed by one respondent who said:

"Generally, active research monitoring is not adequate for both clinical and non-clinical trial research; we normally conduct oversight to very few projects. I would like

> *to see that all projects approved within our IRB are monitored critically to identify gaps. The few oversights we conduct are not sufficient enough to say that the role of oversight has been well done."* (Respondent. 2)

Respondents were in the view that active monitoring was not adequate in terms of its frequency but also concerns were raised on the quality at IRBs that conducted active research monitoring. For example, one respondent reported that:

> *"Active research monitoring is not adequate in terms of its frequency. I am not also sure about the quality at other IRBs, but as far as I know the information that I have, we don't do it much of it here in Tanzania."* (Respondent. 1)

However, one respondent reported that active monitoring was somehow adequate at their particular IRB:

> *"... Active monitoring is done at an average level. We make sure that in each quarter the IRB team goes out to do active monitoring and in case there is any alarming alert from passive reports, we always go."* (Respondent. 1)

In the document review guide, all IRBs were found to have electronic versions of their SOPs in place. The SOPs had been established not later than 7 years ago 2010 and one SOPs had just been recently reviewed theirs in 2015. All the IRBs had indicated on their SOPs the need for them to conduct active research monitoring as one of its important activities. However, one IRBs was found to have been conducting active research monitoring with monitoring reports in place.

4.5.3 Members felt less involved in active research monitoring decisions

Other respondents felt that they were less involved in the actual decision-making of when, how and where to conduct active research monitoring after the proposals were reviewed and approved. For instance, one respondent reported that:

> *"I have not been involved in any active research monitoring and I don't know how it operates."* (Respondent. 5)

One respondent explained that active research monitoring activities were discussed and mentioned during meetings as an important need to assess study implementation. However, little efforts were carried out towards its actual implementation. For example, one respondent reported that:

> *"As a committee member and also as a leader of the IRB, I know that even in the committee it has been actively discussed the need to monitor."* (Respondent. 4)

4.5.4 Factors that constrain implementation of active monitoring at IRBs

The members at IRBs felt that various factors constrained their implementation of active research monitoring. Among them, financial resource was perceived to be the major constraint as illustrated by one respondent:

> *"The money we receive compared with the activities is not enough. We not only conduct site visits but also need to run the IRBs and secretariat i.e. to hold meetings, papers and other tools to work with so the money is not enough. That is why instead of doing let's say four (4) visits we do one or two visits."* (Respondent. 1)

Another respondent emphasized on the institutional financial support in running the cost for IRB, which was annually budgeted for:

> *"Money to run the IRB comes from hospital revenue as it is budgeted for. For example, the direct costs for meetings, reimbursement for proposal review and others. However, we haven't budgeted for active monitoring."* (Respondent. 10)

While another respondent believed that money should not be the cause of not doing active monitoring as it was a responsibility for the IRB by saying:

> *"I strongly refuse to use money as an incentive for active monitoring as it is a moral responsibility for IRB members."* (Respondent. 4)

Furthermore, members reported the lack of specific guidelines and tools for active research monitoring as a constraining factor at IRB. For example, one member said:

> *"We do not have guidelines, SOPs and tools on when and how to do it or a checklist, we don't have that."* (Respondent. 6)

In the review of documents, all IRBs were found to have SOPs in place. But only one IRB was conducting active research monitoring with monitoring reports in place and a specific tool in guiding them to conduct active research monitoring.

One respondent was concerned with prioritization on the need to conduct active research monitoring of approved research studies. It was noted that despite the fact that IRB members did not have enough resources, they held the voice as expressed by one respondent below:

> *"...If you only prioritize in reviewing protocols, you end up doing just that. IRB members and secretariat need to push, because they are the ones that hold the position. Members don't hold financial resources but they hold the voice. And if they have a strong voice on something, then definitely it will happen. If they tell the administrators that we are lugging behind and missing a lot of issues on the ground, we need to go for oversight visits."* (Respondent. 9)

Respondents also reported on the lack of availability in members and devotion to their time to conduct active research monitoring as a constraining factor. One respondent said:

> *"I think sometimes members are not available. As secretariat, it is easy to arrange ourselves but… we wish sometimes to go with different members but they don't have time, so sometimes for the members it is also a hindering factor.*
> (Respondent. 3)

Another respondent added:

> *My plate is full; I am not really devoting enough time to this activity. I am very busy and have a lot of work. Now thinking about active monitoring is difficult as I have a lot of interest in research but limited time."* (Respondent. 8)

Some respondents pointed out lack of training for IRB members as a constraining factor towards implementing active research monitoring. One respondent stated:

> **"***I think we have been trained more on the process of ethics but I don't recall haven been trained on active research monitoring. That is an area we lack training in. The SOPs has some information from the national institute, but I would like more training on how we should do it."* (Respondent. 3)

One respondent was particularly concerned with the monitoring of research conducted in remote areas, far from where most IRBs are hosted in Dar es Salaam. One key informant said:

