THE EXPERIENCES OF MTRH RESEARCHERS IN APPLICATION OF THE PRINCIPLE OF JUSTICE IN HIV RESEARCH AT AMPATH - ELDORET

BY JOHNSTONE MILIMO EYINDA

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DECLARATION

Declaration by the candidate

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Johnstone Milimo Eyinda SM/PGIRE/01/14

Signature…………… Date:…………………….

Declaration by Supervisors

This thesis has been submitted for marking with our approval as University Supervisors.

Name of Supervisor: Prof. Violet Naanyu

Signature:………………….. Date:…………….

College of Health Sciences, School of Medicine.

Moi University, Eldoret, Kenya

Name of Supervisor: Prof. Eunice Kamaara

Signature:………………….. Date:……………

School of Arts and Social Sciences

Moi University, Eldoret, Kenya

DEDICATION

I wish to dedicate this work to all researchers and IREC members who offered the information that made this study a reality.

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ABSTRACT

Background- The impact of HIV in Sub- Sahara Africa in low income countries like Kenya has led to increased research activities. During research activities there is need to apply ethical principle of justice where justice is about doing what is morally right and proper treatment of persons. But it is not always easy to maintain justice in research especially in poor resource setting.

Objectives – The study objectives were i) to analyze the Institution Research and Ethics Committee (IREC) guidelines for application of the principles of justice, ii) examine the factors that MTRH researchers consider in application of the principle of justice, iii) explore the challenges encountered by MTRH health researchers at AMPATH in application of justice in HIV research.

Method- This was a cross sectional exploratory qualitative study design. 16 researchers from MTRH working at AMPATH and 5 members of IREC in Eldoret Kenya were purposively selected and participated in in-depth interviews between June and August 2016. They were drawn from both medical and non-medical affiliations. They were both male and female median age of 45 years. Unstructured interview guides formulated on different themes focusing on justice for HIV patients were used. Transcription of verbatim data was done, similar ideas identified and coded. Similar coded data were grouped into categories and various themes emerged. Analysis was done manually. The findings were presented as summaries including selected quotes.

Results –IREC guidelines were clearly documented and available in both soft and hard copy. The researchers considered IREC requirements for approving research proposal, how to engage participants in ethical research process and the knowledge of community members about ethical research process. It was perceived by the researchers that IREC hindered their progress in ethical research process for it took a long time to get their proposal approved. The researchers had a problem with poverty level within the community which is closely associated with illiteracy and culture of handouts. **Conclusion –** Researchers are knowledgeable about the principle of justice in ethical research process. However they may fail to apply the principle of justice in HIV research due to challenges associated with low income in the communities, researchers' attitudes and lack of practical skills.

Recommendations- There is need to trained researchers on the skills of carrying out ethical research in specific contexts and sensitizes them on the role of IREC as a facilitator of ethical research.

LIST OF ABBREVIATIONS AND ACRONYMS

AMPATH	Academic Model Providing Access to Health Care
ARCs	Advisory Research Committees
CHS	College of Health Science
CIOMS	Council of International Organizations of Medical Sciences
ERCs	Ethics Research Committees
ESI	Ethical and Social Issues
HIV/AIDS	Human Imuno-Deficiency Virus/ Acquired Immunodeficiency Syndrome
IREC	Institution Research and Ethics Committee
IU	Moi AREP- Indiana University, Moi University Academic Research Ethics Partnership
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
MOU	Memoranda of Understanding
MTRH	Moi Teaching and Referral Hospital
NACC	National Aids Control Council
NACOSTI	National Commission of Science, Technology and Innovation
NASCOP	Kenya National AIDS & STI Control Program me
NCST	National Council for Science and Technology
REC	Research Ethical Committee
SOM	School of Medicine
SOP	Standard Operating Procedure
UK	United Kingdom
UNAIDS	United Nations programme on HIV/AIDS

USA	United States of America
WHO	World Health Organization

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

DEFINITIONS KEY TERMS

IREC members: IREC members could refer to the Secretariat, or to committee members or to reviewers from Moi Teaching and Referral Hospital and College of Health Sciences.

Research ethics: Structures of carrying out research that helps to analyze the ethical issues that arise when people are involved as participants in research with broad objective of protecting the human participant. Research ethics seek to ensure that research is conducted in a way that serve the interest of the individual, group or/and society as whole. Research ethics looks into the soundness of research- management of risks, protection of confidentiality and process of informed consent among others.

Justice: Justice is the third primary ethical principle of ethical research involving human beings. This could be described as the moral obligation which ensures equitable distribution of risks and benefits among those who participate in research. In the context of this study application of justice will imply that participants are given adequate information about the research and what is expected of them in the research process, criteria for selection for participants should be clear in teams of information and practice, should there be any form of benefits from research the participants should benefit first, the participants should be informed on what to expect at the end of the study and the community should benefit from the improved infrastructure of health care from benefits of research. It is linked to fairness, entitlement and equality in a research process where each party is accorded what is due to it.

Research Ethics Committees – It is an authoritative body with members from diverse backgrounds created to review all research projects that involve human participants to advice on whether the research is ethical or not.

MTRH researchers - These are individuals who are employed by Moi University or MTRH carrying out research activities at AMPATH and providing health services to patients at both MTRH and AMPATH.

CHAPTER ONE

1.0 Background information

Respect for person, beneficence and justice are the basic principles that form the foundation of all regulations or guidelines governing ethics of carrying out research with human participants (Family Health International, 2007). The principle of justice is about ensuring reasonable, non-exploitative and carefully considered procedures and their fair administration, fair distribution of the costs and benefits among persons and groups (Rice, 2008). Those who bear the risk of research should be among those who benefit from it. Justice requires that people are treated fairly and that research is designed so that its burdens and benefits are shared equitably (Manuel, Andre, Thomas and Meyer, 2014). Justice for research participants can be achieved when both the researcher and the researched understand the context of engagement, (Weijer, Dickens, and Meslin, 2003). The researcher has to ensure from the beginning of research process that there are appropriate structures to achieve justice for participants, (Pogge, 2003). Moi University College of Health Sciences and Moi Teaching and Referral Hospital, Institutional Research and Ethic Committee (IREC) approve research proposals from AMPATH ensuring that the proposals meet the required ethical research standards.

The Human Immunodeficiency Virus (HIV) has been a big challenge to provision of health services all over the world for over 30 years. By the end of 2013 there were 35 million people living with HIV globally and only 11.7 million people in low and middle income countries had access to antiretroviral therapy (WHO, 2014). In Sub-Saharan Africa in 2012, roughly 25 million people were living with HIV, accounting for nearly 70 percent of the global total. The epidemic has had widespread social and economic consequences, not only in the health sector but also in education, industry and the wider economy.

HIV prevalence in East Africa is generally moderate to high and second behind southern Africa (UNAIDS 2013). Kenya has seen its HIV prevalence drop from a high of 14% to nearly 6%. Uganda and Tanzania have prevalence of over 5%, (UNODC HIV and AIDS East Africa, 2014). In the mid- 1990s the prevalence in Kenya was high however it started coming down due to introduction of antiretroviral treatment (UNGASS, 2014). By the year 2012 about 1.6 million people had been infected with HIV and roughly 57,000 people died from HIV related illness (UNAIDS 2013).

Moi Teaching and Referral Hospital (MTRH) in Eldoret is the second national referral hospital in Kenya after Kenyatta National Hospital. It serves North Rift, Western and Nyanza regions, parts of Eastern Uganda and Southern Sudan, a region with a population of over 5 million. The Academic Model Providing Access to Healthcare (AMPATH) was initiated in 2001, initially as a response to HIV/ AIDS only with private philanthropic support to provide care for HIV/AIDS patients. AMPATH brings together Moi University, Indiana University and 16 North America universities whose mission directed program is focused on service, education and research (Einterz, Kimaiyo and Mengech *et al*, 2007). Representing the unique attributes of academic institutions AMPATH structured its patient care programmes to simultaneously serve as a virtual laboratory for HIV- related health events, teaching and research. AMPATH has enrolled 158,000 HIV infected adults and children in its satellite clinics in Western Kenya (AMPATH, 2014). MTRH as many other health institutions and researchers have of recent past increased their research activities involving HIV patients. At Moi Teaching and Referral Hospital most of the HIV research activities are carried out at AMPATH in partnership with the US Agency for International Development – Academic Model Providing Access to Healthcare (USAID - AMPATH). At AMPATH more than 450 research publications have been published on HIV research which implies that more than 450 research studies have been carried out. The increased research activities may be a window for exploitation of HIV research participants if the activities are not well regulated.

1.2 Problem statement

Belmont report, (Rice, 2008) outlines respect for a person, beneficent and justice to be the primary ethical principles in human research. Justice mandates equitable distribution of risks and benefits among those who may benefit from research, (Rice, 2008). Rice et al 2008 further points out that risk and rewards should be applicable and available to all community members. Informed consent process for participants, fair or just distribution of risks and benefits to eligible participants should be considered (Pech et al, 2007). Lack of justice could be caused by various factors and this may imply exploitation for research participants.

Justices is part of the guidelines that have been put in place by various organizations to protect research participants. However the guidelines lack the practical aspect of applying the principle of justice in specific context like the research activities in resource limited area and research activities for epidemic like HIV. Most of the populations in the western part of Kenya live with a lot of resource limitations for it lacks sound economic infrastructure. Poverty, limited health care services, illiteracy, cultural and linguistic differences and limited understanding of the nature of scientific research increases the possibility of exploitation (Wilmshurst 1997, Weijer and Anderson 2001, Wertheimer, 1999 and Benatar, 2000).

At AMPATH most research activities are through collaborations and sponsorship from developed countries supported by international organizations whose agenda could be economic, (Benatar, 2007). This creates a great risk of exploitation for individuals or communities for economically disadvantaged persons are at risk of coercion and undue influence (Benatar, 2000). Inadequate resources can diminish independent ethics review of protocols and ability of researchers to maintain ethical experimental interventions during and after completion of studies.

More information is needed on how the researchers from resource-poor environments go about applying justice to research participants and therefore the interest of exploring the experiences of MTRH researchers. AMPATH clinic at MTRH is the largest amongst the clinics ran by this organization with a high ethnic and geographical diversity of HIV patients with big infrastructure of research within Western region of Kenya making it ideal for this study.

1.3 Objectives

1.3.1 General objective

To examine the researchers’ experiences in applying the principle of justice in HIV research at AMPATH - Moi Teaching and Referral Hospital

1.3.2 Specific objectives

1) To analyse the IREC guidelines for application of the principle of justice to research participants in health research.
2) To examine the factors considered by MTRH researchers in applying the principle of justice in HIV research at AMPATH
3) To explore the challenges encountered by MTRH health researchers in applying the principle of justice in the research process at AMPATH

1.4. Research questions

1) How do IREC guidelines facilitate the application of the principle of justice in a research process?

2) What should be put into consideration by the researchers in order to fulfill application of the principle of justice in HIV research at AMPATH?

3) What are the barriers encountered by MTRH researchers in applying of the principle of justice to HIV research participants?

1.5 Significance and justification of the study

Justice is ensuring non exploitative and carefully considered procedures and their fair administration- fair distribution of risks and benefits among persons and groups ensuring that those who bear the risk of research are among those who benefit from it (Kamaara and Njoroge, 2012). This study will help in understanding how researchers interact with guideline of ethical research process to fulfill the principle of justice. The researchers understanding of the principle of justice and therefore being able to apply justice in HIV research at AMPATH may be established. The challenges encountered by researchers in HIV research may be highlighted and solutions looked for to better research activities at AMPATH. This study may help the community participating in HIV research at AMPATH to be more cooperative in participating for it is ethical and helps in improving the care for HIV patients. Exploring the experiences of researchers may therefore help in grounding structures for application of justice to research participants in Kenya and other resource limited countries and minimizing exploitation of research participants.

1.6 Conclusion

This chapter has provided the problem statement for this study, objectives and research questions derived from the problem of the study and significance of this study. The next chapter presents a review of literature related to this study, how they contribute to this study and the gaps that we have in available literature.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Research process involving human beings ought to fulfill all the research ethical principles including justice. Application of justice to research participants is one of the key fundamental obligations for researchers in a research process. This part of the study discusses research guidelines both local and international, the ethical research process and the challenges of the researchers in fulfilling attainment of justice to HIV research participants.

