

The Experiences Of  
Researchers On  
Application Of The  
Principle Of Justice In  
HIV Research At  
MTRH AMPATH -  
ELDORET

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## ABSTRACT

**Background:** There is need to apply ethical principle of justice during research. Justice is doing what is morally right and proper treatment of persons. It is not easy to maintain justice in research in limited resource setting. The objectives of this study were to assess the IREC guidelines, examine the factors that AMPATH researchers consider and explore the challenges encountered by IREC members in facilitation of application of the principle of justice in HIV research. **Method:** Between June and August 2016 in-depth interviews were conducted using unstructured interview guide with 16 researchers from MTRH who worked at AMPATH and 5 members of IREC who were purposively selected to participate in a cross sectional exploratory qualitative study. Interviews were audio- recorded transcribed and content manually analyzed. **Results:** IREC guidelines were clearly documented and available. The researchers considered IREC requirements for proposal, how to engage participants in research and the knowledge of community members about research. IREC encountered challenges of lack of expertise in approving some research protocols, meeting timelines for feedback to researchers, in ability to monitor approved studies and researchers' attitude issues. **Conclusion:** IREC members and researchers are knowledgeable about justice in research. IREC's work could be compromised by financial limitations. Researchers are struggling with challenges associated with low income in the communities, their attitudes and lack of practical skills. Researchers need training on the skills of carrying out research in specific contexts and sensitize them on the role of IREC as a facilitator of ethical research.

**Keyword:** attitude, low income, expertise, justice, researchers, poverty, handouts, challenges

## 1. INTRODUCTION

### 1.1 BACKGROUND INFORMATION

For over 30 years the Human Immunodeficiency Virus (HIV) has been a big challenge to provision of health services all over the world. All sectors of human economical engagement have been affected by this epidemic. 1.6 million People had been infected with by the year 2012 and roughly 57,000 people died from HIV related illness (UNAIDS 2013) in Kenya.

Moi Teaching and Referral Hospital (MTRH) in Eldoret serving a population of over 5 million people and is one of the referral hospitals in Kenya. In response to HIV/ AIDS to support and provide care for HIV/AIDS patients the Academic Model Providing Access to Healthcare (AMPATH) was initiated in the year 2001. AMPATH structured its patient care programmes to help in diagnosis for HIV- related health events, research and teaching. 158,000 HIV infected adults and children have been enrolled in its satellite clinics in Western Kenya (AMPATH, 2014). Many health institutions and researchers have engaged in HIV/AIDS research and if they are no appropriate structures for regulation of those research activities the participants may be exploited by the researchers missing to apply justice.

The foundation of all regulations or guidelines governing ethical research with human participants is respect, beneficence and justice (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). The application of justice by the researchers towards the participants during ethical research process and is ensured by institutional research ethics committees (Pogge, 2003). For AMPATH ethical research process is regulated by guidelines from the Moi University College of Health Sciences and Moi Teaching and Referral Hospital, Institutional Research and Ethic Committee (IREC) which is an affiliate of National Commission of Science Technology and Innovation (NACOSTI).

In research where human participates both National and international guidelines emphasize primary ethical principles (respect, justice and beneficences and nonmaleficences) outlined in the Belmont's report on all research reviews should be followed, (Rice, 2008). There are various guidelines with wonderful attributes on ethical research however; the practical aspect of those attributes is missing in documentation, (Rice, 2008). There is a gap in knowledge on the practical implementation of those guidelines. Despite guidelines there has been debate at all 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).

Cultural contexts and social justice in relation to international research in poor communities is paramount, this improves existing guidelines and their application in research, (Council on Bioethics, 2002, 2005; Macklin, 2004). 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 collaborative partnership between the researchers and the community could be 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). Collaborative partnership with communities by researchers is a challenge due to cultural orientation of the researched communities (Lo & Bayer, 2003; Chandiwana).

To attain capacity for research in resource-poor settings is a challenge for the activity 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 researchers have to plan, organize and implement ethical research process through the financial assistance from the research partners which are not easy to come by.

It was not clear what the international standards of care in clinical trials in developing countries was, 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). Sustainability of treatment in research is a challenge to the researchers due to the state of the art therapy; (Angell, 1997, 2000; Lurie & Wolf, 1997; Rothman, 2000; Annas, 2001; Shapiro & Meslin, 2001).

Scientific research is viewed as an international economic force for individuals, institutions, communities and nations where the study is carried out; (Marshall and Koenig, 2004). This could pose a challenge to the ERC members to make right judgments on the issues of justice for research participants for fear of losing professional and financial benefits (Marshall and Koenig, 2004). Lack of resources, institutional capacity and institution goodwill are a major challenge to REC members, (Kruger, Ndebele and Horns, 2014). Conflict of interest and official duty of RECs members can be a challenge on their role in research due to their affiliation and socialization (Marshall and Koenig, 2004).