> *"Tanzania is a huge country, IRBs in Dar es Salaam are in the certain. If people are doing research in Rukwa, Katavi, Kigoma or Kagera where most partners are working it is difficult to do active monitoring…"* (Respondent. 8)

4.5.5 Factors have enabled active research monitoring at IRBs

Respondents at the IRBs that conducted active research monitoring mentioned explained the things that enabled them to conduct active monitoring. One respondent acknowledged that their institution management played an important role to support the implementation of active research monitoring as he expressed:

> *"…Financial and administrative support from the organization management is very important. If they do not approve our IRB plans, we cannot go anywhere."* (Respondent. 1)

Another respondent reported that the organization structure enables their IRB to report direct to the Director. This gave the IRB members much power and support in terms of independency and planning for active monitoring activities as stated below:

> *"The IRB secretariat reports directly to the Director. This gives us the independence that the IRB unit more power and credit."* (Respondent. 2)

One respondent felt that it was their obligation as IRB members who review and approve research studies to also conduct active research monitoring and stated that:

> *"We are supposed to do oversight on whatever research is being done because we have provided its clearance.*" (Respondent. 6)

Another respondent was in view that active research monitoring was mostly triggered by alerts raised from passive monitoring reports submitted to the IRB office as well as direct communication from good Samaritans as expressed:

> *"There are some participants who are knowledgeable and call the chairperson to inform them on what researchers are doing in the field. Otherwise Tanzanians are humble, they respect doctors and researchers believing that they are working in their interest."* (Respondent. 6)

Respondents also reported that their tools and SOPs enabled them to plan and conduct research monitoring. As one respondent reported that:

> *"Our SOPs helps to guide us in planning and conducting active monitoring."* (Respondent. 6)

Moreover, in the document review it was found that all four IRBs had well written SOPs established not later than 7 years ago 2010 with one recently reviewed in 2015. All the IRBs had indicated the need for them to conduct active monitoring.

With regard to the use of alterative individuals, one respondent reported that they used Heads of departments to assist in active monitoring. The Head of department would be informed on

research projects after its approval to be conducted at respective departments so as to assist monitoring its conduct. One respondent stated:

> *"We usually empower Head of department to oversee approved research. For e.g. in the labs. if the researchers have been approved to do routine laboratory test, then we make sure that it is only that and they should not order other lab tests not in their research. The Head of department reports back to the IRB."* (Respondent. 10)

The proposal submission fee was seen to be important sources of fund to facilitate IRB activities such as active monitoring. For example, one respondent reported:

> *"The institution financially supports the IRB, but very little thus not able to cover each and everything, therefore we also depend on proposal submission fee for active monitoring."* (Respondent. 2)

4.5.6 Strategies important for active research monitoring at IRBs

Various strategies were reported by the respondents to be important for implementing active research monitoring at IRBs. Training of IRB members on active research monitoring was very important. One respondent stated:

> *"We would like our members to be trained on active research monitoring at least ever after two years. Once you get training you learn new things and you know how to monitor protocols."* (Respondent. 2)

Respondents were of the view that the increase in financial resources was noted as one of the most an important strategy to implement active research monitoring activities. One respondent said:

> *"The institution has to commit itself to fund the activity. Maybe they should apply for funding and find means to sustain the activity. If you depend on fund outside of the country you can get it once, not always."* (Respondent. 3)

Another respondent reported that there was a need to increase the proposal submission fee and said:

> *"…We have been planning to increase the proposal submission fee. But this is an area that we have to agree on. We have not changed our fee since 2005 suggest to increase the amount to 750,000/- for clinical trials and 600$ for extensions and less for non-clinical trials."* (Respondent. 2)

The need to sensitize and strengthen regional and district authorities on the ownership of research and actively monitoring of research conducted at their respective area was reported to be important:

> *"I am not sure if RMO or DMO really own the research which is conducted in their areas. The first thing is to sensitize them to own the research through the RMO's conference held every year. NIMR should sensitize them to ensure that they feel like it is part and parcel of their responsibility."* (Respondent. 8)

Having well established SOPs and guidelines that directed members on how to carry out active research monitoring was seen as an important enabling factor as one respondent said:

> *"We should have a format of what we want to check to get things done in the right way. The researchers, participants as well the country interest should be protected. So, it is a matter of devising a template guideline or checklist of what should be done and at what interval and in case of misconduct, the steps to be taken."* (Respondent 6)

Another respondent emphasized more by saying:

> *"We need the SOPs on monitoring and that SOPs should be followed."* (Respondent 5)

However, the need to subcontract active monitoring activities to well trained and qualified individuals was also seen as a concern for monitoring as illustrated below:

> "I think *you can contract people to do active monitoring. I don't think active monitoring should be a permanent job but anytime you think is right you can announce*

and give terms of reference and well-structured guidelines to qualified individuals." *(*Respondent 6)

Supervision and mentorship in conducting active research monitoring was also perceived as a main concern from the respondents as indicated:

*"NIMR needs to do continuous mentoring of IRBs up to a level that they can do things properly." (*Respondent 8)

Another respondent said:

"NatHREC should oversee the local IRBs and capacitate them in terms of training and see if they are doing their work well. I am not objecting that local IRBs should not conduct oversight, but this role should be done at the national level while the local IRBs be capacitated to review protocols adequately." (Respondent 2)

Respondents were also in view that active research monitoring should be an inner priority that comes from the IRB members themselves. For example, one respondent said:

"There should be a champion organ at the national level say NIMR or another independent organ that frequently evaluates IRBs in Tanzania to ensure that they comply to all ethical standards that are required including active monitoring. Once IRBs know that they are being evaluated, it will motivate them whether they like it or not, have resources or not, they will do active monitoring." (Respondent 9)

CHAPTER FIVE

5.0 DISCUSSION

5.1 Overview

Active monitoring of approved health research was explored at four IRBs in Dar es Salaam. In a situation where IRBs have well established SOPs in place, it was likely to expect that the SOPs would positively influence active research monitoring activities among IRB members. Moreover, as an approving authority obligation to protect human subjects involved in research, IRBs were expected to conduct active monitoring of approved research at local level (NIMR, 2009).

However, the study findings have revealed that, active health research monitoring at IRBs is not done at all or is irregularly done, despite the need and awareness among the IRB members with established SOPs in place. These findings are likely due to the fact that IRB members felt that they were less involved in the decision-making on active monitoring activities and felt that active monitoring was not given much priority compared to the review process. Moreover, active research monitoring required financial resources, training, time devotion, enforcement of existing SOPs with regulate feedback to NatHREC as well as specific guidelines and tools to guide the process.

5.2 Perceived adequacy of active research monitoring

The study finding suggested that perceived adequacy of active health research monitoring among IRB members was seen not to be adequate. The IRB members who reported to conduct active research monitoring at their IRBs, also declared that it was not adequate in both frequency i.e. number of visits per study and its quality i.e. how active research monitoring was being conducted. Members felt that they were less involved in active monitoring activity planning due to the fact that some of them were not affiliated directly to the institution in which the IRB was housed. Some members also believed that much priority had been given to

the proposal review process than active monitoring process despite the fact that the need to conduct active monitoring had at times been discussed during few meetings**.** Nevertheless, inadequacy was not only seen at the IRB level, but members also felt that active monitoring was also not adequate at the national level. A qualitative study that explored quality improvement of human research, points out the importance of using IRB review meetings to discuss active monitoring issues i.e. to discuss, identify studies and plan on when to conduct active monitoring so as to facilitate its implementation (Whicher et al., 2015). The IRBs' own pro-active measures in prioritizing active research monitoring during meetings has also been seen as an important internal motive for IRB members (Ochieng et al., 2013). Likewise, in this study, it suggested that if IRB members could address active monitoring activities in advance, it would help in prioritizing its implementation.

With regards to importance being given to the review process as compared to active monitoring process, similar results where indicated in a study conducted in the US, whereby active health research monitoring was believed to be inadequate. In this study, it was indicated that the review process was time consuming with multiple reviews which created lengthy review process with less effort on active monitoring of the study after it had been approved (Emanuel et al., 2004). However, in another study it was noted that no matter how important the review process might be in approving the research proposal, it could not replace the actual active research monitoring process as this helped to ensure that what had been approved was adhered to during its implementation (Kruger et al., 2014).

5.3 Factors that constrain active research monitoring

Factors found to constrain the implementation of active research monitoring by IRBs were also explored and grouped into three main levels. There include: personal level, the institutional regulation level and financial level.

With regard to the personal level, training of IRB members in conducting active research monitoring of approved research studies was highly insisted which has also been emphasized

in other studies (Nyika et al., 2009; Oakes, 2002; Kruger et al., 2014). Some members were of the view that they were overwhelmed with their main activities (apart from IRB activities) and thus were unable to devote enough time to participate in active monitoring activities especially when it involved traveling. However, it has been noted that having an IRB secretariat with permanently paid staff members was important so as to assist in the day to day activities at the IRB that also included implementation of active research monitoring activities (NIMR, 2009).

As far as institutional regulations were concerned, the need for guidelines and tools for conducting active monitoring was required by several IRB members. Although all IRBs had well written SOPs on guiding how the IRB should run their day to day activities, specific guidelines on the way to conduct active research monitoring of the approved research studies were lacking. Members emphasized on the importance to have clear guideline on how when and which proposals were to be actively monitored. However, there was no form of active reinforcement of the existing SOPs. These findings also relate to a study in Uganda that revealed the nature of having specific guidelines or a model to conduct active monitoring was an important factor in conducting active research monitoring (Ochieng et al., 2013).

Lack of supervision and mentorship from the national level NatHREC, the accrediting authority for local IRBs was noted to be of much concern as some of the IRBs had been established and accredited but with less experience especially on the active research monitoring process. When IRBs are not supervised to assess the quality of the task they have been entrusted to do, has been seen to have implication on the quality of the tasks required (Whicher et al., 2015) in this case active research monitoring of approved research. Moreover, the NatHREC SOPs requires quarterly and annual reports from the local IRBs as a means to monitor activities which are carried on at the IRB level (NIMR, 2009).

