A STUDY OF THE NEEDS AND RESOURCES OF HEALTH RESEARCH ETHICS COMMITTEES IN SOUTH WESTERN NIGERIA

Dissertation by

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DECLARATION

Submitted in partial fulfilment of the requirements for the degree of Master of Social Science, in the Graduate Programme in Psychology, University of KwaZulu-Natal, Pietermaritzburg, South Africa.

I declare that this dissertation is my own unaided work. All citations, references and borrowed ideas have been duly acknowledged. It is being submitted for the degree of Master of Social Science (Research Ethics) in the Faculty of Humanities, Development and Social Science, University of KwaZulu-Natal, Pietermaritzburg, South Africa. None of the present work has been submitted previously for any degree or examination in any other University.

Kolawole Solomon Oyedeji

(Signature)

6 June 2011

SYNOPSIS

Aim: To determine the resources and needs of local Ethics Review Committees in South Western Nigeria.

Method: This is a questionnaire-based descriptive study, where data was collected from the chair and administrators of eight Ethics Review Committees (ERCs) in South Western Nigeria.

Findings: This study found that six of the ERCs reviewed were established 5 years ago and 75% of them were registered with NHREC. Of the ERCs reviewed, 75% are aware of the national ethics code (NHREC code). The majority of these ERCs (75%) had professionals, including doctors and scientists, as well as laypersons and non-scientists as members. Meetings were held once a month and when needed for 37.5% of the committees, while 25% of the ERCs usually meet every 2 months. Only a third (37.5%) of the ERCs pay their members. The majority (87.5%) of the ERCs have standard operating procedures (SOPs) and review an average of 6–10 or 10 protocols per month. Most of the ERCs (87.5%) need research ethics training regarding risk-benefit assessment, scientific design and HIV vaccine trials. Half of the ERCs reviewed have funding and financial support and 50% charge a fee for reviewed protocols. All the ERCs have computers, office space and stationery, while 50% lack access to a library. None of the committees studied have a bank account and facsimile, while 50% do not have internet access, telephone and photocopy machines

Outcome: The majority of ERCs in South Western Nigeria have an adequate number of members, are familiar with international ethics guidelines and are registered with the NHREC. They also have adequate physical resources, but lack internet access and a library. Ongoing training of members is a challenge, as well as providing training programmes for new members and monitoring of research.

ABBREVIATIONS

Abbreviation	Full meaning
ERC	Ethics Review Committee
NHREC	National Health Research Ethics Committee
SOP	Standard Operating Procedures
WHO	World Health Organisation
CIOMS	Council for International Organisations of Medical Sciences
ICH	The International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use

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1. INTRODUCTION

There is increased research collaboration between industrialised and developing countries involved in research with human participants with the potential for exploitation of resource limited countries (Macklin, 2004). A partial cause for such potential exploitation may be due to weaknesses of Ethics Review Committees (ERCs) in resource limited countries (Falusi, 2007). These countries may fall short of promoting high ethical standards for human participant research, as they are poorly funded and lack properly trained staff (Macklin, 2004).

As more research is conducted in developing countries, ethical issues that reflect differences in cultures, politics, wealth, standards of care, individual and group rights, and priorities are surfacing with increasing frequency. The present ethical codes are not always sufficient for the broad new set of problems faced by those who fund international health research, members of Ethical Review Boards, government agencies, and researchers themselves.

Nigeria is the most densely populated African state with an enormous disease burden. Diseases such as HIV/AIDS, malaria, tuberculosis and other infectious diseases are common and have led to a large volume of human health research. This study was undertaken to determine the training needs and resources of ERCs in South Western Nigeria.

2. LITERATURE REVIEW

Biomedical research is important for health care improvement, especially clinical trials and genetic research, which are directed at curing, preventing, modifying and/or eliminating diseases worldwide (WHO, 2000). Biomedical research may include clinical trials, medical devices, medical radiation, surgical procedures, medical record data, use of tissue samples and body fluids, as well as epidemiological, social, and psychological investigations, and all involving human participants. Recent concerted efforts to address the challenges in Global Health (Bill & Melinda Gates Foundation, Dec 2008; Varmus et al., 2003), the 10/90 gap (Global Forum for Health Research, Jan 2008) and to achieve the United Nations Millennium Development Goals have contributed to an unprecedented increase in biomedical/health research involving humans internationally and in Africa. The high burden of diseases such as HIV/AIDS, malaria and tuberculosis in Africa has also contributed to this increase (Falusi, 2007). African populations are often therapy naïve and researchers may see this as a unique opportunity to gain knowledge regarding the efficacy of new drugs and or interventions (Emanuel et al., 2004). This has led to increased international collaborative biomedical research being conducted in Africa, resulting in an increase in the volume and complexity of protocols that ERCs in Africa have to review.

The risk of exploitation of research participants in developing countries may be increased as researchers may take advantage of lower costs and the potentially lax regulatory environment (Farmer, 2000). Biomedical research may pose serious risks to research participants and impact confidentiality of participants, their family and their communities. As such, it is of paramount importance to ensure the protection of

human participants, and ethics review is one component in the protection of human participants against harm (White, 1999; WHO, 2000).

In response to the increased conduct of biomedical research in Africa, the potential for harm and exploitation of research participants and the central role of ERCs in preventing this, there have been concerted responses to the ethical complexities of conducting research in developing countries and these initiatives have been aimed at increasing capacity for ethical review of health research in such countries (Effa et al., 2007).

2.1 Importance of ethics review committees and their functions

Research ethics is a vital aspect of the research process and assists in setting the standards and regulations for biomedical research (Barry, 1988). In the current era of globalisation biomedical research is conducted by international collaborative partners based in countries with different levels of economic development. Every country in which biomedical research is conducted should have a functional research ethics review system in place to ensure the protection of human subjects. Ethics review of biomedical research proposals should precede the actual research process as stated in the Helsinki guidelines (WMA, 2000).

The primary responsibility of ERCs is human subject protection, which involves protecting participants' dignity and rights, facilitating good research, managing conflicts of interest, providing ethics education for researchers, and ensuring the application of good clinical practice (WHO, 2000). Many African ERCs have to review large numbers of complex biomedical research but they lack sufficient

infrastructure, resources and expertise to do so (WHO, 2000). Furthermore, ERC membership is often not the primary role of its members, who have other full time employment.

In addition to reviewing research, ERCs should also monitor approved research (White, 1999). Although the basic requirements of ethics review could be met during the review process, the implementation of approved research protocols in the field, especially in developing countries, is bound to lead to practical challenges that are attributable to socio-economic factors (Emanuel & Pace, 2005; Lurie et al., 1994). Thus, ethical approval alone does not necessarily ensure protection of the safety and welfare of research participants throughout the research, hence the need for approved research to be monitored by ERCs.

Ethics review committees must also be independent of the sponsors, the investigators and any undue influence (Emanuel et al., 2000). They must have appropriate written standard operating procedures (SOPs) to ensure quality decision-making in ethics review, which should be in line with their national and institutional regulatory framework (45 CFR 46; 21 CFR 50). The ERC should be able to evaluate research designs, research-related risks and benefits, subject selection, informed consent, and other prescribed human participant protection issues (WHO, 2000). ERCs are also expected to provide third party review, thereby minimising conflicts of interest, protecting the welfare of research participants through attention to risks, benefits and informed consent and avoiding exploitation of vulnerable individuals and populations (Macklin, 2001). As a result, ERCs do not only protect the research subjects but the researchers too.

In addition, community engagement has recently been recognised as a critical step to address the health care needs of the community and as such demonstrates respect for communities as partners in research (Molyneux et al., 2005; Tindana et al., 2007). It is imperative therefore that there is community representation on ERCs to increase the knowledge and sensitivity to the community's needs and protection (Molyneux et al., 2005).

2.2 History of ERCs in developed countries

Prior to the 1980s many countries had no ethics review committees (Aksoy & Aksoy, 2003). ERCs were established because scientific journals required ethics committee approval of research before publication (Aksoy & Aksoy, 2003). Due to the growing public concern over the complexities of new biomedical technologies and their social, ethical and legal implications, ethics review committees were formed to positively assist in the research process (Kimura, 1989). Japan, for example, established ethics committees specifically for *in vitro* fertilisation research (Kimura, 1989). However, many countries faced several constraints, which included uncertainties regarding which ethical guidelines to follow, who to appoint as members, what procedures to follow and how to train their members (Kimura, 1989). A report on ethics review in the UK, documented the immense variation in membership, workloads and working practices of ethics review committees (Nicholson, 1996).

Before the implementation of compulsory ethics review, there were numerous cases of human abuses recorded in biomedical research. These include experiments on Jews, gypsies, and political prisoners by Nazi doctors during World War II, the 1932 Tuskegee syphilis study, the 1961 Professor Stanley Milgram obedience experiment,

the 1963–1966 Willowbrook study, the mid-1960s Laud Humphrey "Tearoom Sex" study (Beecher, 1966), the Human radiation experiments carried out in 1993 (Makhijani and Kennedy, 1994) and Pfizer's 1996 Trovan clinical trial in Nigeria (www.pfizer.com.,2007).