2.2. The guidelines of the principles of ethics in health research

Throughout the world, independent Research Ethical Committees (RECs) have been established to provide oversight and approval for proposals to conduct health research. Reviews of scientific protocols may be conducted by committees or boards established by local institutions or constituted at the regional, national or, in some cases, international level. The primary aim of RECs is to ensure the protection of human participants by safeguarding their rights. RECs ensures that the risks associated with participation in a study does not endanger the safety of individuals and are reasonable in relation to the anticipated benefits, (WHO, 2000; CIOMS, 2002; Nuffield Council on Bioethics, 2002). RECs are responsible for addressing the primary ethical principles outlined in the Belmont’s report on the review of research involving human participants. This involves regulating application of the principles of respect for persons, beneficences nonmaleficences and justice (Rice, 2008). This includes ensuring; scientific integrity, a sound research design; consideration of risks/benefits; equality in treatment of subjects; monitoring of data collection; informed consent; documentation of informed consent; protection of privacy and confidentiality; and a statement indicating that participation in the research is voluntary and that withdrawing from the study will not result in harm or penalty

(United States Department of Health and Human Services Office for Protection from Research Risks [OHRP], 1991; Medical Research Council UK, 1998, Indian Council of Medical Research, 2000; WHO, 2000; CIOMS, 2002; Nuffield Council on Bioethics, 2002). Justice can only be achieved through appropriate application of guidelines by the researchers to research participants**.**

International ethical research guidelines

The Nuremberg trials following World War II marked an important turning point in public and professional attention to ethical issues associated with human experimentation (Katz, 1972; Annas & Grodin, 1992). These proceedings considered medical experiments conducted by the Nazi doctors on concentration camp prisoners and resulted in the Nuremberg Code (1949) for ethical conduct in scientific research. The World Medical Association's (1964) Declaration of Helsinki reiterated the Nuremberg Code's emphasis on voluntary and informed consent to research as well as other factors important to ethical conduct in scientific investigations involving communities and individuals. The Declaration of Helsinki, revised most recently in October 2013 in Fortaleza, Brazil by WMA, is universally recognized as a foundational guideline for ethical behavior in scientific research.

Research guidelines are important and can only provide ethical road map for accomplishing ethical research process if practically well followed. In the United States of America in 1972, public reports about government research on untreated syphilis among low-income African-American men in Tuskegee, Alabama, called attention to the absence of voluntary participation and the unwillingness of researchers to disclose the availability of treatment (Jones, 1981). This was a violation of the ethical principles of research including justice to research participants. This took place in presences of guidelines which were not appropriately applied by the researchers. There could be well documented structures for a process without appropriate implementation facilitation. It is therefore important to consider the situation of the researchers at AMPATH on how they go about applying research guidelines to fulfill justice to HIV research participants. The Department of Health, Education, and Welfare appointed a panel to review the study and, in 1974, the National Research Act was passed which lead to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission published the Belmont Report in 1979; this report described basic ethical principles regarding research with human participants (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Historically, the Belmont Report represents an important contribution to early philosophical considerations regarding research ethics.

Like any other part of the world research activities have been on increase in Kenya and what has been witnessed in the rest of the world could be witnessed in Kenya (AMPATH- MTRH). Documentation and objectively reporting may be missing to revile the picture on the ground. Application of the primary ethical principles including justice to HIV research participants is core. To understand how the researchers utilize the emerging knowledge to overcome challenges is important. The guidelines have been formulated and declared in important forums. However there is need to understand how the researchers interact with them to fulfill the obligation of justice. The role played by the both local and international guidelines needs to be understood and solutions to specific challenges in application suggested.

There is a gap in knowledge on the practical implementation of those guidelines. Literature or an evaluation on how researchers have been able to apply these guidelines in the Kenyan situation is limited. There is need for surveillance evidence documentation on the performance of the researchers on the ground on how they have applied these guidelines.

2.3 National Commission of Science, Technology and Innovation (NACOSTI)

In 1958 the first medical laboratory was put up in response to the growth in national science and technology and related activities putting in place a mechanism to coordinate and promote Science and Technology (S &T). This led to the enactment of Science and Technology Act cap 250 laws of Kenya 1977. This Act established Advisory Research Committees (ARCs) and the National Council for Science and Technology (NCST). Through the Kenya Vision 2030 Science and Technology and Innovation Act 2013 was formulated which repealed cap 250 of the laws of Kenya. This established the National Commission of Science Technology and Innovation (NACOSTI) which replaced NCST. The act facilitates the promotion, coordination and regulation of the progress of Science, Technology and Innovation (ST&I) in the country. The mandate of NACOSTI is to advice the government on policies and matters relating to the scientific and technological activities and research required for proper development of the country. Through policies guidelines on how research should be facilitated, structures of fulfilling the primary principles including justice to HIV research participants is stipulated and put in place. The development of guidelines is attached to current needs which are dynamic. Like the revisions that have been done on the various international research codes from the time of interception to date, the local research structure has undergone similar revisions. This could be in tandem with emerging challenges and new knowledge in research arena. Understanding the genesis of the structures of research and how the researchers interact with them forms the bases on which to realize how the researchers facilitate application of justice to participants. HIV research is a national activity which is regulated by NACOSTI. At the Moi University College of Health Science (MUCHS) and Moi Teaching and Referral Hospital (MTRH) regulation of all health research, including HIV research is accomplished through IREC which is an affiliate of NACOSTI. Establishing how implementation, monitoring and evaluation of research process need to be understood. Through the researchers experience knowledge on this could be established.

2.4 The institutional Research and Ethics Committee (IREC) at MUCHS/ MTRH

The institutional Research and Ethics Committee (IREC) was constituted jointly by Moi University College of Health Sciences (MUCHS) and Moi Teaching and Referral Hospital (MTRH), (Principal MUCHS and Director MTRH, 2001). IREC reviews, evaluates and decides on the scientific and ethical merits of research proposals. In line with international guidelines IREC is committed to ensuring and guaranteeing the right, dignity, safety and protection of participants and the communities. This promotes justice in health research, (World Medical Association, 2000) and this promotes justice for research participants. The Standard Operating Procedures (SOP) for IREC were developed based on the SOP of Kenya Medical Research Institute (KEMRI) Research ethics committee (REC) (Navrongo, 2001**).** The IREC functions are regulated by the guidelines which are based on the international guidelines which may be a challenge for members to adopt to local situation. Literature on how successful researchers have been delivering justice to the participants of research at MTRH is lacking. Sharing with researchers their experiences opens a window for understanding their challenges which helps in generation of suggestion for improvement.

2.5 The research Ethical Committee (REC) members

The major responsibility of (REC) should be determining the appropriate application of ethics and the science in a given study. The REC members facilitate and promote the application of the ethical principles during and after research process, (CIOMS, 1993). Members attend meetings to debate on issues and participate in decision-making required to ensure protection of human participants meaningfully. Members declare any conflict of interest. It is important that each member keeps abreast of international developments in relation to scientific health and ethical issues. Members of RECs are carefully selected to ensure that a diversity of perspectives is represented when making ethical determinations. Decisions are made by either consensus or voting. In most developing countries in Africa, RECs operate within international guidelines (WMA, 2013, CIOMS, 1991 Geneva. CIOMS, 2002 and WHO, 2000) in guiding application of justice to participants including HIV research participants.

2.6 Duties of REC

One of the duties of REC is to routinely educate and train committee members. This ensures the quality and constancy of review through capacity building by conducting and promoting education and training in research ethics for professionals. REC develops Standard Operating Procedures for ethical reviews. It also supports and facilitates the work of other committees on ethics issues. REC consults with individuals, communities and the government on issues of ethics relating to human participants in research. REC participates in ongoing monitoring of the conduct of research projects that have been approved. This is to ensure that provisions in approved protocols are not varied to the disadvantage of human participants once the project is underway. REC has straight authority and mandate of ensuring that only studies that meet the primary ethical principles are carried out. It considers the role of individual member to be important and to be undertaken with due diligence and commitment, (WHO, 2000, Nuffield Council on Bioethics, 2002)

2.7 Application of REC guidelines by researchers

The obligations to the individual and the community participating in research are well established. However there has been debate at both professional and policy levels worldwide the reports of ethical misconduct in health research, (Angell, 1997, 2000; Lurie & Wolfe, 1997; Levine, 1998; Annas, 2001; Macklin, 2001; Shapiro & Meslin, 2001; Varmus & Satcher, 2001; Killen *et al*., 2002). Sound guidelines have been put across locally and internationally on how to carry out ethical research however there is no literature on practical implementation. All over the world it has been noted that there are challenges associated with informed consent to research conducted in diverse settings (National Bioethics Advisory Commission, 2001). Justice may become a challenge if the consent process is not appropriately facilitated. In diverse setting limited resource leads to research participant to give consent without appropriate consideration of what it is all about. This can lead to undue influence to the participant by the researchers. An example of this is where it was noted that in considerations of local versus universal standards of care in clinical trials to reduce maternal–fetal transmission of human immunodeficiency virus (HIV) in developing countries it has been a challenge (Bloom, 1998; Levine, 1998; Macklin, 2001, 2004). The path to deliver justice has to be used by both the researcher and research participants with clear mind of objective of achieving justice. It is a challenge to apply guidelines if the research participants have a different objective from the researcher's objective. If one's objectives are to gain the benefits attached to the study it is difficult to think of any other thing including risks. It is therefore important to understand how the researchers practically get informed consent from participants for this is the beginning of application of justice.

There are challenges in organizing the appropriate infrastructure for carrying out an ethical study to attain justice through sponsorship of developed countries in a developing country. This is due to different social economic platforms, (Nuffield Council on Bioethics, 2004) report (www.nuffieldbioethics.org) and the (Welcome Trust 2004) report (www, welcome.ac.uk) (Nuffield Council on Bioethics, 2004 and the Welcome Trust 2004) reports points out the cultural differences taken for granted when establishing researcher guidelines and the real role of the researcher in various situations of research as a challenge. This contributes to some of the key ethical dilemmas like how to attain justice for research participants when conducting studies in resource-poor and marginalized communities (www.nuffieldbioethics.org). Unfortunately due to this resource limitation this population tends to have most health challenges requiring research activities. Kenya is a developing country with its population being culturally and economically diverse. It may be useful to gain understanding on how the researchers at AMPATH use guidelines to deliver justice. Literature on how to practically overcome challenges is limited on Kenyan situation. Through sharing with researcher’s their experiences and challenges useful suggestions may be found.

Research is a worldwide activity and to establish acceptable research ethics globally has been a big challenge to various international organizations interested in globalizing research ethics. This has led to practical conflicts (Council on Bioethics, 2002, 2005; Macklin, 2004). It is important to pay attention to cultural contexts and social justice in relation to the conduct of international research in poor communities. This has important implications for improving existing ethical guidelines and their application to research practices (Council on Bioethics, 2002, 2005; Macklin, 2004). Realization of justice for research participants may be grounded in the cultural norms of a people. It is important therefore to understand the cultural practice of the research participants in order to lay down strategies on how to engage them in research activity. Globally there is literature on how one can practically engage research participants based on the cultural context. In Kenya this literature has not been documented or it is missing. Some cultural context could be a hindrance to research engagement making it difficult to do research because of people's perceptions of various health events leading to research. There has been increased attention to the need to respond appropriately to the globalization of biomedical and social behavioral research, particularly in resource-poor environments (Macklin, 2004), (Emanuel *et al.*, (2004) have outlined eight ethical principles and practical benchmarks to guide multinational research: (1) collaborative partnership; (2) social value; (3) scientific integrity; (4) fair selection of study populations; (5) favorable risk/benefit ratio; (6) independent ethical review of protocols; (7) informed consent; and (8) respect for participants and communities. Structures of implementation may be a challenge to put in place, through sharing with researchers their experiences more knowledge may be gained and challenges learned.

Guidelines by the Helsinki Declaration should be applied based on cultural contexts to research participants in both resource-poor and industrialized countries, (WMA, 2002, Nuffield Council on Bioethics, 2002; 2005, National Bioethics Advisory Commission, 2001, Brody and Sugarman *et al*., 1998 and Macklin, 2004). Culture can be used to establish sound research ethics for cultural attributes are responsive to contemporary social and political realities. In addition, it is inherently dynamic and porous in the world of globalization and effective communication (Appadurai, 1996). Application of justice to research participants by researchers at AMPATH has cultural context challenges and there exists gaps of documentation of knowledge on how the researchers in this area have been able to utilize cultural values to practice ethically.