Tanzania being a large topical country, it is favorable in conducting health research due to its widely spread health system that reaches even remote areas. However, the fact of Tanzania being a large country was seen as a challenge in the conduct of active monitoring especially

when research was approved in Dar es Salaam where most of the IRBs are situated. This was noted to have raised financial concern in terms of time and travel cost in conducting monitoring at remote area. However, in this study, it revealed that even the studies that were given approvals to be conducted in Dar es Salaam were not actively monitored.

Financial constrain was a major challenge at nearly all the IRBs visited. Money was seen to be important in not only running the IRB meetings and secretariat needs, but also in planning for active research monitoring activities that required travel costs and allowances for members involved. The debate concerning money has been raised at various points where the impact of not being able to conduct active monitoring due to insufficient fund was seen as leading to a greater cost than that of financial means as in the cost of human life or dignity (Saver, 2009).

5.4 Factors that enable active research monitoring

The IRB members' sense of obligation to protect research subjects and as an approving authority was considered as a motivation towards conducting monitoring at the IRB that had reported to have conduct active monitoring. A favourable institutional structure and reporting system that gave the IRB power and independence to plan and implement active monitoring further enhanced active monitoring. However, other studies in the US have shown the independence of an IRB to stand alone to enhance its function and reduce any form of conflict of interest that may arise with host institution (Emanuel E., 2004). This gives IRBs the flexibility to plan for active monitoring activates that guaranteed independency in managing financial resources and activities.

The use of heads of departments and other institution staff to assist in monitoring on-going research at department level was useful in upholding researchers' adherence to approval requirements. Nevertheless, passive monitoring (though also not frequently conducted) through submission of project reports and good Samaritans whistle alerts were seen to have played an important role in identifying studies that required immediate active monitoring. Similar findings have also been found from other studies in line with the importance of

passive monitoring reports which assist in taking action for further active monitoring activities (Saver 2009; Kruger et al., 2014). Therefore, the sensitization of IRB to perform passive monitoring has been seen as an enabling factor for active monitoring implementation.

5.5 Strategies to address challenges in active research monitoring

Interviews with the different IRB members further highlighted a number of strategies and need for enforcement of existing regulations thought to be important in address some of the challenges considered to hinder active research monitoring. For the purpose of clarity, these strategies have been grouped into two main levels, strategies to be considered at the institution level and by the national level.

At the institution level, the existence of a proactive nature in prioritizing active research monitoring activities during review meetings was seen as a way to assist in planning from active research monitoring and identify who and when it was to be conducted. It is believed that members hold a strong voice to advocate for the need of active research monitoring and thus need to use this voice. A need to raise money was also noted such as increasing proposal submission fee that could help to cover for some of the monitoring expenses. Strategies of alike such as having a proactive initiative from the IRB members themselves have also been considered in other literature where an IRB proactively constructed a monitoring model or tool in Uganda (Ochieng et al., 2013), increasing submission fee and budget allocation to monitoring activities in Canada (Weijer, 2001), as well as using review meetings to plan for active monitoring activities (Whicher et al., 2015).

With regards to the national level, members were concerned with reinforcement of existing regulation, SOPs and guidelines that exist at national and institution level and assist in development of specific guidelines for conducting active research monitoring with supervision and mentorship either from NatHREC or other reliable national or international institution so as to strengthen IRB capacity by providing regular on job training for IRB members. Likewise, members were of the view of subcontracting qualified individuals (apart from IRB

members) to conduct active monitoring due to their limited time to travel and oversee studies conducted at remote areas. Individuals like the regional and district authorities as well as heads of departments were also valued to be useful to sensitize them on the ethical issues required in health research so as to ensure that the researchers implement research ethically at respective study areas.

CHAPTER SIX

6.0 STUDY LIMITATIONS AND MITIGATION

Findings from this study do not go without limitations as illustrated below:

This study focused on exploring active health research monitoring in Tanzania with perspectives from members of five institutional review boards. Out of the five, only four IRBs were involved in the interviews. However, the researcher tried to set several appointments at the fifth IRB through telephone calls, emails and even physical visits without success. Therefore, findings presented represent only four IRBs that agreed to participate in the study interview.

Interviews were conducted with participants at their respective offices where the participant were affiliated. This may have influenced their responses especially at the IRB office. However, this was minimized by conducting the interviews in a privacy room and reassuring the participants of confidential to be taking into consideration their responses as positive so that participants felt free to respond.

Despite the fact that participants were very busy and not available for interviews, rescheduling of for convenient appointments and adjusting to participants' schedules were made that required several visits to the IRB offices. In cases where the participants were not available, efforts were made to select other members from the IRB who could respond to the interview questions.

Moreover, the researcher had to wait several months for ethical approval from MUHAS IRB, due to bureaucratic procedures in getting ethical clearance. This restricted the researchers' time for fieldwork and thus had to begin interviews after addressing the minor comments from the committee for proper time management.