Responses to these abuses included the development of international guidelines, discussion documents and reports (Nuffield, 2002). The major international guidelines on research ethics include: The World Medical Association Declaration of Helsinki (1964), Council for International Organisations of Medical Sciences (CIOMS) International ethical guidelines for Biomedical research involving human subjects (2002), World Health Organisation (WHO) Operational Guidelines for Ethics Committees that review Biomedical Research (2000), Handbook for good clinical Practice (2002), The International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use (ICH) Guidelines for good clinical practice (1996) and guideline and choice of control group and related issues in clinical trials (2000), US Department of Health and Human Services Basic Policy for Protection of Human Research Subjects (2005), Directive on implementing good clinical practice in the conduct of clinical trials (2001), Council of Europe Additional protocols to the convention on Human rights and biomedicine concerning biomedical research (2004), UNESCO Universal Declaration on Bioethics and Human Rights (2005), Nuffield Council on Bioethics ethics of research related to health care in developing countries (2005).

All these major international guidelines include the following requirements: ethics committee approval, scientific merit, favourable risk-benefits ratio, informed consent, confidentiality and honest reporting of results (WHO, 2000).

2.3 ERCs in Africa

It is a requirement that all biomedical research involving human subjects must be reviewed by an independent Ethics Review Committee (ERC) (WHO, 2000; WMA, 2000). However a recent report indicated that about 25% of health-related studies in developing countries were not subject to some form of ethics review by an international review board, national ethics board, or ministry/department of health, which is of great concern (Hyder et al., 2004; WHO/AFRO, 2001). These findings have also led to concerns regarding the safety and well-being of the human participants. In response, there have been concerted efforts to establish and train ERCs in Africa to meet the growing trends in international collaborative research to ensure the safety of persons and communities participating in clinical research (Science, 2002; Weijer & Emanuel, 2000).

It is imperative to ensure the establishment of standards for ethical review and the evaluation of the performance of ethical review systems in developing countries (Marshall, 2007). In addition ERCs in all African member states must be trained, strengthened financially and provided with the resources and infrastructure to critically perform their duties.

The work of ERCs in Africa has been fraught with a number of challenges. The capacity of ERCs in developing countries to review research protocols is often influenced by the complex environment in which they operate. This is usually characterised by power inequalities between government, sponsors, and researchers and/or communities. This has invariably led to compromising ERC independence especially where it is difficult to challenge authority and debate

complex issues (Ofori-Anyinam, 2001; Rugemalia, 2001). Developing country ERCs may also lack transparency and conflicts of interest may be present (Loff, 2002). Limited local expertise, technologies and financial resources have been reported as major constraints to good ethics review (Nuffield, 2002) in these countries.

Although the majority of countries in Africa are reported to now have at least some form of ethical review process in place, (Kirigia et al., 2005; Milford et al., 2006) the operations of these processes are generally hindered by a combination of challenges, including scarcity of resources, inadequate training of members and poor staffing levels (Ikingura et al., 2007; Kirigia et al., 2005; Milford et al., 2006). For instance, a study on health research ethics review and needs of institutional ERCs in Tanzania showed that 49% of 45 respondents had not had any training in health research ethics review (Ikingura et al., 2007). Furthermore, a recent case study on the ethical review processes in a number of African countries identified inadequate training, inconsistent funding, and disproportionate focus on science in the review process, constraints in budget, multiple responsibilities of ERC members and the tendency of some ERCs to “rubber stamp” approvals in order to secure international funding as major challenges (Kass et al., 2007). Milford and colleagues also reported the extent to which limited resources available for ethics committees in Africa could affect preparations for HIV vaccine trials (Milford et al., 2006). In the study, membership, structure, and training characteristics of RECs in 13 African countries, as well as RECs' perceived training and capacity building needs were examined. The general finding is that African RECs view their capacity to review HIV vaccine trial protocols as “moderate to limited”, though the rating was more optimistic among committees that had experience reviewing such protocols. The overall reported

moderate to limited capacity to review protocols for HIV vaccine trials appears consistent with reported inadequate access to infrastructure and limited funding.

Another case study of 12 African ERCs showed inadequate training of committee members and shortage of resources to be some of the major challenges faced by the committees studied (Kass et al., 2007).

As a result, it is important that each country and institution where research is conducted should set a research ethics agenda aimed at protecting the dignity, rights, safety and well-being of potential research subjects and ensuring the highest attainable scientific standards within their territories.

2.4 Situation in Nigeria

Nigeria is a democratic state where human dignity, the achievement of equality and advancement of human rights are respected and protected under the 1999 Constitution. Specifically, Chapter II section 17 (2) (a) states that “every citizen shall have equality of rights, obligations, and opportunities before the law”; (b) “the sanctity of the human person shall be recognized and human dignity shall be maintained and enhanced”; (d) “exploitation of human or natural resources in any form whatsoever for reasons, other than the good of the community shall be prevented” (Kass et al., 2007).

This implies that all health research on both animals and human participants conducted in the country must be scientifically sound and ethical. As such, any study plan or protocol, proposed to be conducted in the country must be methodologically

rigorous, scientifically sound (in purpose and design), valid and feasible. Without validity, the research cannot generate the intended knowledge, cannot produce any benefit, and cannot justify exposing subjects to burdens or risks (Falusi, 2007; Farmer, 2000). Therefore, the ethical and scientific rigour of all research projects to be conducted in Nigeria is expected to be reviewed by a Nigerian-based ethical review committee (National Code for Health Research Ethics, 2011).

The onus is now on the local Institutional Review Boards/ Ethical Review Committees (IRBs/ERCs) to ensure human protection in clinical trials and other studies involving humans, by evaluating study plans *vis-à-vis* the presumed/claimed values of the interventions before approval.

It is also possible through the ERC data safety and monitoring committee (DSMC) to arrest harm as soon as it is noticed during the course of research. A competent ERC in the country should therefore be made up of well-trained members, with well-equipped secretariat (infrastructure) and possibly functional standard operating procedures (SOPs) that would ensure that there are measures in the design of the study that would include precautions, safeguards and alternatives that would reduce the probability of harm to the participants (National Code for Health Research Ethics, 2011).

However, in recent years, controversies have erupted concerning the ethics of biomedical research sponsored by wealthy nations and conducted in Nigeria, generating debate and many editorial articles (Barry, 1988; Farmer, 2000). The process of establishing new ERCs in Nigeria has been slow and existing ERCs often lack capacity to perform the adequate oversight role.

In Nigeria, the Pfizer-Trovan trial of 1996 caused concern over the quality of ethics review in Nigeria. Children in Kano suspected to have meningitis were treated without consent or knowledge that the treatment received was experimental, without proper protocol review, in collaboration with unsuspecting and inexperienced researchers (www.pfizer.com, 2007). This ethical controversy highlights the need to examine the process of ethics review in Nigeria, assess the needs, resources and capacity of ERCs in order to strengthen them and ensure optimal performance of ERCs and adequate protection of human participants (Alison et al., 2006).

In response to this and the paucity of information on the ethics review of ERCs in South Western Nigeria, this study will attempt to explore ethics review committees in South Western Nigeria to determine their physical and training needs, as well as how they might need to be resourced in order to reach optimal functioning.

3. RATIONALE

Ethics review committees are relatively new in Nigeria and formal evaluation of their functioning, capacity and experiences have yet to be conducted (Ashcroft & Pfeffer, 2001; Author Guidelines, 2006). This study was designed to evaluate whether ERCs in South Western Nigeria have adequate human and physical resources to review health research.

RESEARCH QUESTION

What are the resources and needs of ERCs in South Western Nigeria?

4. METHODOLOGY

4.1 Research aims

1. To identify the physical needs and resources of ERCs in South Western Nigeria.
2. To determine the training needs of the ERCs in South Western Nigeria.

4.2 Study Design

This was a descriptive study, using a questionnaire-based survey, where data was collected from the chair and the administrators of ethics review committees in South Western Nigeria.

4.3 Sample

All ERCs in South Western Nigeria were approached for inclusion in this study. The participants were selected purposively from the members' list of each ERC. Two members (the chair and the secretary) were selected per available ethics committee. This was to check the accuracy of responses from the chair's view in comparison with that of the secretary of the committee, since both of them were principal officers of the secretariat. This may also informally evaluate communication link at the ERC secretariats. It was a self administered questionnaire and the participants gave informed consent and completed the questionnaire anonymously. The following ERCs were included in the study:

Table 1: List of studied ERC in South Western Nigeria

1	Association for Reproductive and Family Health IRB	IBADAN
2	College of Medicine Unilag. Idi-Araba IRB	LAGOS
3	Olabisi Onabanjo University Teaching Hospital IRB	SHAGAMU
4	Orile Agege General Hospital ERC	LAGOS
5	University College Hospital/ University of Ibadan IRB	IBADAN
6	Lagos State University Teaching Hospital IRB – Biomedical	LAGOS
7	Lautech College of Health Sciences Ethical Committee IRB	OSHOGBO
8	Nigerian Institute of Medical Research (NIMR) IRB	YABA,LAGOS

4.4 Data Collection

Data was collected using a questionnaire based on a questionnaire designed and developed by the UNAIDS AAVP ELH group for their study regarding REC resources in Africa (see appendix 1) (Milford et al., 2006). The questionnaire did not request any identifiable information but documented the following demographic and basic REC information: training; procedures; regulating and following up on approved research; financial and material resources; and REC independence.

4.5 Data Analysis

The data collected was captured and analysed using SPSS. The completed questionnaires were analysed using descriptive statistical analysis methods

expressing the proportions, percentage, and frequency of responses to the questionnaire.

4.6 Ethics

Both the Nigerian Institute of Medical Research's Institutional Review Board and the University of KwaZulu-Natal's Faculty Ethics Review Committee approved the proposal. The questionnaires from the respondents were anonymous and the data generated did not contain any confidential information pertaining to the respondents. The results include aggregated data that cannot be linked to specific ERCs. Data was stored in the researcher's personal computer, designated for the study, which was password protected and only accessible by the researcher.