It is difficult to establish consensus about a common morality into policies or practical guidelines which is similar to establishing research ethics for justice fulfillment to research participants; (Marshall and Koenig, 2004 and Turner, 2003). The cultural beliefs regarding the cause and treatment of disease may differ radically from various set ups, views about underlying disease etiology making it difficult to come up with standard research ethics for all regions in the world (Tambiah, 1990; Nichter, 1992; Sargent & Johnson, 1996). The moral principles including justice governing research are associated with social context which is an alternative school of thought and it is difficult to determine whether the Western moral concepts applies to the social concept, (King, Henderson & Stein, 1999). Moral concept forms the foundation of social interaction in most communities; however the determination of how the principle of justice is grounded on the moral concept may be a challenge. There is no supporting literature on this aspect and if there is it has not been documented. Lack of supporting literature on how to ground the principle of justice could also be experienced by researchers at AMPATH for they do collaborative research which should be based on both local and international structures of moral concept. It is hoped that through this study the situation of researchers at AMPATH will be understood.

Bioethics is thought to have potential to positively influence global health reforms through developing global state of mind by the researchers; (Benatar, Daar & Singer, 2003). This could be possible through long term self- interest to learn how to balance between all situations of globalization and solidarity. In addition, through strengthening capacity and enhancing the production of global public good for health through ethical principles like justice this could be achieved; (Benatar, Daar & Singer, 2003). The argument about the potential of bioethics is sound. However, how to attain those structures by researchers to facilitate the realization of justice has not been explored. Structural factors and international politics can both contribute and reinforce inequalities on population health leading to challenges in attaining justice for research participants; (Benatar *et al* 2003). The researchers' abilities to have meaningful influence on the international politics and structural factors to gain justice for participants are limited. Ethically responsible research in poor-resource state could be implemented through collaborative partnership, strengthening and building capacity and sound ethical review protocol; (Farmer, 1997, 2003). Through collaborative partnership the researchers and sponsors should involve the community from the start to the end of research activities; (The National Bioethics Advisory Commission, 2001). The collaborative partnership between the researchers and the community is the key to ethical research and it should be an ongoing process from the beginning to the end; (Emanuel *et al*, 2004, Marshall and Rotimi, 2001). Community leadership can assist on the way forward about sharing research financial benefits; (Marshall and Rotimi, 2001) It is important to note that the pillar for research in AMPATH is collaboration with partners. There is need to gain understanding on how the researchers attain the above ethical structures during research process. It is also important to note that achieving ethical process through the above structures cannot be without challenges. The balancing art employed by the researchers in their practice to be able to deliver justice to HIV research participants at AMPATH through collaboration will be understood and will assist in generating suggestions for improvement.

2.8 Challenges encountered by researchers in the application of ethical principles of justice in HIV research

Capacity building in resource-poor settings helps to ensure the sustainability of collaborative partnerships, however it is a challenge to attain, for the activities involved require finances which may not be available; (Jinadu, 1997; Crawley & Himmich, 2000; Kovacic & Laaser, 2001; Nchinda, 2002, 2003; Lo & Bayer, 2003; Chandiwana & Ornbjerg, 2003; Lavery, 2004). Farmer and colleagues in a study on AIDS drugs in Haiti realized that capacity for research could be developed and sustained through improved structural situation and payment; (Farmer, 1997, 2003). The improved structural situation and payment kept workers working in the rural areas (Farmer, 2003). The challenge of limited resources is experienced in developing states and therefore offering incentives as those offered by Farmer is difficult.

It is noted that respect for culture of communities where researchers work and an effort to improve the communities' health infrastructures through collaborative partnership is a challenge to most researchers (Lo & Bayer, 2003; Chandiwana). Those challenges may be solved through alliances between professionals and community representatives in the study areas in both public and private sectors; (Benatar, 2000). Similar structures for realization of justice for HIV research participants may be required.

There was inconsistent interpretation and applications of national and international ethical guidelines in the late 1990s, on the use of antiretroviral therapy for reducing perinatal transmission of HIV in developing countries. The inconsistencies were related to the language and recommendations provided by CIOMs for international guidelines for conducting ethical biomedical research. There were also challenges in considering the local and the international standards of care in clinical trials in developing countries. Lack of accurate information may have led to HIV patients being tried on drugs or given information that may not have been authentic. This point to possibility of exploitation of participants in resource limited setting (Angell, 1997; Lurie & Wolfe, 1997; Varmus & Satcher, 1997; Bloom, 1998; Levine 1998; Lie, 1998; Luna, 2001; Macklin, 2001; Killen *et al.,* 2002). This can compromise application of justice leading to exploitation to research participants. The idea of giving the research participants the best intervention available has not been accepted by all for some assert that it can be an obstacle to conducting important research due to logistics and financial implications; (Wendler *et al*. 2004). Adherence to state of the art therapy for research participants which is a justice issue regardless of sustainability of treatment is a challenge; (Angell, 1997, 2000; Lurie & Wolf, 1997; Rothman, 2000; Annas, 2001; Shapiro & Meslin, 2001). Practically, adherence to certain requirements might need certain support which may not be forth coming and it is not documented on how this adherence to state of the art will be achieved by the researchers. The universal standard is the best treatment available anywhere in the world; (Nuffield Council on Bioethics, 2002). Universal standard is an established effective intervention as an ethical comparison in clinical trials guidelines; (CIOMS, 2002). Scientific necessity, the relevance of the study for the host community, fair level of benefit for the communities participating in the study and improvement of the general status of the community are the four conditions to be ensured by the IRBs and fulfilled by the researchers for attainment of justice for research participants (Wendler *et. al*, 2004). Following a research trial any tested intervention proved to be safe should be made available to the community in which it was tested; (CIOMS, 2002 and UNAIDS, 2000). The researchers should put in place plans to ensure availability to research participants of effective and safe vaccine or treatment; (UNAIDS, 2000).

Scientific research is viewed as an international economic force which brings about a lot of benefits to individuals, institutions, communities and nations where the study is carried out; (Marshall and Koenig, 2004). This could pose a challenge to the ERC members on the way forward on the issues of justice for research participants for fear of losing benefits (Marshall and Koenig, 2004). It is therefore paramount to gain the understanding on how to remain ethical without losing benefits accompanying research activities.

2.9 Conceptual framework

Figure – 1 Conceptual framework for application of basic principles of health research- justice

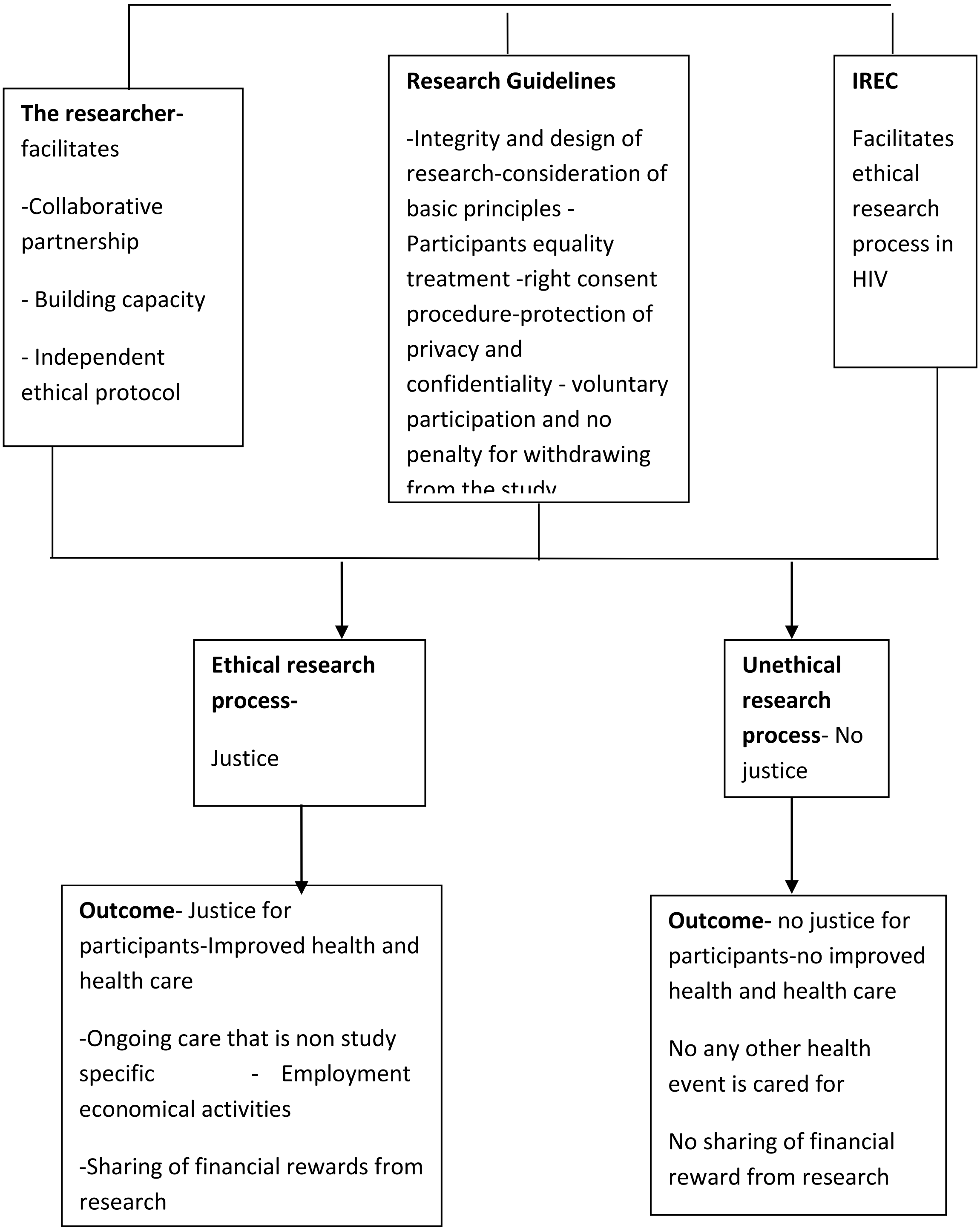


Fig.1: Conceptual frame work

This study focuses on the application of justice to HIV research participants at AMPATH. This conceptual framework considers the influence of IREC, both local and international research guidelines and the researcher's activities during research process. The outcomes are related to fulfillment or non-fulfillment of justice to HIV research participants which includes or excludes: improved health and health care, ongoing care that is non-study specific, employment economical activities and sharing of financial rewards from research. There are situations where the process of research encounters various barriers leading to non-fulfillment of the principle of justice leading to exploitation of the participants of research.

2.10 Conclusion

Although numerous declarations, proclamations, policies and guidelines for ethical conduct in research have been promulgated, the practical application of ethical principles has to be clearly stated. The use of the guidelines by investigators has to be well explained; (Emanuel *et al.,* 2000, and Macklin, 2004). The outcome of research is determined by many factors and it is therefore important to make an accurate judgment on the process. Guidelines for ethical conduct in scientific research throughout the world are informed by the ethical principles of respect for persons, beneficence/ non-maleficence and justice; (Beauchamp and Childress, 2001).

CHAPTER THREE

METHODOLOGY

3.0 Introduction

This chapter presents the process of this study from design to report writing. It includes study site, study population, target population sample and sampling procedure, exclusion and inclusion criteria, study design, instruments of data collection, pilot of data tool, data management and analysis, limitation of study, study validity and reliability and also ethical consideration is presented.

3.1 Study site

The study was conducted at AMPATH in Eldoret town in Uasin Gishu county of Kenya. AMPATH clinic at MTRH is the largest amongst the clinics ran by this organization with a high ethnic and geographical diversity of HIV patients. At AMPATH there are over 100 biomedical and social behavioral researchers providing care and doing health research.

3.2 Study design

This was a cross- sectional, qualitative study which involved MTRH researchers at AMPATH in Eldoret. The primary data was collected a cross a population sampled over one period to investigate and to understand the experiences of researchers on application of the principle of justice to HIV research participants The study also targeted IREC members. The investigator sampled researchers at AMPATH to explore their experiences with HIV research participants at AMPATH and also interacted with IREC members through interviews, between May and August 2016. The investigator focused on the following aspects of justice for the participants: - improved health and health care, ongoing care that is non study specific, economic activity and sharing of financial rewards of research results.