6.1 Conclusion

The study explored active research monitoring of approved health research with perspectives from members of IRBs in Tanzania. The study findings have revealed that active research monitoring at the IRB level as well as NatHREC level were perceived to be inadequate. This was due to various factors which included: lack of finances to conduct monitoring, lack of training among IRB members, lack devoted time from monitoring due to overwhelmed activities, lack of full time secretariat staff, lack of specific guidelines and tools for monitoring as well as the lack of regular supervision and mentorship.

However, strategies considered to be important in addressing these challenges included; to reinforce existing SOPs and guidelines from the national level that address active monitoring, to have a pro-active spirit of IRBs in prioritizing need for active monitoring during review meetings, consider IRB specific means in raising money to support active monitoring e.g. through submission fee. To strengthen IRB capacity through training members for supervision and mentorship and assist IRBs in developing specific active monitoring SOPs and guidelines, that may also be used to subcontract qualified individuals i.e. regional authority, district authorities as well as heads of departments to conduct monitoring of research studies.

6.2 Recommendations

Active research monitoring of approved health research at IRBs is perceived to be inadequate among members. This study provides findings on factors that constrain and enable active monitoring implementation and possible strategies to address the challenges from IRB members. From the findings, it is recommended that the following points be taken into consideration at two main levels i.e. institutional level and at the national level.

Specifically, the following have been recommended:

6.2.1 Institution level

- The IRBs need to be pro-active in how they prioritize studies to be actively monitored at institutional level. The efforts should be considered since submission of the proposals and discussed during the IRB meetings so as to also plan for the studies to be actively monitored.

- The IRBs members need to consider finding means (suitable for specific IRB) to raise financial means to support active monitoring activities e.g. by charging submission fees which a certain percentage may be used for active monitoring activities.

6.2.2 National level

- The NatHREC should enhance its regulatory function to oversee IRBs.
- The NatHREC should strengthen IRB capacity in conducting active research monitoring through training.
- The NatHREC is required to assist and guide the development of specific SOPs, guidelines and tools for active health research monitoring for IRBs.
- Regional authorities, district authorities and heads of departments may be empowered and subcontracted to assist in AHRM of approved research at respective areas.
- A research on passive health research monitoring needs to be conducted as this is an important factor that enables or hinders implementation of AHRM activities.

Existing SOPs and guidelines need to be reviewed, advocated and reinforced to enable active monitoring implementation at IRB and the national levels.

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ATTACHMENTS

APPENDIX 1 : IN-DEPTH INTERVIEW GUIDE FOR KEY INFORMANT

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
DIRECTORATE OF RESEARCH AND PUBLICATIONS

Title: "Active health research monitoring in Tanzania: perspectives from members of the Institutional review boards."

ID-No: …… **Date: ……/……/ 2017**

Name of Interviewer : …...……..……...……

Start : ……..…….. End : …….……

Part I: Introduction

Thank you very much for agreeing to participate in this interview. My name is **Sia E Malekia,** a postgraduate student from MUHAS undertaking Masters in Bioethics.

The purpose of this research is to explore active health research monitoring in Tanzania with experiences from members of the Institutional review boards. You have been selected among other in your IRB as key informant to share your experience on this issue. All responses are accepted and thus there is no right or wrong answer, so kindly feel free to talk. The research findings will be used to understand the challenges that hinder and enable active health research monitoring of approved health research at IRBs. Your shared experience and recommendations are important and thus could be used by the NatHREC to address the challenges to better ensure the safety of research participants.

I would like to remind you that our interview will be recorded for easy analysis after and that it will take approximately one hour.

Part II: Demographic

If you don't mind, may you kindly tell me the following, your:

i. Age …….....
ii. Sex …….....
iii. Education level ……
iv. Ethics training …….
v. Work position (Institution) ……..
vi. Position at the IRB ……..**...**
vii. Length with IRB (years)……..…

Part III: Perceived adequacy on active research monitoring activities at your IRB

1. Based on your position at this IRB, may you kindly tell me about the IRB? (**Probe:** establishment, structure, composition, meetings, funding).
2. Would you kindly explain the general functions of your IRB? (**Probe**: From proposal received to completion of study i.e. submission, ethical review, approval, monitoring (non-clinical/clinical trial research), frequency, other activities).
3. Basing on your experience, what is your opinion on the adequacy of active research monitoring activities conducted by IRBs in Tanzania? (**Probe**: is it done? Non-clinical and Clinical trial research on active and passive monitoring).
4. Specifically, what is your opinion on the adequacy of active research monitoring activities at your IRB (last one year)? (**Probe**: is it being done? Non-clinical and Clinical trial research, how often).

Part IV Enabling factors for active health research monitoring by IRBs.

(***If respondent has mentioned any active-monitoring, ask the following questions***)

5. In your opinion, what was the motive for your IRB to conduct active health research monitoring?
   (**Probe**: IRB plan, SOPs, alerts from passive monitoring reports, demand from IRB

members, request from study collaborators or other reasons).

6. Specifically, what factors enabled your IRB to conduct active health research monitoring? (**Probe**: Institutional structures, team, tools, funds - where from etc).