5. RESULTS

5.1 Demography and information on ERC

Sixteen respondents from eight ethics review committees (ERCs) completed the questionnaire (see appendix 1). The ERCs were institutional committees, of which two had existed for 10 years, four for nine years, and two for five years (Table 1).

Table 1: Demography and information on ERC

Characteristics	**Number of ERCs** (N=8)
Total number of ERCs interviewed	8
Total number of ERC respondents	16
Position of respondents on ERC	
-Secretariat (Secretary of ERC)	8
-Member of ERC	8
Status of ERC	
-Institutional	8
-National	0
-Regional	0
Years in existence of participating ERC	
-Up to 10yrs	2
-6–9yrs	4
-1-5yrs	2

5.2 Composition and Registration of ERCs with the National Health Research Ethics committee:

Four of the respondents reported that their ERCs had at least six members (2 ERCs), eight of them reported that their ERCs (4 ERCs) had up to 19 members while the remaining four (2 ERCs) reported more than 20 members (Table 2). Twelve (75%) of the respondents reported that their ERCs have doctors, scientists, lawyers, and laypersons such as community representatives on their committee. Four respondents reported that their membership did not include representation of all

these categories (2 ERCs). Twelve respondents reported that they were appointed by the management structures of the institution (3 ERCs). The other four respondents reported that their appointments were done based on ethics expertise (n=3) or by the head of department (n=1). The secretary and the member of an ERC differ in this case where the member felt the appointment was the head of department, whereas the secretary's response was by virtue of knowledge in ethics. The majority of respondents (75%) reported that their ERCs are registered with the Nigerian National Health Research Ethics Committee (NHREC), and are aware of the National Codes for health research ethics. Only six (37.5%) respondents reported that their ERCs forward their applications for approval to the NHREC and two of the respondents reported that their ERC only communicates with the NHREC after each of their respective meetings. All the respondents reported that their ERCs review local and international collaborative research while 87.5% agreed that they review HIV-related research (Table 2).

Table 2: Composition/Registration of ERCs with National Health Research Ethics Committee

Characteristics	Number of respondents (N=16)	Number of ERCs (N=8)
Number of membership		
At least 6 members	4	2
7–19members	8	4
>20members	4	2
Composition of Membership		
Doctors	12	6
Scientists	12	6
Lawyers	12	6
Laypersons	12	6
No distribution	4	2
Appointment of members		
By the management	12	6
By virtue of knowledge in ethics	3	2
Head of department	1	1
Registration with NHREC		
Registered	12	6

Not registered	4	2
Awareness of National ethics code		
Aware	12	6
Not Aware	4	2
Communications with NHREC		
Yes, forwarding application for national approval	6	3
Yes, after each ERC meeting	2	1
No	8	4
Type of research reviewed		
Ethical review of local research	16	8
Ethical review for international collaborative research	14	7
Ethical review for HIV research	14	7

5.3 Operations of the ERCs

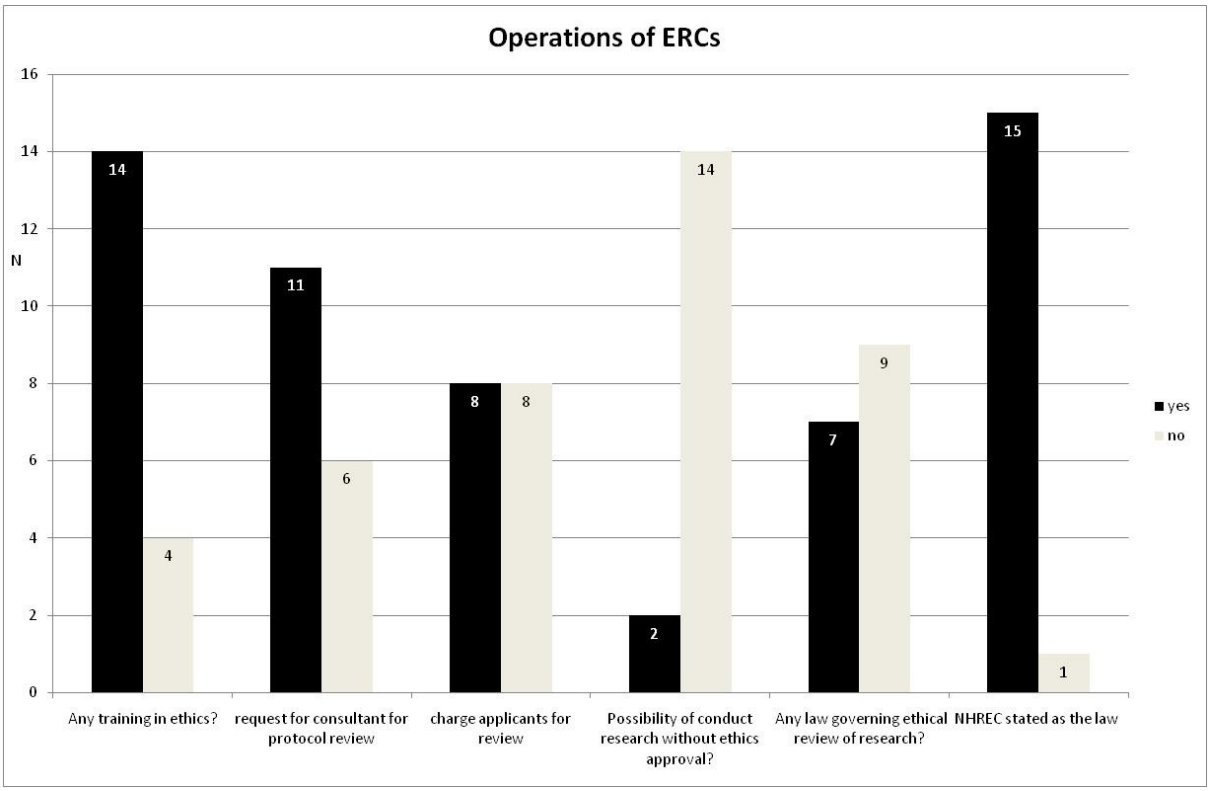
Six respondents reported that their ERCs meet once a month (3 ERCs), four indicated every two months (2 ERCs) and the remaining six respondents (3 ERCs) stated as occasion demands. Six of the respondents reported that their ERCs (3 ERCs) pay their members, while the remaining 10 reported that their ERC members are volunteers (5 ERCs). Almost all the respondents reported that their ERCs (93.75%) have written standard operating procedures (SOPs). One respondent differed from the secretary of his/her ERC that the ERC does not have SOPs. Half (50%) of the respondents reported that their ERCs (4 ERCs) review more than 10 protocols per meeting, five respondents agreed to review of six to 10 protocols per meeting, while three respondents said their ERCs review up to five protocols per meeting. Most of the respondents who were members of the ERCs differed from their secretaries on this question. This could be attributed to the fact that the members may not be privy to this data, which is compiled by the secretary at the ERC secretariat. Approval rate is 80% according to the majority of the respondents (n=14), while only two of the respondents reported 100% approval rate. All the respondents reported the major area of ethical review of their ERCs as research on adults (n=16). Other areas of ethical review included adolescents (10

respondents), children (6 respondents), while two of the respondents reported ethics review of research involving pregnant women and the disabled. None of the ERCs perform any ethics review on research involving prisoners and refugees (Table 3).

Table 3: Operations of the ERCs

Characteristics	Number of respondents (N=16)	Number of ERCs (N=8)
Meeting Frequency:		
Once a month	6	3
Every 2 months	4	2
As occasion demands	6	3
Payment to members:		
Provide payment	6	3
Do not provide payment	10	5
Administrative standards:		
Had standard operating procedures	15	8
Do not have standard operating procedures	1	1
Number of protocols received/reviewed monthly:		
Up to 5 protocols	3	2
6–10 protocols	5	3
>10 protocols	8	4
Approval of reviewed protocols:		
Mostly approved (about 80%)	14	7
All approved (100% approval)	2	1
Major areas of ethical review:		
Youth (Adolescent)	10	5
Children	6	3
Pregnant women	2	1
Adults	16	8
Disabled	2	1
Prisoners and Refugees	0	0

Figure 1: Operations of ERCs



Fourteen of the respondents agreed to have received prior training on ethics review procedure, while almost all the respondents (n=15) agreed to be aware of the law guiding ethics in Nigeria and this is stated as NHREC code. Fifty % of the respondents reported that their ERC charges applicants for ethical review while 11 of them agreed that consultants are sometimes requested to provide scientific expertise in the review of protocols.