3.3.1 Target population

This study targeted 130 biomedical and social behaverioal researchers at AMPATH in Eldoret to understand their experiences in application of the principle of justice to HIV research participants. The Researchers were to have been involved in HIV research at AMPATH for one year and above. This ensured that researchers could provide accurate information.

3.3.2 Inclusion criteria

This study included researchers who were willing to participate in the study. MTRH researchers taking part in HIV research who had been at AMPATH set up for one year and above were included. IREC chair person, the secretary and three other members based on their experience either in biomedical or social behavioral research were included due to their knowledge of the subject matter.

3.3.3 Exclusion criteria

The exclusion criteria included MTRH researchers at AMPATH who were participating in HIV research activities but were not on duty during the period of data collection.

3.4 Sample size and sampling procedure

The sample size for this study was 21. 16 biomedical and behaverioal researchers and 5 IREC members totaling to 21 respondents participated in this study. After interviewing 14 researchers saturation was reached and two more participants were interviewed to confirm the saturation of the in-depth interviews totaling to 16 researchers. 5 IREC members were interviewed. The distribution of the respondents was as illustrated in the section of the results.

Purposive sampling was done to select IREC members. The chair person and the secretary were selected for being most resourceful due to their leadership positions and the long duration they had served. The other two members were selected based on the experience of either biomedical research or social behavioral research. This was to help get enough information from their experience.

Purposive sampling was used to select participants from MTRH biomedical and social behavioral health researchers at AMPATH. Based on the sample size for this study and the sections of interest as mentioned in the distribution of the participants for the study area, researchers were identified to participate in the study. The investigator selected both female and male in equal numbers to ensure gender balance in sharing in their experiences. Biomedical and social behavioral researchers were selected in equal numbers to participate in the study. This was important for the two groups, biomedical and social behavioral play different roles in research. This means that they could be having different experiences. Two sets were for female biomedical and social behavioral researchers and the remaining two sets were for male biomedical and social behavioral researchers. They were approached, requested and invited to participate verbally. The invitations explained the purpose of the study and all the procedures involved. The individuals who consented to participate were notified in one week’s time before the day of the interviews. This was to enable the participants to prepare for the interview.

3.5 Piloting of the data collection tool

The data collection tool (interview guide) was piloted prior to the actual study. Four health researchers were sampled from MTRH, to test the interview guides. This was to ensure they were well phrased, culturally sensitive, and captured the objectives of the study. The results showed no need to carry out any adjustment on the tool before rolling out the interviews.

3.5.1 Methods and instruments of data collection

The investigator used two different interview guides one for researchers and one for IREC members. They were both on the experiences of researchers on application of the principle of justice in HIV research. The data collection process involved an interaction between the researchers, IREC members and the investigator through interviews. The interview sessions took between 45minutes and one hour. Unstructured interview guides were generated from various themes on the application of principle of justice to participants in HIV research. During this process of data collection the key points on IREC research guidelines, factors researchers consider in ethical research process and the challenges researchers encounter in fulfilling justice in research process were addressed. The researchers were probed with both information from the guide and information they gave out during the interview process. The interview process took place in the participant's offices which was convenient for the participants to avoid disruption. This was supportive enough for researchers to open up and give information undisrupted. Throughout the interview process the investigator was an active listener offering verbal mirror to affirm the clarity of the information given by the researchers. The investigator's silence was utilized as a spring board into important topic of discussion for silence was an instance for thoughtful punctuation. The interviews were conducted in English.

3.6 Data management and analysis.

Data management and analysis was manually done from interpretive analysis approach at two levels. At level one transcription, identification and classification of themes was done. At level two of analysis triangulation of data was done.

IREC guidelines were analyzed by the investigator by going through the Standard Operating Procedures for the Institutional Research and Ethics Committee (IREC).

The Reviewers Guide Form was also looked into. This was with a view of identifying the challenges in applying those guidelines in a practical situation. A comparison with national guidelines already on record was also made.

Level one

Data was collected from the researchers through audio-recording and written short notes and it was manually managed. The interview recordings were transcribed verbatim. An interpretive approach was used to analyze data item by item where content analysis was performed. Overlapping issues from each interview were matched to individual subjects. Then all the interview data was compiled and themes identified highlighting areas of concern with the instrument. The findings were presented as summaries including selected quotes. The themes identified were:-

- application of both local and international guidelines of research
- the role of IREC in promoting justice for HIV research participants
- factors researchers consider in applying the principle of justice in HIV research
- the challenges encountered by researchers in fulfilling justice for HIV research participants

The process was largely inductive, inquiring generating meaning from the data collected in the field through themes and emerging concepts and theories.

Level two - Triangulation

Focusing on the study questions data collected by various instruments across different categories of participants was compared and contrasted. This was to enhance in depth understanding of complementary information about the ethical experiences researchers encounter in a researcher process. It was noted that perception for various similar concerns were interpreted differently by the researchers. For example one of the researchers expressed enough being done to achieve the principle of justice in HIV researcher. However another researcher expressed negative asserting that more needs to be done to achieve justice in HIV research. This implies that either there is lack of understanding of certain aspects of ethical research process or there exists breakdown in communication at certain levels of research process.

Data was interpreted and tabulated for reference, comparison and cross checking before presentation in prose as by different levels of analysis.

3.7 Study validity and reliability

To ensure that research questions would be asked in the right way all research questions were pretested. Through triangulation conformation collected by different tools from different categories of participants was allowed. Thematic saturation supported the study validity while classmates and colleagues played the role of independent analysts of transcription. Participants were availed soft copies of the summary of the findings. Validation of the findings was allowed through this process.

3.8. Limitations of the study

This study involved a smaller number of IREC members and a few HIV researchers. This was not representative enough for Kenya’s research population and IREC members. The study focuses on, the individual’s insights own perspective and meaning of experiences. In spite of these limitations, this study is important because it provides fertile grounds for future research on the application of the principle of justice in research. It also provides researchers and IREC members an opportunity to share their understanding on the subject matter and the challenges they encounter.

3.9 Ethical Considerations

Before the commencement of the study, the proposal was submitted to the Moi Teaching and Referral Hospital/ Moi University College of Health Science Research and Ethics Committee (IREC) for approval. The objectives of the study were clearly explained to participants. Participation was voluntary with the autonomy to withdraw from the study at any time. The participants were informed that they were not required to give reasons for refusing to participate. However they were free to share with the investigator their reason for refusing to participate. All participants gave written informed consent before participating in the study. Anonymity was assured by using numbered interviewer guides and ensured that no names of respondents were indicated but, instead unique numbers were used to conceal names of participants. Data collected was secured by keeping it in lockable cupboards accessible to the investigator alone. There is no identifiable information of the respondents in this final thesis.

3.10 Conclusion

This chapter has presented where the study was done, how it was done, what was done and why it was done. The findings of this study will be presented in the following chapter.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter presents the findings of this study whose aim was to explore the experiences of researchers on the application of the principle of justice in HIV research. The study objectives were; 1) To analysis the IREC guidelines for application of the principle of justice to research participants in health research.2) To examine the factors considered by MTRH researchers in applying the principle of justice in HIV research at AMPATH and 3) To explore the challenges encountered by MTRH health researchers in applying the principle of justice in the research process at the AMPATH

Data presented originates from IREC document analyses and interview sessions carried out in this study and are presented in three parts. The first part is the findings from IREC documents analyses. The second part presents demographic characteristic of the sampled population to help in the understanding of the respondents' background. The third part consists of the responses from individuals in depth interview questions that were used to guide the investigator. Transcription of the data was done in ms- word. The themes generated were: IREC guidelines for research, ethical research process to ensure principle of justice and the barriers of attaining the principle of justice in HIV research at AMPATH. In the presentations of the findings, the exact words as used by participants during the interview were used to illustrate response themes and subthemes. The quotations are presented in italics. Omission of unnecessary information given by the respondents was presented by ellipsis points (…). To protect the identity of the participants they were given cryptograms as follows; IREC members – RI 01 – 05, Researchers Behavioral Scientist and

Biomedical researchers- RB and RM 01 to 16 respectively and R represent respondents. The final part of this chapter gives a summary of the results.

4.1 Participants demographic characteristics

Data was collected by using unstructured interview guide from 5 IREC members of MTRH /CHS MU. The respondents were four men and one woman. The ration of female to male at IREC is 1: 4. Their median age was 45 years. They had worked at AMPATH for more than 2years.

Table 1. Researchers working at AMPATH consortium in Eldoret Kenya who participated in the study

Respondents	Age in years	Sex	Occupation	Period in years at AMPATH
01 RB	51 – 60	F	Behavioral Researcher	3 years
02 RB	61 – 70	M	Behavioral Researcher	2 years
03 RB	51 – 60	M	Behavioral Researcher	5 years
04 RB	31 – 40	F	Behavioral Researcher	6 –years
05 RM	41 – 50	F	Biomedical Researcher	2 years
06 RM	41 – 50	M	Biomedical Researcher	3 years
07 RM	41 – 50	M	Biomedical Researcher	3 years
08 RM	31 – 40	M	Biomedical Researcher	4 years
09 RM	31 – 40	M	Biomedical Researcher	4 years
10 RM	31 – 40	F	Biomedical Researcher	3 years
11 RM	51 – 60	M	Biomedical Researcher	2 years
12 RB	41 – 50	F	Behavioral Researcher	5 years
13 RB	41 – 50	F	Behavioral Researcher	3 years
14 RB	31 – 40	F	Behavioral Researcher	4 years
15 RB	31 – 40	F	Behavioral Researcher	6 years
16 RB	41 – 50	M	Behavioral Researcher	3 years

Data was collected using unstructured interview guide from sixteen researchers as shown above. There were equal numbers of female and male researchers eight for each. Their ages ranged between thirty one years and seventy years. Biomedical researchers were seven in number and behavioral researchers were nine. All the researchers had worked at AMPATH for more than two years.

4.2 Organization and process of data analysis

Themes and subthemes

Table 2 – Themes and subthemes

Themes	Subthemes
4.3.1 IREC Ethical research guidelines	4.3.1.1 IREC research guidelines - local and international research guidelines - guidelins and justice issues
4.3.2. Factors considered by MTRH researchers in applying the principle of justice in HIV research at AMPATH	4.3.2.1. Proposal approval level 4.3.2.2. Research implementation level - the community -AMPATH - MTRH 4.3.2.3. Collaborative research engagement 4.3.2.4. Capacity for research development - health and education institutions - the community - the government
4.3.3 Challenges encountered by MTRH health researchers in applying the principle of justice in the research process at AMPATH	4.3.3.1. challenges of applying the principle of justice – reviewers, financial, work and coping with challenges 4.3.3.2. challenges encountered by researchers 4.3.3.3. challenges of capacity building for research

4.2 Analysis of IREC documents

The IREC SOPs and the Reviewers Guideline Form were reviewed with an intention to identify any challenges in application of the requirements that could lead to non fulfillment of the principle of justice in HIV research. No challenges were noted for they were specific and clear on how to facilitate ethical research process. However the IREC Reviewers Guideline Form, has a lot of details providing necessary information. This needs good concentration and adequate time for whoever is looking at it to comprehend. There were no gaps identified in the guidelines that led to challenges of fulfilling justice to HIV research participants.