Part V: Constraining factors for active health research monitoring by IRBs.

(***If respondent mentioned any gap in active-monitoring, ask the following questions***)

7. In General, what is your opinion on the challenges that face IRBs in conduct active health research monitoring in Tanzania?
8. Specifically, what is your opinion on the challenges that face your IRB with regard to active health research monitoring of approved researches?

   (**Probe**: IRB plans, SOPs/guidelines, unavailability of competent members, unavailability of tools, lack of funds etc).

Part VI: Strategies to address active research monitoring of health research at IRBs.

9. What is your opinion on how best to address challenges on active health research monitoring in Tanzania? (**Probe**: At IRBs in general, specifically at your IRB).

Part VII: Ending

10. Do you have any other question/opinion on active health research monitoring that you think we have not discussed but you would like to share with me?

THIS IS THE END OF OUR INTERVIEW

THANK YOU VERY MUCH FOR YOUR COOPERATION

APPENDIX 2 : FOMU HOJAJI

CHUO KIKUU CHA AFYA NA SAYANSI YA TIBA MUHIMBILI

KURUGENZI YA UTAFITI NA UCHAPISHAJI

Kichwa cha habari: "Ufuatiliaji wa rasimu za afya Tanzania: maoni ya wanakamati wa kamati za kimaadili za Taasisi."

ID-No: ……

Jina la Mhoji : …..……..……..……....……

Mwanzo : ……..…….. Mwisho : …….……

Sehemu ya I

Asante sana kwa kukubali kushiriki katika majadiliano haya. Naitwa **Sia E Malekia**, ni mwanafunzi wa Shahada ya Uzamili ya Sayanis ya Tiba Muhimbili. Nafanya utafiti kuhusiana na **Ufuatiliaji wa rasimu za afya Tanzania: maoni ya wanakamati wa kamati za kimaadili za Taasisi.**

Dhumuni la utafiti huu ni kujaribu kuchunguza juu ya Ufuatiliaji wa rasimu za afya Tanzania: uzoefu wa wanakamati wa kamati za kimaadili za Taasisi. Umechaguliwa kati ya wajumbe wengine katika kamati hii ili kuelezea uzoefu wako juu ya jambo hili. Majibu yoyote yatakubalika kwa hiyo hakuna jibu lisilokuwa sahihi, kwa hiyo tafadhali kuwa huru kuzungumza. Matokeo ya utafiti huu yanaweza tumika katika kuelewa changamoto zinazozuia au kuwezesha ufuatiliaji wa rasimu za afya katkia kamati za kimaadili za Taasisi IRBs. Maelezo yako ujuzi na maoni ni muhimu sana na huweza tumika na NatHREC katika kuboresha changamoto katika ufuatiliaji wa rasimu za afya ili kuhakikisha washiriki wa tafiti za afya wanakuwa salama.

Napenda nikukumbushe kuwa majadiliano yetu yata rekodiwa kwa ajili ya urahisi wa kuyadadavua baadae. Pia mazungumzo yetu yatachukua muda takriban wa dakika 45.

Sehemu ya II: Taarifa za awali

Kama hutojani, naomba tafadhali nieleze juu ya:

i. Umri ……..……
ii. Jinsia …….
iii. Elimu …….
iv. Mafunzo ya maadili ...……
v. Nafasi yako ya kazi (Cheo) ……
vi. Nafasi katika IRB ……...…….……
vii. Muda katika IRB (Miaka) ……

Sehemu ya III: Maoni juu ya utoshelevu wa ufuatiliaji wa rasimu za afya katika kamati za kimaadili katika taarifa (IRBs):

1. Kutokana na nafasi yako katika IRB, unaweza nielezee juu ya IRB hii?
   (**Uliza zaidi juu ya:** ilipo anzishwa, mchanganyiko, mikutano, ufadhili).
2. Unaweza tafadhali eleza juu ya kazi kwa ujumla katika hii IRB?
   (**Uliza Zaidi juu ya:** kuanzia kupokea rasimu hadi tafifti i.e. kupokea, kupitia, kupitisha kufuatilia (non-clinical/clinical) mara ngapi, mengineo).
3. Kutokana na ujuzi wako, nini maoni yako juu ya utoshelevu wa ufuatiliaji wa rasimu za afya katika kamati za kimaadili katika Taarifa (IRBs)?
   (**Uliza Zaidi juu ya:** (non-clinical/clinical research).
4. Mahususi, nini maoni yako juu ya utoshelevu wa ufuatiliaji wa rasimu za afya katika kamati yenu hii (kwa muda wa miaka moja ulioisha)?
   (**Uliza Zaidi juu ya:** (non-clinical/clinical research).

Sehemu ya IV: Mambo yanayowezesha ufuatiliaji wa rasimu za afya katika kamati za kimaadili katika Taasisi (IRBs):

(Kama ametaja jambo wanalofanya juu ya ufuatiliaji wa rasimu za afya, uliza yafuatayo)

5. Kwa maoni yako, kwanini Taasisi yako IRB ilifanya ufuatiliaji wa rasimu za afya?
   (Uliza Zaidi juu ya: Mipango ya IRB, SOPs/miongozo, hisisa katika ufuatiliaji wa

barua/repoti, kulazimishwa kwa kamati, ombi toka kwa watafiti shirikisho wa utafiti na mengineo).

