ORGANISATIONAL STRUCTURE, OPERATIONS AND TRAINING NEEDS OF RESEARCH ETHICS COMMITTEES IN SOUTHEAST NIGERIA

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ABSTRACT

Context: The 10/90 gap in disease burden and available funding for research, calls for increasing collaborative research between developed and developing countries. Independent protocol review by well constituted Research and Ethics Committees (REC) is essential for ethical conduct of investigations.

Aims/Objectives: To assess the capacity of RECs in Southeast Nigeria in terms of composition, organisation and operations and as well, evaluate their training needs.

Methods: This was a cross sectional descriptive study. Chairpersons of RECs were identified and completed a 68 item self-administered questionnaire. The study lasted between January and June 2010 (six months). Information was collated and analysed using Stata 11 statistical programme. Data is presented in simple frequency distribution tables and charts.

Results: Seven of the nine public institutions who responded had RECs. None of the privately owned tertiary health facilities had RECs. The RECs were local in operation, only one was registered with the National Health Research Ethics Committee of Nigeria and none had a Federal Wide Assurance number from the USA OHRP. The mean membership was 7.6 members (range 7-9). Health scientists/clinicians and males dominated in all the RECs. All had lay members and 71.4% had community

representatives. About 50% of the members were not trained in research ethics. Institutional support, funding and infrastructure were limited. Their focus was primarily science and ethics and mainly carried out reviews, modification and approval of protocols through consensus. Two of the committees met monthly while the rest scheduled meetings following availability of protocols. Oversight functions and project monitoring were not undertaken. Most pressing training needs included basic health research ethics, protocol review, informed consent procedure and risk/benefit analysis. Training on international collaboration was also required by some of the committees.

Conclusion: Surveyed RECs are at a nascent stage in southeast Nigeria. Challenges abound in their funding, composition, registration with local and international regulatory bodies, operations, oversight functions/monitoring, and training of members and researchers. There is an urgent need for national and international agencies to collaborate with them in areas of training and capacity development.

INTRODUCTION

The heavy burden of disease and poverty in sub Saharan Africa provides fertile ground for various research activities including clinical trials. Health research has played a major role not only in epidemiological evaluation of disease and health events but also in evaluating the efficacy and safety of interventions including drugs. Inasmuch as health research provides invaluable knowledge and benefits to society and individuals, it also entails some level of risk to the participants and the communities. Sound ethical judgment should weigh the risk: benefit ratio in favour of the participants.

The need to protect research participants in the context of experimental research was first enunciated by Claude Bernard[1] and ethical issues in research became prominent following the inhuman Nuremberg experimentations on prisoners during World War II with the consequent Nuremberg trials and finally the Nuremberg code in 1948[2-4]. Ever since, the field and scope of research ethics has continued to broaden and with notable deficiencies in the Nuremberg code, later ethical guidelines including the Helsinki declaration of 1964[2,3] [with latest modification in 2008][5,] the Belmont Report of 1978[2,3,6] and the CIOMS of 1993[2 3] and modified in 2002[7] among others have been published.

Increasing globalisation has led to tremendous international collaboration in health research between developed and developing countries. Heavy disease burden, high poverty level and paucity of health facilities and treatment options render sub Saharan Africa vulnerable to exploitation from foreign sponsors and investigators[7], hence the need to protect the African population and communities from abuse. In the United States of America (USA), Institutional Research Boards are set up and equipped to

ensure ethical conduct of health research and trials involving human beings[2.] However, there seems to be a disparity between the ethical implementation of health research between developed countries and developing countries in international research[8.] Recently some authorities have raised similar concerns[9].

For countries that have National Research Ethics Committees or a Council (NREC) in sub Saharan Africa, such committees/councils are expected to ensure ethical conduct of health research within their boundaries[9.] An audit of NRECs in the WHO African region conducted in 2003 had only a 61% response rate from the 46 countries surveyed. Ten (36%) out of the 28 countries that responded, did not have a NREC[9]. Nigeria, the world's most populous black nation is burdened with poor health indices and high poverty rate[10]. Medical literature is replete with research findings coming out of Nigeria. There is an urgent need therefore to audit the composition, organisation and operations of Research Ethics Committees (REC) in Nigeria. This will provide baseline data and a basis for rational recommendations aimed at improving the functionality and relevance of such committees in Nigeria, should such improvements be indicated by the data.

LITERATURE REVIEW.

Health research is critical to understanding disease processes/health events and formulating remedies for them. The ultimate goal of research is the improvement of well-being of the individual and society. However, research must take place in an ethical manner, so as to maintain respect and human dignity for the participants, protect them from harm and ensure accruable benefits[7,11].