4.2.1 Ethical research guidelines

Guidelines for research are general rules or instructions on how research should ethically be carried out. All respondents from IREC asserted that there was no difference between local and international guidelines. However they all agreed that studies which originate from elsewhere have to be approved by IREC. This is because of differences in both economic and culture that exist in different regions of the world. It was also noted that IREC is locally affiliated to NACOSTI which is the National regulator for research in Kenya. In turn NACOSTI is affiliated to WMA which is the international origin of research guidelines;

> *”... there is no difference between the two…NACOSTI is the national body in Kenya regulating… and IREC is affiliate member. NACOSTI structures are drawn from the international structures..., ... however specific situations may lead to specific guidelines to help realizing ethical research activities.”*(R 02-RI,)

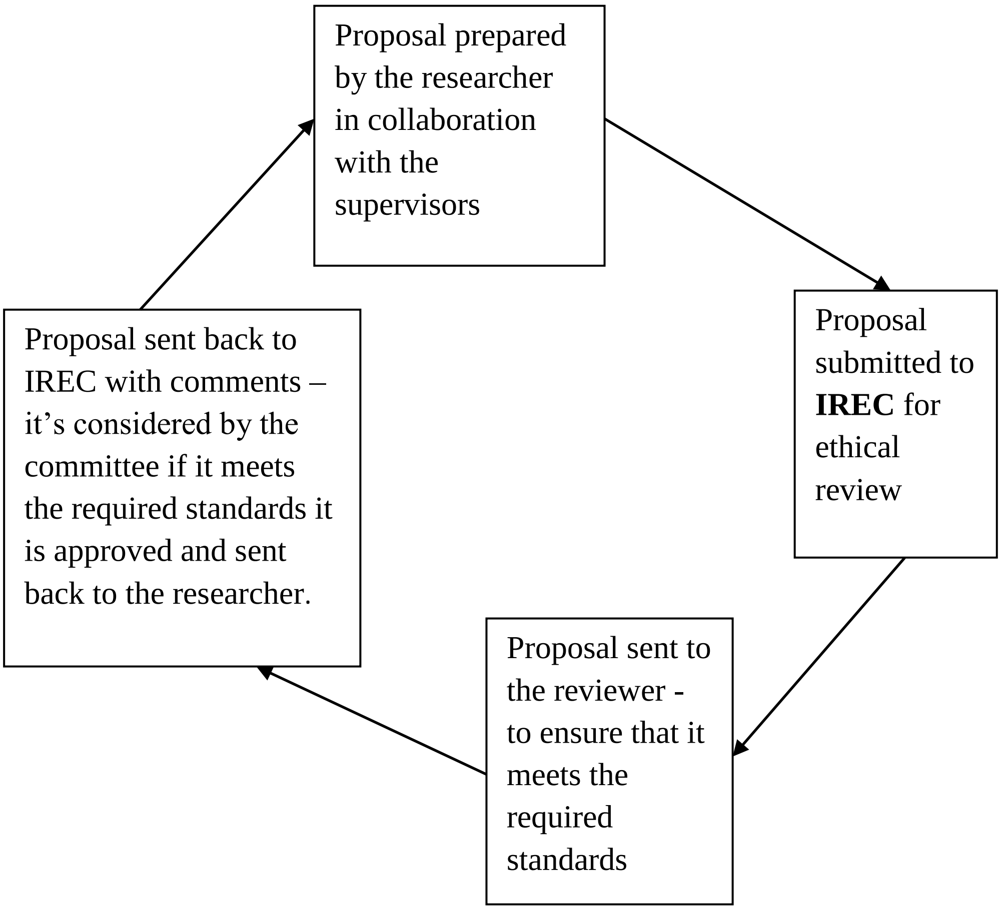
Different situations and regional needs may lead to certain adjustments to fit in certain situations this was expressed by two respondents;

> *“…local guidelines are formulated from the national guidelines from NACOSTI which observes the International research guidelines from WMA... however the difference could be due to regional policies and different situations encountered during research process.”*(R 05- RI)

Research guidelines are important to achieve the principle of justice in research and the regulatory body like IREC’s biggest obligation is to ensure that guidelines are available, understood and adhered to by all players in research process.

4.3 The ethical research process to ensure principle of justice

Figure- 2 Research proposals approval process



4.3.1 Research proposals approval level

Health research is one of those important scientific activities involving human beings that cannot be done without appropriate organization. Research process involves three main players the researched, the researcher and the regulator who have to work complementing each other. The researchers need to be organized to carry out research and therefore need guidance from IREC on the ethical process of research through review and approval of research proposals. The researched have to be protected from risks and harm that could result from participation in research and they also have to be co-operative to make research successful. Approval of research is the entry point of research process and it is done at two levels, reviewers' level and IREC itself. All the researchers acknowledged that IREC regulates research process:

> *"...IREC serves as a regulatory institution for research where human beings are involved ... reviews proposal ensuring ... ethical requirements ...no exploitation of the participants. ...Protects community and ensure benefit from research activities ... approves research proposals."*(R 02 -RI)
>
> *"...IREC members review and approve research proposal and also monitor the approved studies..."*(R 03 - RI)

All the researchers agreed that IREC has benchmarks for approving research proposals. They expressed that at proposal level it was assumed that a proposal must meet those benchmarks to be approved:

> *"...IREC sent the proposals to reviewers..., looks into the science...,... necessity ..., ... methodology should be correct and ethical principles correctly addressed..."*(R 01 - RB)*"...main aim being to protect the participants of research in several ways ...correct consent process..., ensure no harm... and benefits accessible to participants...*(R 03 - RB)

Unfortunately some of the researchers were not familiar with those benchmarks for they have never been educated on them by IREC. This was expressed by one of the social behavioral researcher who acquired research knowledge through other training:

> *"...Unfortunately I have never been able to interact with IREC guidelines..., look at the type of study..., ...the population, the length of study and finally if you are going to be fair..."*(R 04 - RB)

A biomedical research respondent had this to say about the review and approval of a research proposal;

> *"…IREC want to ensure the science in the study is correct and new useful information…, fill knowledge gaps … undue influence to the participant by the researcher...,… the qualifications of the researchers should resonate with the type of the study under consideration…"*(R 09 - RM)

All the respondents agreed that what IREC considers before approval of the proposals forms the benchmark for approval of all the proposals that go through it and is necessary for all the respondents to be familiar with them. Some research players gained ideas of ethical research process through other learning other than IREC although this also is a part of IREC's mandate. Such players are still capable of carrying out ethical research process through IREC approval.

4.3.2 Research implementation level

The community - The players at the implementation level of research are basically the researchers and community members. In order to have a smooth interaction to bring about authentic results both sides must understand their roles and expectations. The respondents expressed different experiences in regard to this level of research. Most of the respondents expressed that it was difficult to deal with the community. One needed to have the intention to interact with the community clearly and precisely explained to the stakeholders. It was also explained by one of social behavioral researcher that one needs to understand the cultural aspects of the community before engaging it in research process:

> *"… community is a very challenging area…, … need to clearly explain to stakeholders to avoid misunderstanding, misinterpretation and*

> *misrepresentation of your intentions.... ....Cultural orientations are also a challenge need to understand before engagement in research..."*(R 01 - RB)

Two behavioral researchers expressed that one has to understand the cultural perception about gender roles and community order of communication to avoid misunderstandings:

> *" ... Cultural perception of various communities on gender and roles of each person in the community ideas to be communicated through leaders and not directly to community members…, ... research requires direct communication to participants to avoid misrepresentation…"*(R 15- RB and R 16 RB)

Two of the biomedical research respondents had issues with the culture of expectation of handouts by community members leading to dependence syndrome. They attributed this to poverty and asserted that it had implications on making a decision to participate in research by participants;

> "…*the culture of hand outs and dependence syndrome in the community is a challenge…. Poverty is a challenge – one may easily make a decision without understanding what the study is all about in order to be assisted".*(R 02 – RB and 15 - RB)

When one wants to recruit participants from the community there is need to do education first to community members about the structures of research and reassure them that they all stand to benefit. This will defuse being misunderstood for favoring a certain group. One of the respondents expressed how some of the community members reacted about being excluded from a study. One of the biomedical respondents asserted that some community members expressed it openly:

> *"…You are recruiting those ones so that they can get free things and not us-you are unfair..."*(R 03 - RB)

Two of the respondents from experience at AMPATH expressed that there was research fatigue. It was noted by two of the social behavioral research respondents that some community members resisted to participate in research and it required the effort of the community leaders for them to participate:

> *"... at AMPATH I have realized there is research fatigue ... repetitive collection of data and information from participants..., uncertainty on what will happen when the study comes to an end… a gap in giving feed back to…".* (R 04 - RB) *"…research fatigue in communities… researched on repeatedly… likely to show resistance to participate..., ...community leaders to engage community members… may be taken to be coercing… give consent to participate to please their leaders…"*(R 12 - RB)
>
> One behavioral research respondent expressed that there existed very high expectations from the population being engaged in research. This fosters the negative attitude of (munatutumia) you are using us:
>
> *"... high expectation from the population is a challenge… over researched community members developing negative attitude..., say munatutumia…"*(R 13 - RB)

A biomedical and a behavioral research respondent expressed that transition of research findings to policies has not been well handled by the government and institutions of higher learning. This denies the community from benefiting from research activities. It is also expressed that the regulatory systems are weak to push for the agenda of the participants getting their benefits;

> "*… direct benefits no obstacles ... community benefits… a challenge to implement the recommendations and policies ... informed by the knowledge generated by the study... Transition of research to policies… a challenge."*(R

> 05 - RM) *"...study findings are hardly taken care of by the stakeholders – the government and learning institutions..." "... regulatory bodies are weak... difficult for communities participating to benefit from research ... no fairness I would say in most of research activities...*"(R 12 - RB)

It was noted by two biomedical and one social behavioral research respondents that there was both fear and unwillingness to participate in research among the community members. They participate with a perceived gain. It takes the community leads effort to make some of them to participate. This could be perceived as forced or coerced participation;

> *"...people don't like participating in research studies..., participate with perceived gain not just purely to participate in the study..."*(R 06 - RM) *...people don't like participating in research; through their leads they accept..., ... a challenge of coercing or forced participation.*(R 12 – RB and R 07 - RM)

It was expressed by two social behavioral and two biomedical research respondents that feed back to research participants was not well facilitated. Researchers do not go back to the community to give feedback which is demoralizing to the participants;

> *"...most of researchers never communicated the results to the participants..." "...personal experience feedback to the community has not been well facilitated...".*(R 10 - RM) *"...true, most researchers do not give feedback to the community after the study..., do not go back to the community to give feedback..."*(R 14 - RB)

Two of the biomedical and two of social behavioral respondents asserted that it is paramount to get adequate sample size when carrying out a study. They expressed that getting adequate sample size for some health events is hard;

> *"...getting adequate sample size for certain health event is ...most difficult... through community advisory boards members are sensitized to support the study...*(R 08 - RM) *need to have community leader to interact with other members... ...suspicion and phobia for research a big challenge ...without community option leaders..., ...becomes an ethical issue for the decision to participate should be individual... ...organizations employ people from those communities in order to do research in those communities... an ethical issue... "* (R 09 - RM)*... getting the right population to engage in research has been a challenge..."*(R 13 - RB)

Research activities have numerous advantages in most cases when well organized and conducted. Some of the provisions from research are beyond ordinary situations. One of the social behavioral respondents alluded to some of the participants regretted their attitude that they are being used. This follows the realization of the benefits of participating;

> *"....others have expressed regrets for the attitude that they are just being used for others people's interest after realizing the gains..."*(R 16- RB)

The community is major stake holder in implementing ethical research process. There are numerous issues which need appropriate restructuring in order to bring about the realization of the principle of justice in research process within the community. Being knowledgeable and upholding sound integrity is an asset for a researcher to succeed in achieving the principle of justice in research process at the community level.

AMPATH has been in this region for over twenty years carrying out a lot of research activities in HIV and chronic diseases in Western part of Kenya. The initial agenda for AMPATH was to provide care for HIV patients. A long the way a window for research and training came by. The large population may not be able to make distinction between care and research. One of the social behavioral research respondents thought that some of the HIV research patients got involved in research without knowing:

> *"... in certain situations patients who come to AMPATH for care may not be aware that they are coming to participate in research... ...however the information acquired through these studies help to change the care for patients for the better..."*(R 03 - RB)

One of social behavioral research respondent asserted that there were some activities and decisions made by AMPATH which could compromise justice;

> *"....for example the idea of disclosing about the HIV status of the orphans and the care givers..."*(R 04 - RB) *...to be just!! To be fair to all including chance to participate is a challenge... ...drugs generated from clinical trials should benefit participants..., however it hardly does..."*(R 12 - RB)

Two of social behavioral research respondents expressed that AMPATH idea of developing benefits through service and training was noble. The participants need to have earlier information and needs also to benefit from the products of the research process;

> *"... started by developing benefits ... through service, training and research, people go to AMPATH for care and along the way they get involved in research, ...data generated utilized for research activities..."*(R 13 – RB and R 14 - RB)

According to another social behavioral research respondent, there is no adequate justice application in HIV research, asserted that the researchers have other agendas other than achieving justice for participants;

> *"…we need to do more in trying to apply justice to HIV research participants beyond what we have been able to do ... ... implementation of information generated from HIV research need to be addressed by all stake holders of research…"*(R 15 - RB)

Contrary to what others had expressed HIV research participants have adequate benefits for participating in research this is according to one of the social behavioral research respondent;

> *"… research participants have largely benefited from participating in research, ... benefits outweigh the perception that they are being used, …AMPATH takes care of any other health challenge….in the community HIV patients found are put on treatment…participants benefit from being in the study at AMPATH - justice is applied…"*(R 16 - RB)

Patients who attend AMPATH clinic who interact with researcher are from various regions within Western Kenya. One biomedical and two social behavioral respondents expressed concerns about the sites which are commonly used by AMPATH for research implementation. Those sites have populations that may be classified as vulnerable. Vulnerable populations are likely to have health events that draw the attention of researchers. There are high chances of coercion compromising ethical process taking away justice;

> *"...a challenge in understanding why certain areas are commonly chosen by AMPATH… areas where AMPATH choose is rural where majority live below poverty line and low levels of education have been repeatedly used...."*(R 04 - RB)

Two biomedical research respondents alluded to challenges of poverty which compromises application of justice to research participants. They expressed that it is on this premises that one can easily conclude that a participant is being exploited;

> *"...AMPATH only cares for poor people… … chances of the poor participating in studies at AMPATH to be coerced to participate… not ethical and therefore no justice..."*(R 05 – RB and 06 - RM)
>
> *"...poverty among study population hind the realization of justice, ...we are dealing with poor people… out of the clinical trials the patients cannot afford drugs that are used for their care...may be coming for trials because ... only alternative for getting care..., ... looks like enticement ... not ethical. ...some of drugs given in the clinical trials cannot be found anywhere else".* (R 09 – RM and 08 RM)

Poverty is associated with poor health. Research looks into correcting poor health by establishing the causes and looks into the solution. It is therefore difficult to avoid associating research with poor people in developing countries like Kenya.