6. Mahususi, ni mambo gani yaliyo wawezesha Taasisi yenu IRB kufanya ufuatiliaji wa rasimu za afya zinazopewa kibali? (**Uliza Zaidi juu ya:** Taasisi, watu, tools/vifaa, ufadhili/pesa nk).

Sehemu ya V: Mambo yanayozuia katika ufuatiliaji wa rasimu za afya katika kamati za kimaadili katika taasisi?

(Kama ametaja upungufu wowote juu ya ufuatiliaji wa rasimu za afya, uliza yafuatayo)

7. Je kwa ujumla, nini maoni yako juu ya changamoto zinazo kabili kamati za maadili za taasisi IRB Tanzania?
8. Mahususi, nini maoni yako juu ya changamoto zinazo kabili kamati yenu ya maadili ya taasisi IRB kwa kuzingatia ufuatiliaji wa rasimu za afya zinazopitishwa? (**Uliza Zaidi juu ya:** Mipango ya taasisi, SOPs/miongozo, upatikanaji wa watu, vifaa, fedha, nk.).

Sehemu ya VI: Mikakati ya kuimarisha ufuatiliaji wa rasimu za afya katika IRBs.

9. Je, nini maoni yako juu ya namna ya kuboresha changamoto katika ufuatiliaji wa rasimu za afya Tanzania? (**Uliza Zaidi juu ya**: Ujumla, katika Taasisi yako).

Sehemu ya VII: Mwisho

10. Je, kuna jambo lolote unaloona ni muhimu unieleze juu ya mahojiano yetu ambaya hatujaongelea?

TUMEFIKIA MWISHO WA MAHOJIANO YETU

ASANTE SANA KWA USHIRIKIANO WAKO

APPENDIX 3 : DOCUMENTARY REVIEW GUIDE

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

Title: "Active health research monitoring in Tanzania: perspectives from members of the Institutional review boards"

ID-No…… **Date……/……/ 2017**

Name of site (IRB) : …….……

Type of IRB: …… Year established: ……..……...

Table 1. IRB monitoring activities within the period of Jan. – Dec. 2016

NO.	ACTIVITY (JAN-DEC. 2016)	NON-CLINICAL TRIAL RESEARCH	CLINICAL TRIAL RESEARCH
1.	No. of researches submissions		
2.	No. of approvals granted		
3.	No. of active research monitoring conducted		
4.	No. of active research monitoring reports		

Table 2. Document in place for active research monitoring at IRBs

No.	Documents	In place (Hard/Electronic)	When established	Does it include active-monitoring (Yes / No)
1	SOPs			
2	Monitoring Tools			

APPENDIX 4: INFORMED CONSENT FORM

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

ID-No……..

Introduction: Greetings!

My name is **Sia Malekia,** a postgraduate student from Muhimbili University of Health and Allied Sciences. I am conducting a research study on: **"Active health research monitoring in Tanzania: perspectives from members of the Institutional review boards"** I am inviting you to participate in this important study, however before you decide to, I would like to go through this informed consent form with you in case you need clarification.

Purpose of the study: The purpose of this study is to explore on active health research monitoring with experiences from members of the Institutional review boards in Tanzania.

What participation involves: If you agree to participate in the study, you will be required to participate in an oral interview that may take 45 minutes to an hour. The interview will be recorded with your permission to ensure that we do not miss your point and for the purpose of easier data analysis later. You will also be requested to sign this consent form if you agree to participate and interview to be recorded.

Participant selection: You have been selected among many other IRB members in this IRB as a key informant to share your experience and insight concerning active health research monitoring of approved research proposals at IRBs.

Risks: We do not expect any harm to happen to you because of your participation in this study.

Benefits: The information you provide will put give a better understanding of active health research monitoring of the approved proposals at IRBs and help in making recommendations that may assist to designing strategies towards addressing these issues.

Confidentiality: The information you provide will be kept confidentiality. Only the researcher will have access to the information. All information collected in the in-depth interviews and document reviews will be entered in the computer with only the study identification code.

Right to withdraw: Taking part in this study is entirely voluntary. So, you are free to choose whether to participate or not. You may change your mind later and stop to participate even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty.

Reimbursement: You will not be provided with any compensation to take part in this study.

Who to Contact: In case of any question latter about this study, you can contact the Principle investigator Ms. Sia E. Malekia, of Muhimbili University of Health and Allied Sciences, P.O. Box 65001, Dar es Salaam, Tel. No. 0754 499 293. If you ever have questions about your rights as a participant, you may contact Dr. Joyce Masalu, Chairperson of the Senate Research and Publications Committee, P.O. Box 65001 Dar es Salaam. Telephone 2152489, Dar es Salaam.