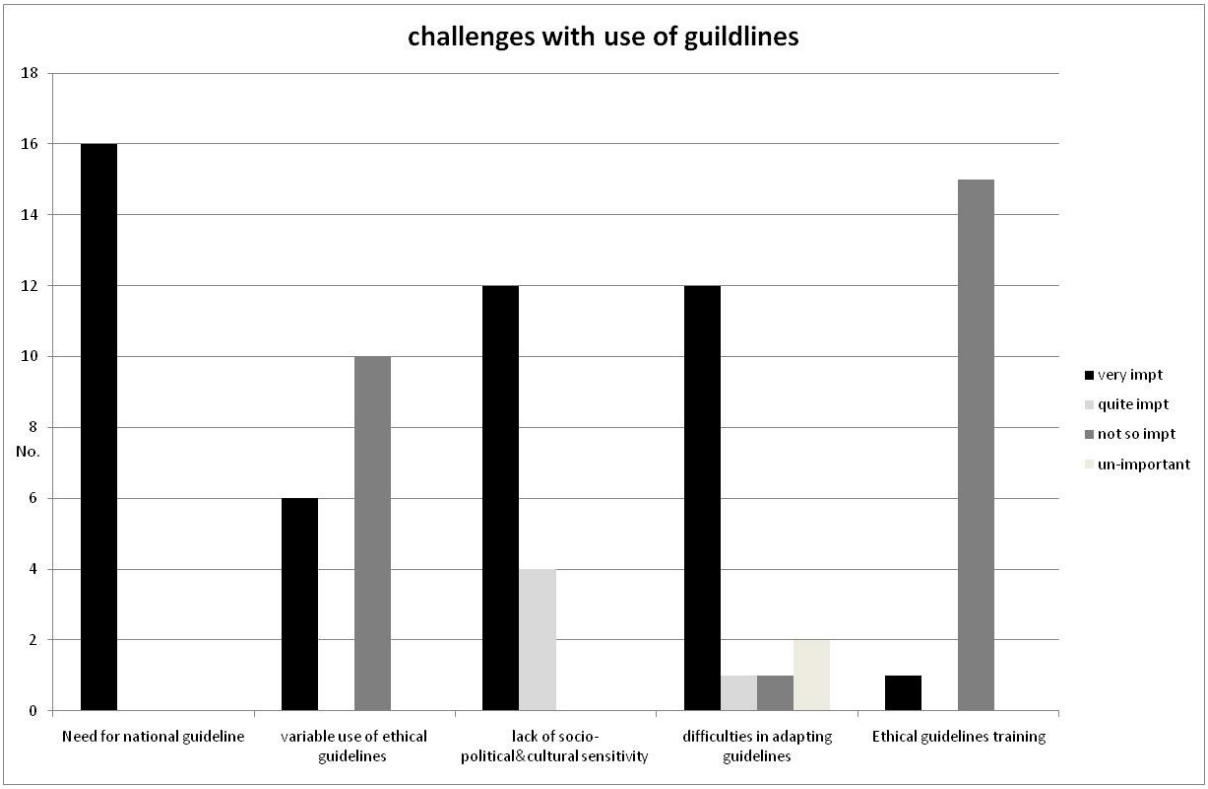
5.4 Use of guidelines

All the respondents (100%) reported that their ERCs use CIOMS, the Declaration of Helsinki and Belmont report (8 ERCs). Only eight (4 ERCs) reported using the UNAIDS (2000) ethical guidelines, while some respondents (4) also reported using other ethical guidelines such the NHREC code (Table 4).

Table 4: Use of Guidelines

Issues	Number of respondents (16)
Use of ethical guidelines:	
CIOMS	16
Declaration of Helsinki	16
Belmont Report	16
UNAIDS (2000) Ethical consideration	8
Others	4

Figure 2: Challenges with the use of ethical guidelines:



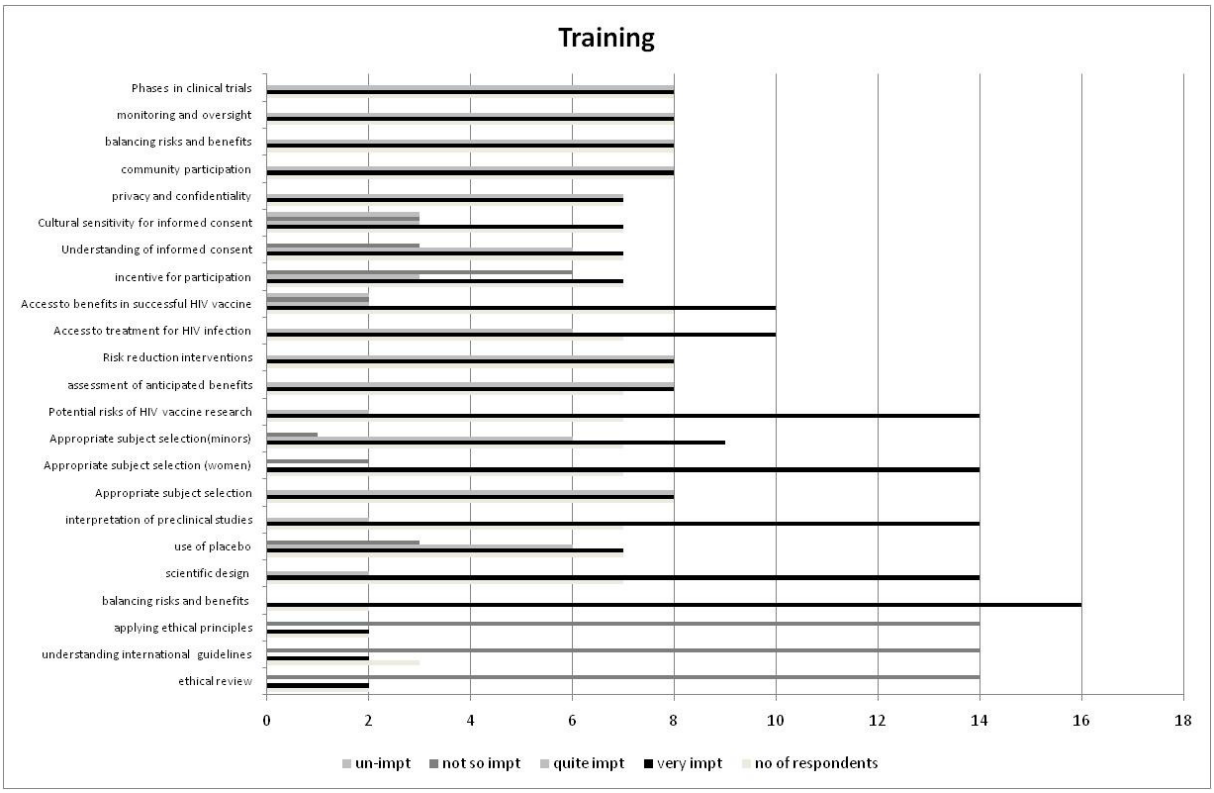
All the respondents considered the need to develop appropriate national, regional and institutional guidelines very important, while 75% of the respondents considered lack of sensitivity to local socio-political economic cultural context as the major challenge (Figure 2). Almost all the respondents agreed that the need for training on the use of the guidelines is not so important.

5.5 Training

All the respondents reported that the need for training in risk-benefit assessment of proposed research is very important, while 75% attest to being very important

training needs in scientific design issues in health research, the interpretation of pre-clinical studies, subject selection in vulnerable populations and determination of potential risks in HIV vaccine research. Seventy-five% of the respondents reported that training needs in ethical review, interpretation of international ethical guidelines as well as the application of ethical principles are not so important (Figure 3).

Figure 3: Perceived training needs of the ERCs



5.6 Challenges of the ERCs

The majority of respondents (93.75%) reported a lack of ongoing ethics training as a challenge. Eight respondents reported that their ERCs lack training programmes for their new members and almost all the respondents (93.3%) reported that there is no mechanism to monitor the conduct of research after approval (Table 5).

Table 5: Challenges of the ERCs

Issues	Number of respondents (N=16)
No Mechanism to monitor conduct of research after approval	14
Lack of training for new members	8
Lack of ongoing training for members on health research ethics	15

5.7 Resources

Half of the respondents (50%) of the ERCs studied reported that their ERCs have funding and financial support, while 93.5% of the respondents reported that their ERCs charge a fee for review of protocols. All the respondents stated that their ERCs have computers, office space, and stationery but half of the respondents reported that their ERCs do not have access to internet, telephone, photocopy machines and a library. However, all reported that their ERCs do not have a bank account and facsimile (Table 6).

Table 6: Resources

Available resources	Number of respondents(N=16)
Funding/financial support	8
Payment for ethical approval by participants	15
Office space	16
Computer equipment	16
Printer	12
Photocopy machine	8
Office furniture	16
Library	8
Typewriter	2
Stationery	16
Telephone	8
Facsimile	0
Email	16
Internet	8
Secretarial support	8
Bank account	0
Electricity	8