4.3.3 Collaborative research engagement

Collaboration in research is important for it gives researchers an opportunity to share ideas and exchange scientific views about certain health events. The idea of collaboration research could originate from local or international platform depending on the need of certain information about certain health event. Collaboration is bone out of challenges of establishing certain facts about a health event. These challenges could be funds, expertise, and health event of interest or need to understand different concepts of research. Respondents at AMPATH - MTRH have had various experiences on collaboration research for most of their activities are through collaboration. On the question of equity in collaborative research one of social behavioral research respondents expressed how well prepared the international collaborators are compared to local researchers;

> *"... major problem is that collaborators engage us with their agenda and their budget... our situation is that we have agenda without money... difficult to accomplish our agenda ...collaborators influence the situation to have their agenda worked on... danger- our needs will not be taken care of...".*(R 02 - RB)

It was expressed by one of the social behavioral respondent that the structures and situations made it difficult to achieve equity in collaboration research;

> *"...collaboration requires task sharing appropriately... lack of understanding the community structure ... a challenge to attain equity in collaborative research."*(R 03 - RB)

Sometimes you feel misused; this was expressed by two social behavioral respondents;

> *"...feel misused for if you have no funds to carry out the study the collaborators will fund and carry the day... hard to get equity whatever effort you put in…*"(R 12 – RB and 15 - RB)

Different views we expressed by another social behavioral respondent that equity is attainable from the experience when one sticks on the MOU established from the start;

> *"... no challenges about equity in collaborations I have been involved… hear people complain that collaborators do not recognize local collaborators no acknowledgement in publication of the work that results from the collaboration…"*(R 14 - RB)

One of the social behavioral respondents expressed that it is a good platform for achieving research goals if it is well grounded;

> *"... collaboration makes research easier, put ideas together from different aspects... makes funding to be available… funding makes a difference but researchers are equal... funding agents may favor one side…but funds are centrally placed... can help in institutions development… through collaboration publishing done with all getting their rights …"*(R 16 - RB)

One of the social behavioral respondents acknowledged the existence of different research levels between the collaborators, expressed that it is an uphill task to achieve practical equity;

> *"... our collaborators have international standards of doing research, we are not at the same level their experiences and resources are enormous... our collaborative activities tend to favor international collaborators leading to researchers accomplishing the collaborators agenda…"*(R 13 - RB)

Another social behavioral respondent expressed that the local researchers need to do more on the research frontier for they have not done equivalent to their intellectual capacity;

> *"…local researchers have not been able to develop strong protocols for carrying out research… collaborators influence the type of research to be carried out making equity elusive… Kenya's researchers take back sit letting the collaborators take their way without due consideration of equity…"*(R 04 - RB)

One of the social behavioral respondents expressed strongly that the PI has a very important role to play, ensure ethical process and therefore justice;

> *"…PI is the main person and equity can easily be taken away when one considers personal gains ignoring the MOU…integrity important for researchers…*"(R 05 - RB)

One of the biomedical respondents alluded to equity being a challenge to understand for it basically depends on the role played by each party;

> *"… Is a different game ball… not easy to talk about equity with partners for it is all about your role in the partnership… can agree that we become co-principle investigators at that theory level... benefits of research are basically determined by person or institutions role."*(R 11 - RM)

Collaboration need to be well structured through a sound MOU and adhered to by both parts to achieve meanful goals.

4.3.4 Development of Capacity for research

Capacity building entails the infrastructures and human resource development for the purpose of carrying out research both in the community and institutions of health care and training. The government, health and education institutions and the community have important role to play towards capacity development for research.

Health and education institutions

The researcher has a big role to play in facilitating this activity. One of the social behavioral respondents expressed that most of the researchers are not doing enough to develop capacity for research;

> *"… Kenya researchers have not been pro-active enough about research activities... they consider monitory benefits that accompany research other than knowledge generated… research is not easy it requires a lot of resilient and determination to achieve capacity…"*(R 04 - RB)

One of the biomedical respondents expressed that the biggest challenge for human resource development has been structures to facilitate this activity;

> *"... biggest headache is the framework and the structures of development... development should be through faculty for either Moi University or Moi Teaching and Referral Hospital… however the employment capacity is limited by funds ...getting people to develop becomes a problem… the available funds are through fellowships ...aligned to specific areas of development dictated by the sponsors. ...a challenge the sponsors' interests ...different from what the available people could be interested in…"*(R 06 - RM)

Contrary to above one of the biomedical respondents expressed that much had been done through the education institution:

> *"...through CHS/ SOM we get donors and collaborators who provide funds and grants for doing research enabling us to train people in research… able to improve our infrastructure though not enough through the proposals we make for grants ...we include budget for infrastructures."*(R 07 - RM)

One of the social behavioral respondents expressed that the problem of human resource development for research is rooted at the facilitation of learning of research at school, asserted that local mentorship has been bad;

> *"...learning of research at school is extremely poor for both undergraduate and post graduate levels…my experience, through interaction with partners in collaboration improved my knowledge about research… the local researchers are poor mentors… usually very conservative on knowledge of research… after training in research limited opportunities for practice…"*(R 14 - RB)

It was expressed by one of the biomedical respondent that AMPATH as a health institution has been able to assist in both human and infrastructure development;

> "*…at AMPATH through research office funds are collected from researchers for administration and infrastructure improvement...this helps to improve laboratories for clinical trials…. help in training staffs in the laboratories…*"(R 08 - RM)

Another biomedical respondent expressed that some trained researchers for capacity development are not engaged in research due to lack of opportunities and funds;

> *"... our institutions are unique… trained researchers are not facilitated to engage in research no funds most of scholars in Kenya do not earn money through research."* (R 09 - RM)

One of the social behavioral respondents expressed that capacity development for research is highly depended on collaborators;

> *"...we still depend a lot on the collaborators for funds to develop…we have good intellectual capacity but inadequate infrastructures and grand proposal writing by local researchers…"*(R 13 - RB)

One of the biomedical respondents expressed this about capacity building;

> "*… is a challenge for where there has been no collaborative research there are no structures for research... no adequate time allocated to research most clinicians are busy with clinical work at the same time doing research work… inadequate time devoted to research activities."*(R 08 - RM)

Another biomedical respondent expressed that capacity development should be approached differently;

> *"...capacity building should be a two way process targeting both researchers and research participants for better understanding and communication…. funds for capacity building, are limited."* (R 10 - RM)

One of the biomedical respondents alluded to situation in learning institution;

> *"…being in learning institution automatically capacity building starts here for it is a part of the university mandate… unfortunately we have very few programs that train people in research… can only specialize in research after other professional courses… not easy to train researchers from the start due to expenses and structures for training…"*(R 11 - RM)

Education and health institutions require funds and appropriate planning to enable development of capacity for research. Appropriate infrastructure should be put in place in learning institutions to facilitate more people to acquire research knowledge. Health institutions should be able to have put in place mechanism for training and mentorship for research for upcoming researchers.

The community

The community dynamics are very essential in capacity building for any activity involving community members. It is important to understand the community entry strategies to be able to gain co-operation from the leaders and the population. One of the social behavioral research respondents expressed that for capacity building in the community one needs help from advisory board members;

> *"…recruitment for participants within the community one needs to engage advisory boards to assist to get the right information to make my study meaningful… guides me to understand the participants and the community in general".*(R 01 - RB)

Two social behavioral research respondents asserted the importance of community need assessment before engagement in capacity development for research:

> *"…carry out appropriate need assessment first to convince community members that the study is for their good…there is need for education first before the study takes off…"*(R 12 - BM) *"…no adequate human resource,*

> *poor care for ones available … no appropriate infrastructures for research … community members are not willing to participate in research…"*(R 15 - RB)

Within the community the working terms originate from both the community members and the researchers. It is necessary to bring about proper understanding between the researchers and the community for easy interaction.

The government

Two social behavioral respondents expressed that it is the government responsibility to develop capacity for research. This can be facilitated through formulation of polices and allocation of adequate budgetary funds;

> *"… it is a national issue which the government should provide… there is limited budget for research capacity building...it is a policy issue..."*(R 02 - RB) *"… a challenge worldwide …there are people in research institutions for association and not to do research … others are willing to do research but don't get a chance to be facilitated … institutions have not been supportive enough through planning workshops seminars and finances...*''(R 16 - RB)

For the government to achieve capacity building more needs to be done for it is not enough to have funds with wrong personnel in position to spear head capacity building in research. Sound policies need to be supported with good structures and strong financial support to attain the essence of research in research institutions and the government should be able to support this.

4.4 Challenges encountered by researchers

Researchers have various experiences and challenges through engagement in research projects at AMPATH. One of the social behavioral respondents asserted that some misunderstanding around finances and gifts existed within the community;

> *… some of option leaders in the community demand for tokens... paying research participants is unethical… the researchers who do not pay participants meet resistance from the community they are thought to be keeping funds meant to pay participants…”*(R 03 - RB)

Biomedical and social behavioral respondents expressed that one needs to be close to people taking part in research to make work easier;

> “*…there is need to keep participants very close to participate in your study* …(R 06 – RM and R 12 - RB)

One of the biomedical respondents expressed that challenges are within the institutions;

> “*… the challenges are at the level of institutions of higher learning like our university and the service providers like MTRH for general gain from research is supposed to inform policies... it is unfortunate that the government and institutions of higher learning may not respond to the recommendations from research to formulate sound policies to improve care and that is where the challenges are.”*(R 11 - RM)

One of the social behavioral respondents alluded on the community entry as a challenge;

> *“…attitude of some community members and poor community entry by researchers leads to refusal to participate…. most of the community members have limited knowledge about the importance of research”*.(R 14 - RB)

Knowledge, right attitude towards research work focusing on the research ethics is important for researchers. This can help in overcoming challenges.

4.5 Conclusion

In this chapter the study findings have been presented according to study objectives. Those findings will be discussed in the next chapter.

CHAPTER FIVE

DISCUSSION

5.0 Introduction

This chapter presents discussion of the findings in the preceding chapter. There were different themes generated from the researchers and IREC members' accounts. There will be discussion in the following themes, Guidelines for ethical research, factors considered by researchers in ethical research process to ensure principle of justice and challenges of attaining the principle of justice in HIV research at AMPATH.

5.1 Guidelines for ethical research

IREC SOPs and reviewer guideline forms are very clear documents having a lot of information which may require adequate time to comprehend. Some of items on the SOPs are not in place. This includes; a) structures for site visits for approved projects being implemented with purpose of monitoring and b) structures for training on research proposal writing and critical appraisal of scientific literature.

The research guidelines used by IREC are universal and can be used on both local and international platforms for facilitating research activities. They address the primary ethical principles; respect for a person, beneficence and justice as stipulated in the Belmont's report (Rice, 2008). All the respondents were conversant with the fact that there was no difference between the local guidelines and what is used international. Most of them expressed that some adjustments could be required depending on the situation and policies of different regions.