This is to confirm that, I have read and understood the contents in this consent form. I therefore agree/disagree to participate in this study.

Circle correct response. 1. YES. 2. NO.

Signature of interviewee …… Date ……..

Signature of interviewer ……. Date ……..

APPENDEX 5: FOMU YA RIDHAA

CHUO KIKUU CHA AFYA NA SAYANSI YA TIBA MUHIMBILI

KURUGENZI YA UTAFITI NA UCHAPISHAJI

Namba ya utambulishi ID: .....

Utangulizi

Salamu! Naitwa **Sia E. Malekia** ni mwanafunzi wa Shahada ya Uzamili ya Sayansi ya maadili ya kibailogia katika Chuo Kikuu cha Afya na Sayansi ya Tiba Muhimbili. Nakualika katika utafiti muhimu juu ya: **Ufuatiliaji wa rasimu za afya Tanzania: maoni ya wanakamati wa kamati za kimaadili za Taasisi.** Nakukaribisha kushiriki katika utafiti huu muhimu lakini kabla ya kuamua, ningependa upitie hii fomu ya ridhaa pamoja nami endapo kama utakuwa unahitaji ufafanuzi zaidi.

Madhumuni ya utafiti: Lengo la utafiti huu ni kuchunguza juu ya ufuatiliaji wa rasimu za afya na uzoefu wa wanakamati wa kamati za kimaadili za Taasisi Tanzania.

Ushiriki: Ukikubali kushiriki katika utafiti huu, utatakiwa kushirikiki katika mahojiano ambayo yatachukua takriban saa moja. Kwa ridhaa yako mahojiano haya yatarekodiwa ili kuniwezesha nisisahau mapendekezo yako wakati wa kuandika hapo baadae. Utaombwa pia kuweka sahihi yako katika form hii ya ridhaa.

Uteuzi wa washiriki: Unaombwa kushiriki katika utafiti huu miongoni mwa wanakamati wa kamati hii ya maadili katika taasisi ili uweze kutupa uzoefu wako juu ya mambo yanayozuia ufuatiliaji wa rasimu za afya baada ya kupewa kibali.

Hatari: Hatutarajii madhara yoyote kutokea kwa sababu ya ushiriki wako katika utafiti huu.

Faida: Taarifa utakazo tupa zitatuweka katika kuelewa nafasi nzuri zaidi ya kuelewa mambo yanayo zuia ufuatiliaji wa tafiti baada ya kupata kibali katika kamati ya maadili ya taasisi IRB na zinaweza kuwa msaada katika kutoa mapendekezo yanayoweza saidia katila kubuni mikakati ya kushughulikia masuala haya.

Usiri: Taarifa utakazo toa zitawekwa siri kati yako na mtafiti. Taarifa zote zilizokusanywa katika mahojiano ya kina na maoni yataingizwa kwenye kompyuta na namba tu ya utafiti na sio jina.

Haki ya kutoka: Kushiriki katika utafiti huu ni hiari kabisa. Kwa hiyo upo huru kuamua kushiriki au kutoshiriki. Unaweza badili mawazo yako na kuacha kushiriki katika utafiti wakati wowote, hata kama ni baada ya kutoa ridhaa yako. Kujiondoa kutoka utafiti huu haitohusisha adhabu ya aina yoyote.

Malipo: Hakutokuwa na malipo ya aina yoyote katika kushiriki kwao kwenye utafiti huu.

Nani wa kuwasiliana: Kama una swali lolote kuhusu utafiti huu, unaweza kuwasiliana na mtafiti mkuu wa utafiti huu Bi Sia E. Malekia ya Chuo Kikuu cha Afya na sayansi ya Tiba Muhimbili, S.LP. 65001, Dar es Salaam simu 0754 499 293. Kama una maswali kuhusiana na haki zako kama mshiriki, unaweza kumpigia Dkt. Joyce Masalu, Mwenyekiti wa Kurugenzi ya Utafiti na Uchapishaji, S.L.P. 65001 Dar es Salaam. Simu 2152489, Dar es Salaam, Tanzania.

Hii ni kuwajulisha kuwa nimesoma fomu hii ya ridhaa na kuielewa. Kwa hiyo nimekubali/kutokubali kushiriki katika utafiti huu.

Unakubali? Zungushia majibu sahihi. 1. NDIYO. 2. HAPANA

Sahihi ya Mhojiwa …..... Tarehe .....
Sahihi ya anaye hoji ..... Tarehe ……..

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

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Ref. No. MU/ PGS/SAEC/Vol.X/

7th August, 2017

Dr. Sia Ellison Malekia
MSc. Bioethics
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RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: ACTIVE HEALTH RESEARCH MONITORING IN TANZANIA: PERSPECTIVES FROM MEMBERS OF THE INSTITUTIONAL REVIEW BOARDS

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 4th August, 2017 to 3rd August, 2018. In case you do not complete data analysis and dissertation report writing by 3rd August, 2018, you will have to apply for renewal of ethical clearance prior to the expiry date.

Prof. Andrea B. Pembe
DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Public Health and Social Sciences