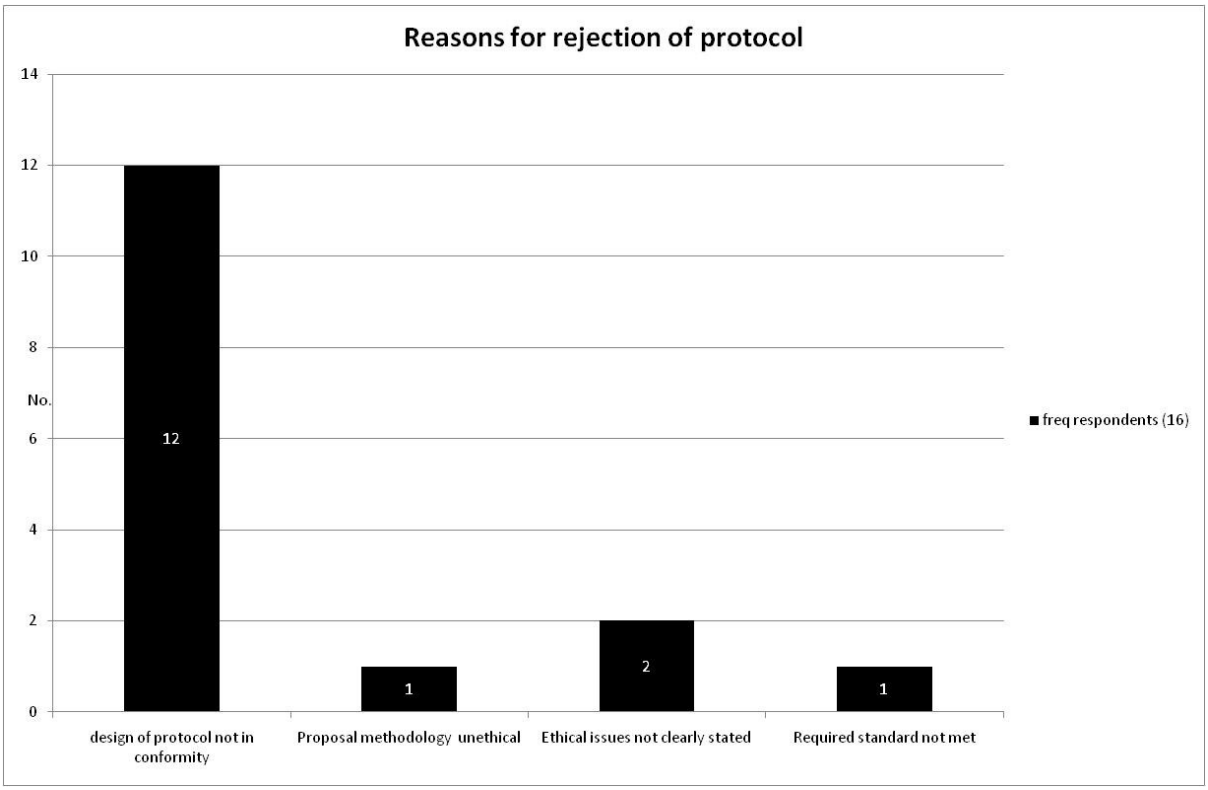
5.8 ERC independence

All the respondents, except one, reported that their ERCs were transparent in their actions (n=15). Only four out of the 16 respondents said that there is pressure from political power, while only one respondent reported pressure from sponsors (this respondent is an ERC member not a secretary). The majority (81%) reported that inviting investigators into ERC meeting could be beneficial (Table 7).

Table 7: ERC Independence

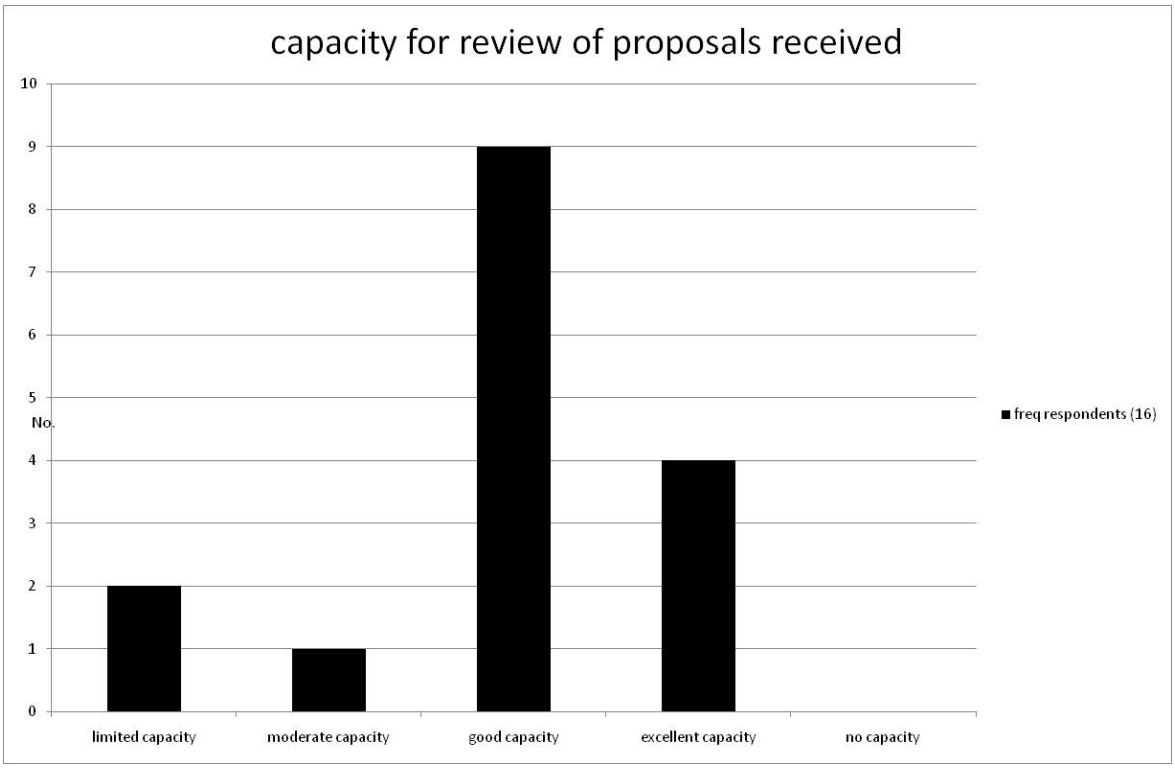
Issues	Number of respondents (N=16)
Transparency of ERCs	15
Pressure from political power	4
Pressure from sponsors	1
Unequal treatment of applicants	2
ERC independence in Nigeria	8
Invitation of investigators to ERC meetings beneficial	13

Figure 4: Reasons for rejection of protocol



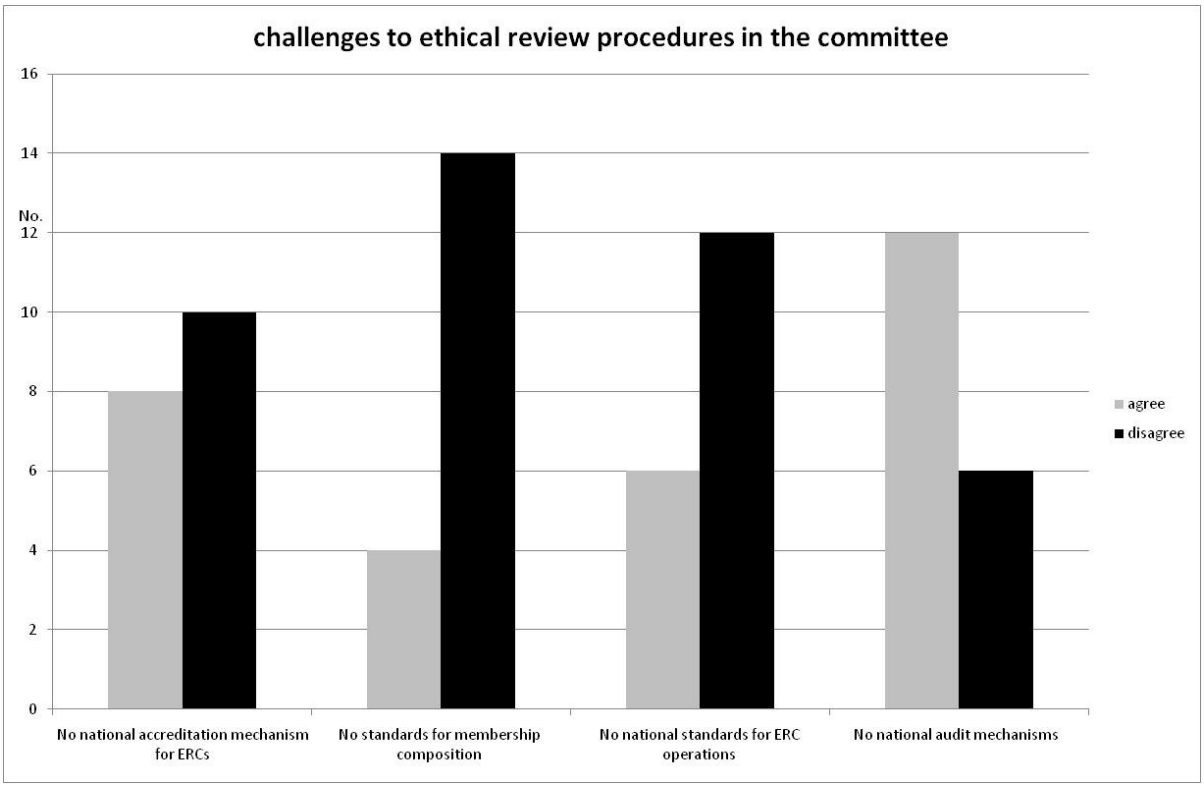
Most of the respondents reported non-conformity of the protocols as the main reason for rejection of these protocols (Figure 4).

Figure 5: Capacity for review of proposals received



Four of the respondents reported excellent ethics review capacity, while nine respondents reported good capacity. Two of the respondents agreed to have limited capacity, while a member respondent and the secretary of the same ERC disagree, the member reported moderate capacity for their ERC while the secretary reported good capacity (Figure 5). None of the respondents agreed that their ERC have no capacity to review proposals.

Figure 6: Challenges to ethical review procedures in the ERCs



No national audit mechanism was perceived by 75% of the respondents as one of the major challenges to ethical review procedure. Fourteen respondents however do not agree with the fact that membership composition is a challenge to ethical review in their ERC (Figure 6).

6. DISCUSSION

This study shows that majority of the institutions in South Western Nigeria have established ERCs that are registered with NHREC and aware of the national health research ethics code. This is a great improvement from previous times (Global Forum for Health Research, 2008; Rugemalia & Kilama, 2001; White, 1999) when the absence of ethics committees was common. The Nigerian National Code for Health Research, prepared in 2006, has as its main purpose the regulation of all health research involving human participants in Nigeria. A positive finding in this study was that 75% of respondents reported that their ERC is aware of the existence of the National Code for Health Research Ethics in Nigeria and that they are currently registered with National Health Research Ethics Committee (NHREC).