The purpose of this study was to assess the IREC guidelines, and identify requirements researchers consider and challenges IREC members encounter in facilitating ethical research activities to attain the principle of justice in HIV research at AMPATH MTRH. Specifically the objectives were to assess the IREC guidelines and identify the factors considered by MTRH researchers for application of the principle of justice to research participants in health research and identify the challenges encountered by IREC members in facilitating application of the principle of justice in HIV research at AMPATH MTRH. This could help in grounding structures for application of justice to research participants in Kenya and other resource limited countries. This could be through education and sensitization of IREC members, researchers and research participants.

## **2. METHODS**

### **2.1 SITE**

The study was conducted at AMPATH HIV clinic at MTRH and IREC in Eldoret town in Uasin Gishu county of Kenya. Over 100 biomedical and social behavioral researchers providing care and doing health research could give rich encounters of research experiences for this study.

### **2.2 STUDY POPULATION**

This study targeted researchers at AMPATH - MTRH in Eldoret to establish their experiences in application of the principle of justice to HIV research participants. The Researchers should have been involved in HIV research at AMPATH for one year and above. IREC members were also targeted to help in the understanding on how they facilitated researchers in attaining the principle of justice to HIV research participants. This ensured that both researchers and IREC members could provide accurate information.

### **2.3 TARGET POPULATION**

Researchers participating in HIV research at AMPATH – MTRH and IREC members

### **2.4 SAMPLE POPULATION AND SAMPLING PROCEDURE**

This study involved 16 researchers' respondents and 5 IREC members. The study had initially targeted 28 researchers and 4 IREC members. 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. After interviewing 4 IREC members saturation was reached and one more member was interviewed to confirm saturation. 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 we 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.

### **2.5 INCLUSION CRITERIA**

MTRH researchers taking part in HIV research and had been at AMPATH set up for one year and above and were willing 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.

### **2.6 EXCLUSION CRITERIA**

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

### **2.7 STUDY DESIGN**

This was a cross-sectional, exploratory, 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

establish 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.

## **2.8 METHODS AND INSTRUMENTS OF DATA COLLECTION**

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 IREC members encounter in facilitating the attainment of justice in research process were addressed. The IREC members and 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.

## **2.9 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 and 2 IREC members, 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.

## **2.10 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.

### **3. DATA ANALYSIS AND PRESENTATION**

#### **3.1 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 IREC members 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.

#### **3.2 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.

#### **3.3 LIMITATIONS OF THE STUDY**

This study involved a smaller number of IREC and HIV researchers. This was not representative enough for Kenya's research population. The study focuses on, the individual's insights own perspective and meaning of experiences. Consequently, this work is not generalizable beyond its current context. 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 an opportunity to share their understanding on the subject matter and the challenges they encounter.

### 3.4 STUDY VALIDITY AND RELIABILITY

To ensure that research question would be asked in the right way it was pretested through a pilot study. 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.

### 3.5 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. Participation was voluntary with the autonomy to withdraw from the study at any time. 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.

## 4. RESULTS

IREC review guides - There were no gaps identified in the guidelines that could lead to challenges of fulfilling the principle of justice to HIV research participants

This study involved 5 IREC members and 16 researchers, had initially targeted 28 researchers and 4 IREC members. 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. Saturation for the IREC occurred after interviewing 4 members but one was added to confirm the saturation. The distribution of the respondents was as illustrated below.

Table 1: IREC members from MTRH/CHS MU

Respondents	Age in years	Sex	Occupation	Period at IREC in years
01-RI	51 – 60	M	Non medical	8 years
02- RI	31 – 40	M	Medical	4 years
03- RI	31 – 40	F	Non Medical	3 years
04-R I	41 – 50	M	Medical	1 years
05-RI	51 – 60	M	Medical	7 years

Table 2: Demographic characteristics of researchers from MTRH/CHS MU working at AMPATH in Eldoret Kenya

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 six in number and behavioral researchers were ten. All the researchers had worked at AMPATH for more than two years.

#### 4.1 THEMES AND SUBTHEMES

Table 3: Organization and process of data analysis - Themes and subthemes

Themes	Subthemes
4.3.1 Ethical research guidelines	4.3.1.1 IREC research guidelines - local and international research guidelines - the guidelines 4.3.1.2 IREC and justice issues 4.3.1.3. challenges of applying the principle of justice – reviewers, financial, work and coping with challenges
4.3.2. Ethical research process to ensure principle of justice.	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. Barriers of attaining the principle of justice in HIV research at AMPATH.	4.3.3.1. challenges encountered by IREC as a regulatory body 4.3.3.2. challenges of capacity building for research

During this process of data collection the key points on IREC guidelines and requirements, what researchers consider and challenges IREC members encounter in facilitating ethical research activities to attain the principle of justice in HIV research at AMPATH MTRH were addressed. During the interview process the researchers were probed with both information from the guide and information they gave. Here are some of the quotes from those interviews.