From those guidelines IREC has formulated benchmarks for approving research proposals. Some of the respondents expressed that they real did not know what IREC considers to approve their proposals. Not knowing may be a window for not applying the principle of justice to research participants. It is expected that the researchers will seek clarity from IREC where they are not clear of what is expected of them in ethical research process. Most of the researchers do not seek clarity from IREC due to the attitude that IREC is an obstacle to their research progress. It is similar to what happened in the Tuskegee Albama case where the same attitude issues made the researchers not to disclose that there was treatment for syphilis, (Jones, 1981). Some researchers struggle to meet the expectations of IREC when approving research proposals taking too long to get approval of their proposals. To improve the accomplishment of a smooth ethical research process by researchers there is need for them to be proactive and seek clarity from IREC before and during research process.

In approving research proposals IREC addresses the right, dignity, safety and protection of participants and the communities which is in agreement with what is termed as promoting justice in health research (World Medical Association, 2000). There is agape in teams of literature on how practically researchers apply the principle of justice in research. Approval of proposal by IREC does not amount to fulfillments of justice to research participants, personal integrity of the researcher, the researched and the regulator has a big role to play. Furthermore there have been debates worldwide on the reports of ethical misconduct in health research despite the studies having been approved by the necessary authorities, (Killen el at, 2002). It is through personal integrity that ethical research process will be achieved fulfilling the principle of justice to research participants.

5.2 Factors that researcher consider in ethical research process.

Under this theme there were four subthemes namely; proposal approval level, research implementation level, collaborative research engagement and capacity for research development. The four themes are all about factors researchers consider in a research process which includes IREC requirement for approving research proposal, engagement of participants in an ethical research process and knowledge of community members about ethical research process.

At research implementation level the main stakeholders are the researchers and researched. For the researched the entry point is the consenting stage. Consenting is a global challenge in resource poor countries like Kenya and may lead to research misconduct by researchers, (National Bioethics Advisory Commission, 2001). The researched may give consent without appropriate consideration of what participation entails. The consequences of such an act may by device effects to the participants. For example in clinical trials with drugs whose effects are still unknown can cause harm. Researchers attributed this to poverty, the fact that participants can consent without consideration of what is involved which is a challenge in attaining justice for research participants. Resource limitation in some communities pauses dilemma in applying justice in research, (Welcome trusts, 2004)

At MTRH researchers observed that there were high expectations from the community leading to dependent syndrome. The researchers acknowledged that the research participants are poor. In the absence of careful consideration of a practical interaction between the researcher and researched one may imagine of the existence of exploitation for sharing of burdens and benefits will be difficult. Yet in a practical situation some of the benefits researched population gains are beyond reach out of the research process, for example the drugs used in treatment of HIV are very expensive to afford.

There is the issue of equity which implies giving as much advantage, consideration to one part as it is given to another, (Rice, 2008). In HIV research the generated knowledge is used to care for all regardless of whether one has participated in research or not. Only benefits are shared and not equally but burdens are mostly carried by the research participants. However the ethical aspect here is that the participants of research should benefit from the knowledge generated. To attain justice in developing countries through sponsorship of developed countries is hard; (Nuffield Council on Bioethics, 2004). Some respondents expressed mixed experiences with collaborative research with partners. The researchers expressed that they existed markedly disparities between them and partners from developed countries in terms of funding and experiences. There is lack of level playing ground between the collaborators and local researchers. This leads to challenges of attaining justice for research participants for the local researchers are limited in decision making on the way forward in a research process.

When the study come to an end it may be a challenge for research participants to get trial drugs for there are not locally manufactured. Other respondents had different views, expressed that collaborative research was very supportive and cleared several obstacles of carrying out research in the local setup with limited funds. For collaborative research to attain justice for research participants the PI must effectively play his role and ensure that the MOU is implemented to the letter. As a developing country a lot has been achieved through collaborative research including human resource and infrastructure development for research. However more needs to be done especial for participants who are not sure of what will happen after the study. They also cannot afford the drugs which are developed out of their participation and even the once being given during the study. The stakeholders need to put in place structures to uphold the principle of justice for research participants during and after research process.

It is important for researchers to develop a global state of mind on the issue of capacity development; (Benatar, Daar and Singer, 2000). This gives researchers a wide scope for developing adequate research capacity from various research backgrounds worldwide. Researchers on the local platform appreciated the idea of globalization of research activities as advocated for by (Benatar et al. 2000). They recognized the let down by limited funds. The learning institutions, the health service provision institution and the government offers limited recourses.

There is inadequate intellectual capacity and funds for infrastructure and human resource to push the local standards to the same platform with developed partners. The implications here would be to continue depending on the partners who may favor to foster their agendas and not the local needs in research. The situations at our institutions encourage this state of affairs making justice to remain an issue in the research activities. The realization of this can help in developing this mind set of global research for it makes the stakeholders to target and finance the establishment of appropriate local structures for research.

It was important to note that researchers appreciated the significance of understanding the community being researched. It was expressed by (Emanuel et al, 2004 and Marshall and Rotimi, 2001) that collaborative partnership between the researchers and the community is the key to ethical research. Understanding the dynamics of the community is the foundation to the community entry. The reception and therefore co-operation one will be accorded will depend on the community entry strategy. Researchers at AMPATH expressed how working with the community was a challenge. Some expressed that some of the community members were uncooperative requiring communication through proxy (through their leaders). Some of the community members alluded to being used by the researchers (*munatutumia*). Those are indication of a relationship that requires improvement to foster smooth interaction between the researchers and the community members. If there is a challenge on cooperation then there are chances of justice missing for research participants. Education, need assessments and feedback to the community could improve this interaction levels. Involving the community throughout the research process as suggested by; (Marshall and Rotini, 2001) could give a valid partnership. This will help to undo the myth that researchers use the community members as means to achieve certain ends. Researchers at AMPATH expressed that it requires a lot of effort to accomplish an ethical research process.

Following the implementation of research there are expected outcomes. According to (CIOMS, 2002) and (UNAIDS, 2000) effective trial drugs should be made available to participants. The situation at AMPATH is that most of the research participants are economically weak. They cannot afford those drugs given during trial when the study ends. The manufactures of those drugs are found in faraway locations and if the drug is effective there are issues of patent and therefore it cannot be manufactured locally by any other companies. It was expressed by one respondent that it was a challenge for the participants to benefit from what they helped to generate when the study ends because of affordability. This is justice issue therefore ethical issue (Marshall and Koenig, 2004). The essence of research is that knowledge generated from research should benefit all who need to benefit.

5.3 Challenges of attaining the principle of justice in HIV research at AMPATH.

The challenges of fulfilling the principle of justice to research participants by researchers in carrying out ethical research process are discussed. Under this theme there are two subthemes all about challenges encountered by the researchers and capacity building for research those subthemes are related and therefore they will be discussed together.

The researcher has a big responsibility of ensuring that the research participants benefit from research activities, (Family health International, 2009). Justice for participants should be focused on improved health and health care, ongoing care that is non-study specific, economic activities and sharing of financial rewards from research, (Emanual, Wendler and Grady, 2000). Researchers' challenges revolve around their attitude that IREC is an obstacle to their progress in research process and challenges of low income country communities which include poverty, illiteracy and culture of handouts to the community members.

Capacity building for research which includes education for researchers is a challenge in resource limited communities, (Nehinda el at, 2003 and Lavery, 2004). Underdeveloped capacity leads to the need for incentives to have people function in certain remote areas (Farmer, 2003). If incentives are missing the researchers in these areas may be challenged on how to handle ethical research process ending up not applying justice to research participants. Some researchers expected IREC to educate them on what IREC consider on approving research proposal which is the researcher's responsibility to find out before engaging in research activity. This creates an impression that IREC is not supportive enough which may not be the case and this could be handled by attitude change by researchers. Some researchers expressed that they do not do enough after attaining research knowledge due to other responsibilities – clinical work. Researchers' attitude change should help them to balance between research and clinical work.

Most of these research activities are done in remote areas where the population may be classified as vulnerable and the surveillance structures are weak. Community members who are economically strong and are literate are able to handle their health situation better. It is on this ground that researchers will come in conduct more with illiterate and poor people during their research activities. It is a challenge to judge the research process on the ground of justice. It requires wisdom and integrity by researchers to achieve justice in the developing countries. Research is viewed as an international economic force with a lot of benefits to all involved, (Marshall and Koenig, 2004). The researchers are seen by community members to be bringing material benefits of research and therefore demand for handouts. It is trick from the beginning for the researcher to come up with selection of participants in the study for all wants to participate so that they do not lose out on the benefits, (Marshall and Koenig, 2004). Without handouts the general view by the community is that they are being misused (*munatutumia*) and yet there exists events that require research activities within the community.

The government has not been supportive enough as expressed by all the respondents. Most of findings of research and recommendations originating from various studies have only been translated into policies to improve patients care at AMPATH and not other government health facilities as learned from one of the researchers. This denies the population from benefiting from research activities within the community which is a justice issue.

5.4 Conclusion

This chapter discussed the major findings of the study in line with the study objectives. This study adds knowledge on existing gaps although it is limited to researchers at MTRH Eldoret Kenya. Chapter six will present a summary of the study, the conclusion and recommendations.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.0 Introduction

This chapter presents summary of the findings, conclusions, recommendations and areas for future research on application of the principle of justice.

6.1 Summary of the findings

1. IREC research guideline documents have adequate information to facilitate application of the principle of justice in a research process.
2. Application of the principle of justice in the community could be influence by the level of poverty of the community members. This could determine the decision to consent to participate.
3. It has not been smooth for some researchers to interact with the community in applying the principle of justice in HIV research.
4. Challenges encountered by researchers in applying the principle of justice in HIV research: source of IREC requirements to approve research proposals, the attitude of researchers towards IREC as a regulatory institution, strategies for community entry during research process and the culture of handout expectations of the community members.

6.2 Conclusions

Researchers are knowledgeable about the principle of justice in ethical research process. However they may fail to apply the principle of justice in HIV research due to challenges associated with low income in the communities, lack of practical skills and researchers' attitudes. Poverty among community members makes them to expect hand-outs from researchers any time they have to be involved in research. Hand-outs could be considered as an inducement to participate which is unethical. The hand-outs may not have been budgeted for which makes the researcher's work very difficult for the researcher may not be having money to give out. Participation in research needs a personal decision by adults of sound mind. However in some communities leaders of the community and heads of house holders have to make the final decision about participating in research for their members. This is a challenge to the researchers who are not familiar with certain norms within the community of the study. This may lead to wrong community entry strategy which can result to interaction challenges within the community. Some of the researchers have bad attitude towards regulatory institution (IREC) expressing that it’s a hindrance to their work and this could not be justified. IREC guidelines for research are adequately documented on both SOPs and Reviewers Guide Forms.

In order to facilitate justice for research participants the researchers consider their interaction with the community members. There are various challenges encountered by researchers in applying the principle of justice in HIV research. Most of those challenges are related to personal attitude, infrastructure for research, level of poverty in the community and community entry strategies. The government through the ministry of Education has not offered adequate support for research activities by not allocating adequate budgetary funds. Without funds application of research ethics principles including justice is a challenge.

It is clear from IREC members and the researchers that justice for research participants cannot just be looked at from the point of view of having guidelines but there is need to look at the practical aspect of what goes on in the field. Learning virtue ethics supports researchers in upholding personal integrity in research activities. This will help researchers to remain ethical even without strong monitoring activities from the regulators of research.

6.3 Recommendations

There is need to train researchers on the skills of carrying out ethical research in specific contexts and sensitizes them on the role of IREC as a facilitator of ethical research.

It is important for researchers to understand community dynamics which is all about the community norms and expectation. This can lead to attaining cooperation from community members for the approach for interaction will be tuned to the expectations of the community.