It is also encouraging to note that, most of these ERCs are reasonably equipped to provide review, and have diverse membership in terms of composition. Most of the ERCs have medical doctors, lawyers, scientists and laypersons representing the communities on their committees as corroborated in the findings of Ikingura et al. (2007) in Tanzania where she reported that the majority of the ERC members were biomedical researchers and others including medical doctors, social scientists, laboratory technologists, religious leaders, statisticians, teachers and lawyers.

This is in fulfilment of WHO operational guidelines on the formation of ethics committees that review biomedical research. The World Health Organisation publication Operational guidelines for ethics committees that review biomedical research (2000) states:

> Countries, institutions, and communities should strive to develop ECs and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of ECs at the national, institutional, and local levels that are independent, multi-disciplinary, multi-sectorial, and pluralistic in nature. ECs require administrative and financial support (WHO, 2000, p. 2).

This will gradually enhance protection of human subjects in health research, considering the number of ERCs in South Western Nigeria alone. This is also an improvement over the findings of Nyika et al. (2009) who reported that membership is still problematic for some ERCs in sub-Saharan Africa, with some having as few as three members and others 19 or more. The major reasons cited for the wide variation in membership include unwillingness of potential members to participate in the committees over and above their normal duties and the lack of compensation for the costs incurred in attending ERC meetings. These issues need to be addressed if ERCs are to function properly.

As documented in this study, many ERCs in African countries lack expertise in monitoring and evaluation research, which impedes research undertaking (Milford et al., 2006; Nyika et al., 2009). This lack of capacity to monitor research implementation means that the committees are unlikely to detect fraudulent practices by researchers. There is currently no effective monitoring process in place in most of the ERCs studied. This has similarly been reported in Tanzania (Ikingura et al., 2007; Nyika et al., 2009) and the United Kingdom (Pickworth, 2000). Ikingura et al.

(2007) reported that the current monitoring process of ERCs in Tanzania is largely confined to collecting progress reports and reviewing changes in protocols without formal study site visits for proper monitoring. The limited ability of ERCs to provide oversight of approved studies negates the whole objective of protection of research participants (Pickworth, 2000). It should be mentioned that harm to participants could happen intentionally and/or inadvertently, hence the need to continue working with researchers during the implementation of protocols. Thus, if these ERCs are to be gatekeepers for health research, sufficient efforts should be made to ensure that capacity to monitor research activities is maximised.

Training of committee members emerged as the greatest need of the ERCs in this study whereas training on joining the ERC is also necessary to acquaint new members with the ethical review process. Continuing training is critical to keep the committee members abreast of new developments in the health sector that could change the nature of ethical issues or lead to new ethical issues emerging.

According to the findings of Milford et al., (2006) in a similar study" RECs have an underlying need for sound ethics training. While there is a need for ethics training applied to HIV vaccine trials, generic ethics training needs could also be addressed by ethics initiatives and sponsors of ethics training programs" the majority of the ERCs studied reported a lack of adequate training of members to justifiably carry out their functions effectively. Respondents emphasised the importance of training to boost the capacity of their members for effective participation and review of protocols (Emanuel et al., 2004; Varmus et al., 2003; White, 1999). Training in balancing the risks and benefits of proposed research was identified as the most pressing need of the ERCs in this study, a finding reported before regarding studied African ERCs

(Ikingura et al., 2007; Kass et al., 2007; Nyika et al., 2009). Kass et al. (2007) reported that two of the 12 ERCs studied had members with no training at all, while those that had training acquired it through workshops and possibly such training is not elaborate.

Despite this, most of the ERCs studied have written standard operating procedures and provide payment to their members and also charge investigators for review of their protocols. This is similar with the findings of Kass et al. (2007) who highlight that before ethics review committees can operate effectively, transparently and independently they must be able to strive towards self-reliance (Kass et al., 2007). This could be achieved mainly through levies; the committees could charge for ethical review and oversight of health research as was reported by some ERC members who participated in this study. Ikingura et al. (2007) in their findings reported that the National Health Research Ethics Review Committee (NHRERC) in Tanzania requests ethics review fees from investigators regardless of whether it is a commercially sponsored proposal or not, which was also the case for ERCs in South-West Nigeria. However, they also reported that ERC members were not paid for their services, as found in this study, although some of the ERCs studied pay their members. It is worth noting that there is little or no international guidance regarding the funding of ERCs. Potential sources of funding could include governments, universities/hospitals, and fees for reviewing protocols; hence the observation in this study that about half (50%) of the ERCs charge fees for protocol review.

However, the ERCs in South Western Nigeria face some challenges that may have impact on good ethical review such as inadequate funding, lack of some resources

such as libraries, no bank account for suitable accountability, no facsimile for faster communication. It is good to note that many of these challenges described here are not unique to ERCs in South Western Nigeria only but also common to African ERCs as well as ERCs in wealthier countries too. The latter have heard criticism about inadequate funding, staffing, and even training of committees (Bell et al., 1998; De Vries & Forsberg, 2002). However, ERCs in developing countries, inevitably feel these needs more acutely. Further, additional challenges may arise from resources being limited and factors affecting the independency of the ERCs such as pressures from political power and sponsors from developed countries.

In conclusion, the above discourse according to Milford et al., (2006) depicts that despite the highlighted constraints, the ERCs in South Western Nigeria can conduct review of health research proposals, but there is a need for other interventions apart from training per se that would assist RECs in their core business of protocol review. These include ensuring that RECs have mechanisms for ongoing monitoring of approved protocols, assistance to negotiate with institutions regarding financial support for the REC, support to manage pressure from sponsor institutions, and assistance with developing appropriate national ethical guidelines for HIV vaccine development.

6.1 Limitations

Not enough members per ERC participated which may lead to bias. ERCs situated in regions that are better equipped in general and therefore may not reflect the true picture of shortage of resources or dearth of training in the remaining part of the country

6.2 Recommendations for future research

Further works needs to be done to study the ethics review process in the ERCs studied, using qualitative study design. This will enhance the evaluation of these committees in meeting international ethical standard of review procedures and the ethics review of international collaborative research. This study is limited to South Western Nigeria and should be extended to other geopolitical zones in the country to compare data. This process can assist in determining the training and other resources that will improve ethics review in Nigeria.

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APPENDICES

APPENDIX 1:
QUESTIONNAIRE[43]:

UNIVERSITY OF KWAZULU-NATAL
SCHOOL OF PSYCHOLOGY
SOUTH AFRICAN RESEARCH ETHICS TRAINING INITIATIVE (SARETI)

Title of Study:

RESOURCES AND NEEDS OF HEALTH RESEARCH ETHICS COMMITTEE IN SOUTH WESTERN NIGERIA

Date

Dear [Chairperson] / [REC Member],

You are invited to participate in the above research study which has been designed to determine the resources and needs of the RECs in South Western Nigeria. You will be asked to complete the attached questionnaire and it will take you 30minutes to complete. This questionnaire is adapted from UNAIDS –African AIDS Vaccine Programme(AAVP), School of Psychology, University of KwaZulu- Natal, identifying resources and needs of Research Ethics Committees in Africa with their permission. The aim is to identify the capacity and needs of the Ethics Review Committee, of which you are a member. The information generated from this survey will not necessarily provide direct benefit to you, but will probably help to identify the needs of the ethics review board that will enhance the ethics review process.

This survey is in partial fulfilment of my degree in Master in Social Science (Health Research Ethics) at the University of KwaZulu-Natal.

The study will not disclose any confidential information pertaining to the respondents and their RECs. The gathered data shall only be used for the purpose of the dissertation of the Master degree and academic publication. However, the information can be used for the capacity development of the RECs in South Western Nigeria or to formulate policies for improved ethics review in Nigeria.

Your decision to participate is voluntary. You are free to decline to participate in this study, or to withdraw your information, at any time.

Before you complete the questionnaire, please ask questions on any aspect of the study that is not clear to you. If you have any additional questions later; contact Dr KS Oyedeji (+2348025187261).

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Signature Date

It will be appreciated if the completed questionnaire can be returned to

Dr Kolawole Solomon Oyedeji.
Address: Nigerian Institute of Medical Research (NIMR),
6, Edmond Crescent, PMB 2013, Yaba.
Lagos, Nigeria.
Tel: 08025187261
Fax: +27865192768 (faxtoemail).
E-mail: kolaremi95@yahoo.com

Should you have any further queries regarding this research, please contact the chairman NIMR-Institutional Review Board, at the address given below.

Dr PU Agomo

Nigerian Institute of Medical Research (NIMR),
6, Edmond Crescent, PMB 2013, Yaba.
Lagos, Nigeria.
Room 207, Biochemistry Division, Research Block
Tel:+2348039297301
Fax:+23413425171
Email:nimr_irb@yahoo.com

Yours sincerely,

ETHICS REVIEW: CAPACITY AND NEEDS

Please complete the following details and return to Dr Kolawole Oyedeji at:

Address: Nigerian Institute of Medical Research (NIMR),
6, Edmond Crescent,
PMB 2013, Yaba.
Lagos, Nigeria.
Tel: 08025187261
Fax: +27865192768 (faxtoemail).
E-mail: kolaremi95@yahoo.com

Questionnaire

A Demographic and basic REC information

Please complete the following information.

**Completing your name and position is optional.*

Please complete the details of your ethics committee in order that capacities and needs of individual committees can be identified for potential development of training programmes.