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)

All the IREC respondents expressed strongly that there are no funds to facilitate monitoring of approved studies;

“...in my opinion monitoring of research is not adequately done by IREC for there are no adequate funds...”(R 03 - RI)

With regrets two of the IREC respondents expressed that monitoring has not been well implemented opening a window for exploitation for those being researched;

“...we do not have a good surveillance or monitoring structures in place... not able to go to the field and see what the researcher is doing ...we can only make sure that the proposal is ethically acceptable ...I am sure that there could be a lot of mal-practice that go on...”(R 04-RI)

They regretted that there was no structure at IREC for educating researchers;

“...IREC has no structures for educating researchers on the appropriate researcher practice for it is assumed that all who engage in research have undergone training on how to carry out research...”(R 05- RI)

Some reviewers take a very long time to review a proposal compromising IREC performance of feedback within two weeks as stipulated by the SOPs; this makes the researchers to perceive IREC as an obstacle to their progress.

“IREC depends on professionals who are not members of IREC to review research proposals for members are few– less control over them ... reviewers are overloaded with work which has no direct benefits.”(R 02 - RI)

...many reviewers are not experienced with drug trial so when you want to try something new there are no experts who can do the best review such a proposal pass easily.”(R 02 - RI)

One of the respondents expressed how work at IREC was challenging;

“...work at IREC is laborious, boring, a lot, poorly written and hard science to understand and which may not be interesting to the committee member looking at it.”(R 05- RI)

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)

## 5. DISCUSSION

The research guidelines used by IREC are universal and can be used on both local and international platforms for facilitating research activities. However there are challenges in putting in place some of what is stated in the guidelines. Structures for monitoring approved studies and training researchers on research ethics is not in place. From those guidelines IREC has formulated benchmarks for approving research proposals which some of the respondents expressed that they were not familiar with. Implementing what is proposed could be a big challenge if one doesn't understand how and why approval has been done. Not knowing may be a window for not applying the principle of justice to research participants.

It is unfortunate that some of researchers expected to be educated by IREC. Most of the researchers do not seek clarity from IREC due to the attitude that IREC is an obstacle to their research progress. According to Standard Operating Procedure for IREC part of their mandate is to educate researchers on ethics for research. However on the ground the researcher has to have been familiar with research ethics before getting into doing research. This is a gap that needs to be addressed so that to avoid researchers struggle to meet the expectations of IREC when approving research proposals. This will shorten the time for approval for proposals.

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). 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. It is through personal integrity that ethical research process will be achieved fulfilling the principle of justice to research participants.

IREC challenges revolve around lack of expertise in approving some research protocols, meeting timelines for giving feedback to researchers, inability to adequately monitor approved studies and researchers' attitude issues. In many places there are hardly adequate funds for research activities (Kruger, Ndebele and Horns, 2014). All IREC members and researchers pointed out that resources problem was a challenge that carrying out there mandates was hard. One of its noble mandates is to protect the research participants including even those for HIV research from harm. The means to do this is through thorough review of proposals and monitoring of the approved studies which have financial challenges as expressed by one of the members. It may be on paper that review is thoroughly done but there are grey areas mentioned by members as lack of some experts, conflict of interests and delayed reviews which may have justice implications. Delayed reviews could be due to use of professionals who are busy with their other responsibilities. Review is the gate for ethical research process and should it be done below the expected then justice for participants may never be attained for it will not be clear of what the participants expect from research process.

Monitoring is the protection tool, but no funds for IREC facilitation, implication of this is that it is likely that some injustice may be committed in the field during the research process. IREC members lamented that they have been reduced to relying on PI for their mandate of protection. It becomes challenging to relay on information given by some researchers for they expressed that they were not sure of what IREC looked for in their research proposals and this is an attitude issue.

Researchers' attitude 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. This was expressed by one of the members. Health events occur everywhere among community members. However, those community members who are economically strong

and are literate are able to handle their 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. 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.

## 6. CONCLUSION

Though IREC has adequately documented guidelines for research is struggling to attain its mandate due increased volume of work with shortage of human resources, lack of funds and researchers attitude. Monitoring of implementation of approved projects is lacking and this could compromise justice for research participants and the community. Both guidelines and practical aspect of what goes on in the field are important to attain justice for research participants.

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