6.3 Areas for further studies

There were various gaps in knowledge that emerged from this study. The identified area for further studies towards filling those gaps are;

1) To explore the experiences of the HIV research participants on the attainment of the principle of justice at AMPATH
2) The perception of the researchers on the role of the regulatory body (IREC) in HIV research

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APPENDICES

APPENDIX 1: IREC Approval

APPENDIX 2: Permission from AMPATH

APPENDIX 3: Informed Consent Form

Study Title: Exploring application of justice in HIV research at AMPATH- Moi teaching and Referral Hospital – Eldoret Researcher: *Johnstone Milimo Eyinda* (MSc. International Health Research Ethics candidate)

I am trying to learn more about the experiences of researchers of HIV on how they apply ethical principle of justice in research practice at AMPATH. The principle of justice is about ensuring reasonable, non exploitative and carefully considered procedures and their fair administration, fair distribution of the costs and benefits of a study among research participants. This principle is directly linked to issues of equality and fairness in determining who receives the benefits and who bears the burden of research. For example drugs used for clinical trials putting minimal risks to the participants should benefit them should they be found effective before they are rolled out to others regardless of the cost. The financial benefits gained from research activity should be to all involved, the participants for their time and goodwill and the research organizers for providing the requirements for research. Health facilities being used for research activities should be improved by the gains from research in terms of knowledge for better service and physical infrastructures. This health facility may undergo organizational and structural adjustments which may be costly and inconveniencing to their operations. Participant’s health should be taken care of beside the health events for research. During research process other non study health events may be discovered by researchers. Those health events may be taken care of for free by the researchers to show good will to community. Much of this research is done through answering questions based on; i) demographic data, ii) IREC guidelines on ethical research iii) the researcher's activities in fulfilling justice in research activities at AMPATH and iv) challenges encountered by researchers in fulfilling obligation of justice to HIV research participants.

I am asking you to participate in this discussion by sharing information on application of justice to participants in HIV research. This is because you fall within my study criteria of being an MTRH researcher at AMPATH or a member of IREC. It is your choice to take part in this study or not. This consent form gives information to help you decide. It explains the purpose of the research, what it involves, the risks and benefits, other options you have, and your rights as a participant. Please read this form carefully and make your choice. Be sure to ask me as many questions as you want.

Before you agree to take part in this research, kindly know that:

- Research is done to gain knowledge that may help people in future. You may benefit by gaining more understanding on the principle of justice but, you will not monitory benefit from taking part.
- Taking part in research is completely voluntary. You can choose not to take part. If you choose to take part, you are not obliged to answer all questions and you can quit at any time.
- No matter what you decide, now or in the future, it will not affect your relationship with the researcher.

The purpose of this study

The purpose of this project is to explore the experiences of HIV researchers from MTRH in fulfilling justice to HIV research participants at AMPATH consortium-

Eldoret. The researcher will also want to understand the researchers' challenges and how they interact with IREC guidelines on carrying ethical research.

This will involve

If you agree to take part in this project, here is what will happen:

- You will be asked to sign this consent form.
- I will give you a signed copy to keep.
- I will ask you to answer some questions

The possible risks

Physical Risks: this study does not involve any invasive procedures and thus no physical risks are involved.

Privacy Risks: There is no risk that someone could get access to the data I shall collect about you for I will keep it under key and lock. If those data suggested something serious about you, it will not be misused by anybody for it will only be accessible to me. The confidentiality of your data is important to me and I will make every effort to protect it.

How to keep information about you private

I will not require your name or anything else that could directly identify you from your information generated from the guide, however, the interview guides will have a serial number. I will not release any information that I get or create as part of this project to other parties unless with prior permission from you. Lastly, the results of the study published will not bear your name or any other form of identification.

The possible benefits

You will not benefit directly for taking part in this study. The main reason you may want to take part is to help me and other researchers get information that might benefit health researchers to improve practice in the future.

Costs or payments

There are no costs to you for taking part in this study. You will not be paid for taking part in this study.

The results of the research

Research Results: you will receive results about the study because at the end of the study a presentation will be made in a public forum or I will arrange for you to get the results.

Your option

Taking part in this study is entirely your choice. Taking part in the study means accepting to give your responses to questions raised in the interview guide to the best of your knowledge and belief. In answering the questions give answers that best present your views and, where applicable you give explanations when the need arises. You can change your mind at any time about taking part in the study. No matter what you decide, now or in future, it will not affect your relationship with the researcher. There will not be any penalty to you and you will not lose any benefits you would otherwise be able to get.

More questions

You should feel free to ask any questions about this study. Your questions should be answered clearly and to your satisfaction. For questions about the project, contact Johnstone Milimo Eyinda, the Principal Investigator, at 0727004941 during normal business hours. For questions about your rights as a research participant, write to Human Research Subjects Administrator, Institutional Research Ethics Committee at P.O BOX 4606, Eldoret or call +254 722475227 for assistance.

Consent statement

The researcher explained to me the purpose of the study, the procedures involved, and the risks and benefits. I have asked all the questions I have now, and I know who to contact if I have more questions.

I voluntarily agree that my information can be used in the study.

_____________________________ _________________________________

Signature of the participant Date

_________________________________ _________________________________

Signature of Person Obtaining Consent Date

Oral interview schedules

Before interview time the respondents of the study should have read the content of the informed consent form, agreed to participate in the study and completed and signed the informed consent documents. It should be confirmed at the beginning of every interview.

Section 2.1 Preliminaries

Thank you for agreeing to meet me today. My name is Johnstone Milimo Eyinda and I am a student in the department of Behavioral Sciences at Moi University. I am interested in understanding how guidelines for application of the principle of justice to research participants in health research are facilitated. The principle of justice is about ensuring reasonable, non exploitative and carefully considered procedures and their fair administration, fair distribution of the costs and benefits of a study among research participants. This principle is directly linked to issues of equality and fairness in determining who receives the benefits and who bears the burden of research. For example drugs used for clinical trials putting minimal risks to the participants should benefit them should they be found effective before they are rolled out to others regardless of the cost. The financial benefits gained from research activity should be to all involved, the participants for their time and goodwill and the research organizers for providing the requirements for research. Health facilities being used for research activities should be improved by the gains from research in terms of knowledge for better service and physical infrastructures. This health facility may undergo organizational and structural adjustments which may be costly and inconvenience to their operations. Participant’s health should be taken care of beside the health events for research. For goodwill the researchers could also be able to take care of other health event challenges within the community of the research activities for there could be financial capabilities.

I am requesting you to share with me your experiences at IREC or as a researcher in application of the principle of justice to research participants. The information that you will share with me will greatly help in understanding the influence of research guidelines and the researchers’ activities on the application of the principle of justice to research participants.

This discussion will assist in grounding my understanding of local, national and international health research guidelines and factors researchers and challenges they encounter in applying the principle of justice. This will enable me to deeply understand how IREC facilitate the researchers in application of the principle of justice to research participants. I am requesting that I take notes and audio-record our conversation so that I can be certain to remember all you tell me. If you have no objection, I kindly require your consent to begin this interview. Your name will not be recorded on any of these documents instead unique numbers will be used for identification. Anything you tell me will not be traced back to you individually. Everything you tell me will be kept completely confidential. You should understand that:-

-This is a research study

- You are free to participate or not as you choose

- Your participation will not cost you anything and I request you to volunteer your time and information. There will be no compensation.

- Everything you tell me will be kept completely confidential and your name will not be recorded anywhere that could be associated with what you tell me today.

If you are willing to participate in this interview sign for me the consent form.

Section 2.1.1: Oral interview guide for IREC members

Serial No…………

Background information

Age in years

20 to 30 ☐ 31 to 40 ☐ 41 to 50 ☐ 51 to 60 ☐ 61 to 70 ☐

Sex male ☐ female ☐

Occupation

Social behavioral ☐

Biomedical ☐

Period of service at IREC

1 year ☐

2 years ☐

Above 2 years ☐

1) From your experience at IREC; how will you rate the interaction between the IREC and researchers at AMPATH in the process of research?

   Probe – the interaction is focused around what?

2) IREC as an institution has been facilitating researchers in applying the principle of justice (fair distribution of burdens and benefits of research) to HIV research participants at AMPATH. How is IREC guided to facilitate researchers?

3) Talk about the difference between IREC guidelines and international guidelines for realization of justice for research participants.
4) Mention and explain some of the challenges that are associated with application of the principle of justice (fair distribution of burdens and benefits of research) that you have noted at IREC.

   Probe- how have you been overcoming those challenges?
5) Can you explain the main responsibility of IREC in application of the principle of justice (fair distribution of burdens and benefits of research) to HIV research participants?

Section 2.1.2 Oral interview guide for researchers

Serial No ………………..

Background information

Age in years

20 to 30 ☐ 31 to 40 ☐ 41 to 50 ☐ 51 to 60 ☐ 61 to 70 ☐

Sex male ☐ female ☐

Academic qualification

Certificate ☐

Diploma ☐

Degree ☐

Occupation

Medical doctor ☐

Nurse ☐

Public Health officer ☐

Behavioral scientist ☐

Others ☐

Period of service at AMPATH

1 year ☐

2 years ☐

Above 2 years ☐

The role of the researchers

1. Can you comment on the IREC procedure of reviewing a protocol to ensure application of justice (fair distribution of burdens and benefits of research) to HIV research participants?

   Probe –Mention explain any benchmarks considered by IREC to review and approve research proposals.

2. Prior to engaging with participants in your research activities, what preparation do you put in place to ensure that you apply the principle of justice (fair distribution of burdens and benefits of research) to the research participants in HIV research?

   Probe- Please explain on how you ensure that you implement an ethical research process.

3. Highlight on what you consider as your obligations to research participants during and after the health research process is complete to fulfill justice.

   Probe – please explain the benefits you will ensure that the participants get during and after research activities.

The challenges of the researchers

1. Please explain what you would consider to be the challenges you encounter in meeting your obligations to research participants within the community.

   Probe – briefly expound on obstacles that exist in the community in facilitating those obligations.

2. Mention and explain any challenges about the following;

a) attaining equity in collaborative partnership,

b) Local capacity building

c) Harmonization of international and local protocols for carrying out research process?

3. Please highlight on any challenges you encounter in applying the principle of justice (fair distribution of burdens and benefits of research) to HIV research participants at AMPATH.

   How do you overcome those challenges?

   Probe – the challenges to meet the focus for justice beyond approval of the study for research participants

APPENDIX 4: STUDY BUDGET

S/No.	**Item**	**Quantity**	**Unit Cost (KShs)**	**Total (K.Shs)**
1.	Printing interview guides and consent forms	35	15	700
2.	Airtime	6	1000	6000
3.	IREC fee		1000	1000
4.	Printing Proposal	6	100	600
5.	Data analysis	35	250	8750
6.	CD	10	20	200
7.	Spring files	6	100	600
8.	Box file	3	300	900
TOTAL				**18750**

APPENDIX 5: TIMEFRAME

This study lasted for 6 months, following IREC approval.

Time Frame

MONTH 1&2					
	Weeks – 1 to 2	Weeks- 3 to 4	Weeks- 5 to 6	Weeks- 7 to 8	
Pilot and revise measurement instrument	☆				
Recruit participants		☆			
Carry out interviews with IREC members			☆	☆	
MONTH 3&4					
Carry interviews with researchers at AMPATH	☆				
Carry interviews with researchers at AMPATH		☆	☆		
				☆	
MONTH 5 & 6					
Data entry	☆				
Data analysis	☆	☆			
Report writing		☆	☆		
Dissemination of findings				☆	

Appendix 6 :Data collection schedule

respondents	Names	category	Date of interview	Place
1	01-RI	IREC member	29/4/16	Office
2	02-R I	IREC member	10/05/16	Office
3	03- RI	IREC member	13/05/16	Office
4	04- RI	IREC member	13/05/16	Office
5	05-R I	IREC member	25/05/16	Office
6	01-RB	Behavioral researcher	16/05/16	Office
7	02-RB	Behavioral researcher	17/05/16	Office
8	03- RB	Behavioral researcher	23/05/16	Office
9	04-RB	Behavioral researcher	24/05/16	Office
10	05-RB	Behavioral researcher	30/05/16	Office
11	06- RM	Biomedical researcher	9/06/16	Office
12	07 -RM	Biomedical researcher	13/06/16	Office
13	08- RM	Biomedical researcher	15/06/16	Office
14	09- RM	Biomedical researcher	17/06/16	Office
15	10- RM	Biomedical researcher	21/06/16	Office
16	11- RM	Biomedical researcher	23/06/16	Office
17	12- RB	Behavioral researcher	8/8/2016	Office
18	13 - RB	Behavioral researcher	10/8/2016	Office
19	14- RB	Behavioral researcher	13/8/2016	Office
20	15 - RB	Behavioral researcher	14/8/2016	Office
21	16 - RB	Behavioral researcher	14/8/2016	Office