Gender			
Position:			
Ethics Committee Name:			
Collaborating Institution (wherein committee is housed):			
Postal Address:			
		Region:	
Physical address of REC:			

		Region :	
Tel (with area code):	( ) ( )	Fax :	( ) ( )
E-mail address:			

Is this research ethics committee (*delete answer which does not apply)*	National	Regional	Local / Institutional

Please tick the appropriate answer (1=yes; 2= no; 3=don't know (DK)):

1. After conducting ethical reviews on the proposals do you inform the national HREC on the decisions **(1) Yes (2) No (3) DK**

2. Do you report to the national HREC in order to receive national approval for the proposals **(1) Yes (2) No (3) DK**

2a. Is your REC registered with the national HREC **(1) Yes (2) No (3) DK**

2b. Is your REC aware of the new national code for health research ethics (2006) **(1) Yes (2) No (3) DK**

3. When was this REC formed? (Year) :_____

4. How many members are presently serving on the REC? _____

Eg	***For example (if the appropriate answer is yes):***	**(1) Yes ✓**	**(2) No**
5.	Has your committee been involved in ethical review for local research?	**(1) Yes**	**(2) No**
6.	Has your committee been involved in ethical review for international collaborative research?	**(1) Yes**	**(2) No**
7.	Is your ethics committee likely to be involved in ethical review of HIV vaccine trials?	**(1) Yes**	**(2) No**

8a ***Please Choose one by a tick***

From the list below please indicate how you became a member of the REC

(1) representing a community
(2) a scientist in your organisation
(3) a medical doctor
(4) representing a specific professional organisation e.g. lawyer
(5) member of secretariat (chair/secretary/administrator/recorder)
(6) interested in ethics, willing to devote the necessary time and effort
(7) other, please specify_____

8b	Were you nominated/appointed by: 1) the management; 2) your organization; 3) automatically being head of Dept; 4) having taken an ethics course/workshop; 5) other, please specify_____
8c	***The following questions (8c-8g) are aimed at Secretariat members*** ***Please choose by a tick*** How many proposals does your committee receive per month?.....
8d	***You may choose more*** Do you review proposals intended to do research with: 1) youth (adolescents) Yes No 2) children Yes No 3) prisoners Yes No 4) disabled Yes No 5) refugees Yes No 6) adults Yes No 7) Pregnant women Yes No 8) Others Yes No
	Is it always that all get approved? 1) all of them 2) some of them 3) Don't know
8f	Reasons for rejection …… …… …… …… ……

	Communication with the national HREC	**(1) Yes**	**(2) No**
8e	Does your committee have established means of communication with the National HREC		
8f	If the answer to **8e** is yes, ***(Please tick one or both)***		
	1) after each REC meeting		
	2) forwarding applications for national approval	**(1) Yes**	**(2) No**
8g	Does your committee receive guidance on ethical review?		

B Training

Please read **all** the questions in this section before answering.

	Please tick the appropriate answer:				
9	Do you think your committee have capacity to review all the proposals received?				
	(1) No capacity	**(2) Limited capacity**	**(3) Moderate capacity**	**(4) Good capacity**	**(5) Excellent capacity**
10a	Have you received any training in ethics or ethics review of health research proposals **(1) Yes (2) No**				
10b	What are some of the training needs do you think your committee members may find most useful? **(*Please indicate which ones by a tick*)** 1) Ethical review 2) Understanding the International Ethical Guidelines 3) Applying the ethical principles 4) balancing the Risks and benefits of proposed research 5) others (specify)				

11	**Please indicate whether training on the following aspects are/might be important for your committee:** ***Please rate by marking the appropriate answer in the corresponding space:***	**(1) Very Important**	**(2) Quite important**	**(3) Not so important**	**(4) Un-Important**
Eg	**If the appropriate answer is "very important":**	✓			
11a	Scientific design issues in health research proposals.				
11b	The use of placebo controlled trials.				
11c	Identification of ethical issues arising from involving communities				
11d	The interpretation of pre-clinical studies.				
11e	Determination of appropriate subject selection in vulnerable populations.				
11f	Determination of appropriate subject selection with regards to women.				
11g	Determination of appropriate subject selection with regards to minors.				
11h	Determination of potential risks of HIV vaccine research.				

11i	Assessment of anticipated benefits.				
11j	Provision of appropriate risk reduction interventions.				
11k	Provision/access to treatment for HIV infection.				
11l	Post trial access to benefits e.g. successful HIV vaccine.				
11m	Incentives for participation.				
11n	Assessment of understanding for informed consent.				
11o	Assessment of cultural sensitivity for informed consent.				
11p	Privacy and confidentiality.				
11q	Community participation.				
11r	Balancing of risk and benefits of proposed research.				
11s	Monitoring and oversight.				
11t	Determinations to run phases (I, II, III) in a country or community.				

Please mark the appropriate answer (1=agree; 2=disagree):

12	**The following issues are challenges:**		
12a	Lack of training for members in health research ethics.	**(1) Agree**	**(2) Disagree**
12b	Lack of ongoing training for members in health research ethics.	**(1) Agree**	**(2) Disagree**
12c	Inadequate ability to monitor approved protocols.	**(1) Agree**	**(2) Disagree**
12d	Other (please specify): _____ _____		

C Guideline use

Please read **all** the questions in this section before answering.

13	**Which of the following are challenges to the use of *ethical guidelines* in your committee? *Please rate by marking the appropriate answer in the corresponding space:***	**(1) Very Important**	**(2) Quite important**	**(3) Not so important**	**(4) Un-important**
E.g.	**If the appropriate answer is "very important":**	✓			
13a	The need to develop appropriate national/institutional/regional ethical guidelines.				
13b	Variable use of ethical guidelines across committees within the country.				
13c	Lack of sensitivity to local socio-political-economic-cultural context.				
13d	Difficulties adapting international guidelines to local conditions.				

13e	Other (please specify): _____ _____ _____			
	Please mark the appropriate answer (1=yes; 2=no, 3=don't know (DK)):			
14	**Which international ethical guidelines does your committee use to review biomedical/ health research?**			
14a	CIOMS (Council for International Organizations of Medical Sciences)	**(1) Yes**	**(2) No**	**(3) DK**
14b	Declaration of Helsinki (1964, 2000)	**(1) Yes**	**(2) No**	**(3) DK**
14c	Belmont Report (1979)	**(1) Yes**	**(2) No**	**(3) DK**
14d	UNAIDS (2000) Ethical Considerations for HIV Preventive Vaccine Trials	**(1) Yes**	**(2) No**	**(3) DK**
14e	Other (specify): _____ _____ _____ _____			

D Procedures

Please read **all** the questions in this section before answering.

	Please mark the appropriate answer (1=agree; 2=disagree):		
15	**The following are challenges to the *ethical review* procedure in your committee:**		
15a	Lack of a national accreditation mechanism for ethics committees.	**(1) Agree**	**(2) Disagree**
15b	Lack of national standards for composition of committees.	**(1) Agree**	**(2) Disagree**
15c	Lack of national standards for operation of committees.	**(1) Agree**	**(2) Disagree**
15d	Lack of a national audit mechanism for research ethics committees.	**(1) Agree**	**(2) Disagree**
15e	Variable procedures, across committees, for review of protocols.	**(1) Agree**	**(2) Disagree**
15f	By-passing institutional REC decisions by researchers.	**(1) Agree**	**(2) Disagree**

	Please mark the appropriate answer (1=agree; 2=disagree):				
15g	Other (please specify): _____ _____ _____ _____				
	Please mark the appropriate answer (1=yes; 2=no 3=DN):				
16	Does your committee have written standard operating procedures?			**(1) Yes**	**(2) No (3) DK**
17	Does the Committee use the SOPs to run its activities? **(1) Yes (2) No (3) DN** _____ _____ _____ _____				
18	How often does your committee meet for review of research studies? (*mark appropriate answer*)				
	(1) Once/week	**(2) Twice/month**	**(3) Once a month**	(4) Every 2 months	**(5) Other, specify: _____**
19	Does your ethics review committee request a consultant to provide scientific/other expertise for review of a protocol? (**1) Yes** **(2) No**				
20	How many biomedical/health protocols does your committee review per meeting? (*answer in space below by putting a number*) _____ _____ _____ _____				

E Regulating and follow up on approved research

Please read **all** the questions in this section before answering.

	Please mark the appropriate answer (1=yes, 2=no, 3=don't know (DK)):			
21	In your region, is it possible to conduct biomedical/health research without any ethics approval?	**(1) Yes**	**(2) No**	**(3) DK**
22a	Do you know if there is a law that governs ethical review of health/biomedical research?	**(1) Yes**	**(2) No**	**(3) DK**
22b	If yes, please list these laws in the space below: _____ _____ _____ _____			
22a	Are there mechanisms to monitor the conduct of research after getting approval by your committee?	**(1) Yes**	**(2) No**	**(3) DK**
22b	If yes, please list and describe these mechanisms: (*answer in space below*) _____ _____ _____ _____			

F Financial and material resources

Please read **all** the questions in this section before answering.

	Please mark the appropriate answer (1=yes; 2=no):					
23a	Does your ethics committee receive funding/financial support?				**(1) Yes**	**(2) No**
23b	Do you charge applicants for ethical review?				**(1) Yes**	**(2) No**
24	Are all of your committee members remunerated for their time and travel?				**(1) Yes**	**(2) No**
25	Is the following infrastructure available to your committee?					
	a. Office space	**(1) Yes**	**(2) No**	j. Telephone	**(1) Yes**	**(2) No**
	b. Computer equipment	**(1) Yes**	**(2) No**	k. Facsimile	**(1) Yes**	**(2) No**

Please mark the appropriate answer (1=yes; 2=no):						
	c. Printer	**(1) Yes**	**(2) No**	l. Email	**(1) Yes**	**(2) No**
	d. Photocopy machine	**(1) Yes**	**(2) No**	m. Internet	**(1) Yes**	**(2) No**
	e. Office furniture	**(1) Yes**	**(2) No**	n. Secretarial support	**(1) Yes**	**(2) No**
	f. Library	**(1) Yes**	**(2) No**	o. Bank account	**(1) Yes**	**(2) No**
	g. Typewriter	**(1) Yes**	**(2) No**	p. Electricity	**(1) Yes**	**(2) No**
	h. Stationery	**(1) Yes**	**(2) No**		**(1) Yes**	**(2) No**
	Other (specify): _____ _____ _____ _____					

G REC independence

Please read **all** the questions in this section before answering.

Please mark the appropriate answer (1=yes; 2=no; 3=don't know (DK)):				
26	**The following issues related to independence of ethics committees provide challenges to the *ethical review process* in your REC:** *(The information received will be kept confidential)*			
26a	Lack of transparency of committees.	**(1) Yes**	**(2) No**	**(3) DK**
26b	Pressure from political powers.	**(1) Yes**	**(2) No**	**(3) DK**
26c	Pressure from sponsors.	**(1) Yes**	**(2) No**	**(3) DK**
26d	Biased committee members.	**(1) Yes**	**(2) No**	**(3) DK**
26e	Unequal treatment of applicants in the review process.	**(1) Yes**	**(2) No**	**(3) DK**

	Please mark the appropriate answer (1=yes; 2=no; 3=don't know (DK)):			
26f	Other (please specify): _____ _____ _____ _____			
27a **27b**	Do you believe that the research ethics committees in the country are truly independent? If no, why? ……..	**(1) Yes**	**(2) No**	**(3) DK**
28a	Are conflict of interest issues with research ethics committees members sufficiently managed such that they are resolved?	**(1) Yes**	**(2) No**	**(3) DK**
28b	If yes, how are they managed? _____ _____ _____ _____ _____			
29	Do you think invitation of Researchers to attend a session during discussion of their proposal would be beneficial?	**(1) Yes**	**(2) No**	**(3) DK**

H Composition

Please complete the following table (use additional sheets if necessary):												
30	**Please outline the composition of your ethics committee:**											
	Position on committee (eg. Chair, Administrator, Member) *Please indicate Gender*	**Sector which member represents** (eg. Community Member, Medical Doctor, Lawyer, Nurse, Scientist, Ethicist, etc.)	**Level of education** 1=Primary 2=Secondary, 3=Tertiary 4=Masters, 5=PhD, 6=Other (specify).						**Formal ethics/bioethics training** (e.g. courses) Specify in hours.		**Formal training in HIV vaccine trials ethics (yes/no)**	**Paid member (yes/no)**
									Prior to assuming position	**After assuming position**		
A	Chairperson		1	2	3	4	5	Other_____				
B	Administrator/Secretariat		1	2	3	4	5	Other_____				
C	Member		1	2	3	4	5	Other_____				
D	Member		1	2	3	4	5	Other_____				
E	Member		1	2	3	4	5	Other_____				
F	Member		1	2	3	4	5	Other_____				
G	Member		1	2	3	4	5	Other_____				
H	Member		1	2	3	4	5	Other_____				
I	Member		1	2	3	4	5	Other_____				
J	Member		1	2	3	4	5	Other_____				
K	Member		1	2	3	4	5	Other_____				
L	Member		1	2	3	4	5	Other_____				
M	Member		1	2	3	4	5	Other_____				
N	Other (Specify)		1	2	3	4	5	Other_____				
O	Other (Specify)		1	2	3	4	5	Other_____				

31	What issues related to diversity of membership are challenges in your committee? (*answer in space below*) _____ _____ _____ _____

Thank you for giving up your time to assist in this project.

APPENDIX 2

UNIVERSITY OF
KWAZULU-NATAL

University of KwaZulu-Natal
Research Office
Govan Mbeki Centre
Westville Campus
University Road
Chiltern Hills
Westville
3629
South Africa
Tel No: +27 31 260 3587
Fax No: +27 31 260 2384

05 MARCH 2010

Dr. KS Oyedeji
Faculty of Humanities
School of Psychology
Pietermaritzburg Campus

Dear Dr. Oyedeji

ETHICAL APPROVAL NUMBER: HSS/0061/10M
PROTOCOL: "The Ethics review of the Health Research Ethics Committees in South Western Nigeria"

In response to your application dated 27 January 2010, Student Number: **207529229** the Humanities & Social Sciences Ethics Committee has considered the abovementioned application and the protocol has been given **FULL APPROVAL.**

Any alterations to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study must be reviewed and approved through the amendment /modification prior to its implementation. Please quote the above reference number for all queries relating to this study.
PLEASE NOTE: Research data should be securely stored in the school/department for a period of 5 years.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully

Professor Steve Collings (Chair)
HUMANITIES & SOCIAL SCIENCES ETHICS COMMITTEE

cc. Supervisor (Prof. M Kruger)
cc. Carla Pettit
cc. Mrs. B Jacobsen

APPENDIX 3

INSTITUTIONAL REVIEW BOARD

IRB-NIMR

NIGERIAN INSTITUTE OF MEDICAL RESEARCH

6, Edmond Crescent Off Murtala Muhammed Way, P. M. B. 2013 Yaba, Lagos.
Tel: 01-4823123, 01-7744723, 08050254484, 08033460947 Fax: 01-4823123, 234-1-3425171
E-mail: nimr_irb@yahoo.com *Website:* www.nimr-nig.org
Secretariat: Room 207, Biochemistry Division, Research Block, NIMR

13th August-08

PROJECT TITLE: **THE ETHICS REVIEW OF HEALTH RESEARCH ETHICS COMMITTEE IN SOUTH WESTERN NIGERIA**

APPROVAL LETTER.

The above named proposal has been adequately reviewed; the protocol and safety guidelines satisfy the conditions of NIMR IRB, policies regarding experiments that use human subjects.

Therefore the study under its reviewed state is hereby approved by Institutional Review Board, NIMR.

DR. P. U. AGOMO
Name of IRB Vice Chairman

13th August 2008
.....
Signature & Date of IRB vice Chairman

DR. A.A ADEIGA

A.A 14th Aug. 2008
.....
Name of IRB Member

Signature & Date of IRB Member

This approval is given with the investigator's Declaration as stated below;
By signing below I agree/certify that:

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.
2. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
   - I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
   - I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.

APPENDIX 3
(CONTINUED)

3. I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping; and (f) the current IRB approval status of the research study.

4. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.

5. I will submit the research study in a timely manner for IRB renewal approval.

6. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his /her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).

7. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.

8. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.

9. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.

10. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.

11. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

12. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.

Dr.kolawole S. Oyedeji
Principal Investigator Name

08-08-08
.....
Principal Investigator signature and Date

APPENDIX 4

As @ 26 October 2006

Faculty of Humanities, Development and Social Sciences

UNIVERSITY OF KWAZULU-NATAL

CONTRACT BETWEEN SUPERVISOR AND CANDIDATE

The relationship between supervisor and a candidate for a research degree is one of mentorship. A supervisor should advise about the structure of the degree, should direct the candidate to sources and material, may suggest better forms of expression, but in the end the dissertation or thesis must be the candidates own work.

CORRECTION OF STYLE AND GRAMMAR

A completed dissertation or thesis must be satisfactory as regards form and literary expression. Although the supervisor will point out any passages in it which are stylistically poor, or which are grammatically weak, it is not possible for a supervisor to correct great numbers of language errors, nor is it the supervisor's responsibility to do so. A student may, if necessary, and at his or her own cost, employ a copy editor to proofread the dissertation or thesis and correct errors of expression or style.

PLAGIARISM

A candidate may not include in the dissertation or thesis any quotations from another writer, or adopt substantial ideas from another writer, without acknowledgement and without reference to the source of the quotation. Direct quotations must be indicated by the use of quotation marks. All cases of plagiarism will be reported to the University Proctor for disciplinary action, and may lead to the dissertation or thesis and the degree being failed.

MAXIMUM PERIOD ALLOWED FOR COMPLETION

Masters: A Masters degree undertaken on a full-time basis should be completed in 4 semesters. There is a maximum of 8 semesters.

PhD: A Doctoral degree undertaken on a full-time basis should be completed in six semesters. There is a maximum of 12 semesters.

Permission of the Board of the Faculty is required for extensions beyond these periods and will only be granted in special circumstances.

EXPECTATIONS OF SUPERVISOR AND CANDIDATE

Projected date for the submission of the research proposal 15/10/2007

Will the candidate be expected to attend group seminars? ..... All ready done

Approximate frequency of such seminars ..... monthly

How often will the candidate present written work? E.g. monthly, quarterly, etc ..... Monthly

How often will the supervisor and the candidate expect to meet? e.g. monthly, every two months, etc. ..... Electronic meeting monthly

APPENDIX 4
(CONTINUED)

Approximately how soon after submission of written work may the candidate expect comments from the supervisor? Two weeks

Any other special provisions agreed on?

Incorporate suggested changes as soon as possible.

Candidate

Signed

OYEDEJI KOLAWOLE

Name: (print)

05/10/2007

Date:

Supervisor

Signed

M. KRUGER

Name: (print)

05/10/07

Date

NOTE:
The supervisor's consent is required in order to submit the completed dissertation or thesis for examination and no thesis will be accepted by the Faculty Office for examination without the supervisor's approval. The supervisor must see the final version of the thesis before submission. A candidate may, if he/she wishes, insist on submission without the supervisor's consent, but this fact will be noted in the supervisor's report.

(24-10-2006)