The World was horrified by the inhuman experimentations on human beings performed by Nazi doctors during the Second World War. The subsequent trial of the doctors (Nuremberg trials) and judgment gave rise to the Nuremberg code in 1948 as we know it today[2-4]. The Nuremberg code principally articulated guidelines to ensure respect for study participants by detailing the necessity of informed consent, voluntariness, and the participant's right to withdraw at any stage without repercussions, as well as a risk/benefit analysis in favour of the participants[2,3.] The Nuremberg code generated much interest among scientists and researchers worldwide, provided baseline for research ethics but remained deficient on certain issues. Further unethical studies including the Thalidomide study were undertaken[2]. Here expectant mothers were given Thalidomide for discomforting pregnancy symptoms (hyperemesis – severe vomiting in pregnancy) without being informed that the drug was still in the trial stages. The drug caused some limb abnormalities in the infants including Amelia and Phocomelia. The World Medical Assembly (WMA) thereafter built upon the Nuremberg code – the Helsinki declaration, and provided guidelines for physicians and researchers to protect the interest of the research participants and prioritising it above that of the society[2,3]. This declaration has undergone various modification since then[5], but still maintains

that in any clinical research the study participants should get the best known treatment. In spite of the different codes and principles, further ethically-deficient studies did go on including the United States' federally sponsored Tuskegee Syphilis study between 1932 and 1972, and the San Antonio contraception study in the early 1970s[2,3]. The studies generated much ethical concern and elicited debates, congressional hearings and wide deliberations which culminated in the Belmont report of 1978[2,3,6] and lately a Presidential apology to the families of the participants in that Syphilis study. The Belmont report emphasised respect for persons, beneficence and justice to research participants. The foregoing led to the establishment of Institutional Review Boards (IRB) in the United States with the broad aim of ensuring rights, safety and welfare of the individual in research[2]. The IRB reviews, evaluates, approves and monitors research proposals and procedures by evaluating 'what ought to be done and how it ought to be done'[2]. Research Ethics Committees (RECs) in many other developed nations are patterned after the United States' IRB. They derive their membership from individuals with different professional background while ensuring a conglomeration of racial, gender and cultural diversities[2,3].

The current globalisation trend also affects health issues. Disease burdens weigh heavily on sub Saharan African countries, and are thus of research interest. Emerging pandemics like the Human Immune deficiency Virus (HIV) infection and the Acquired Immune Deficiency Syndrome (AIDS), as well as Malaria and tuberculosis make international collaboration in health research not only necessary but also imperative[2 9]. The poverty that permeates most African countries where health care facilities and infrastructure are poor makes them and their populations vulnerable to research

exploitation especially in foreign sponsored studies[7]. This is made worse realizing that only 10% of research funds is made available for research in developing countries which have 90% of global disease burden[12.] Growing international research collaboration informed the Council for International Organisation for Medical Sciences Studies' (CIOMS) in conjunction with the World Health Organisation (WHO) effort at proclaiming guidelines, for protecting a vulnerable population in 1993 and amended in 2002[2,3,7]. The economic and power differences between developed and developing countries limit the autonomy of the developing countries and their inherent capacity for decision-making in terms of which research is acceptable and which is not. The CIOMS guidelines for biomedical research involving human subjects emphasised that research, especially with vulnerable populations, is accompanied by benefits to the research participants and communities[2,3,7]. Inability to protect human rights and welfare of research participants in the vulnerable developing nations, may engender further disparities in health indices between developed and developing countries[8].

RECs have at times been criticised for concentrating mainly on procedural exactitude of research protocols[13] to the detriment of the ethical values of such protocols[14]. This conflict becomes more evident in foreign-sponsored research in developing countries[15-18], as foreign interpretation and interest may supplant local considerations of ethical imperatives inherent in the study[19]. It is widely acknowledged that local (RECs) are generally better equipped to deal with issues of informed consent and cultural acceptability of a programme rather than the study design, ethics and justice thereof, – a prerogative of the foreign sponsors[20], but even then, some believe that the elaborate and stringent procedure of getting informed consent from research participants, is

intended to protect the researchers and institutions against litigation rather than serve the larger interest of the research participants[20-22]. It is also argued that some research sponsors may be more interested in getting the initial informed consent, without further steps to evaluate the validity of such consent as the study proceeds[19,23]. Technical correctness of informed consent may not be enough to engender acceptable ethical standards in research, and may breed exploitation of study participants if the issue of distributive justice is ignored[14,19]. Local RECs should therefore move to resolve this legalistic versus ethical conflict, in such as a way as to prioritise safety and welfare of study participants[19] and circumvent paternalistic tendencies and double standards[24].

Nevertheless, even as debates on foreign-driven studies continue, it is noted that more health research in developing countries originates locally, and has to be reviewed by a local REC using local codes[8]. But how are local Research Ethics Committees in developing countries faring? In 2001, the WHO was worried about the ethical conduct of health research in Africa[9] and doubted the quality of RECs in some cases. Different RECs were shown to return different conclusions on the same research protocol[25-29]. In a review of RECs in Latin America, only 45% had standard operating procedures[30]. In a study evaluating RECs in the WHO African Region[9], 46 countries were enrolled for the survey but only 28 (61%) responded. Of the 28, 18 (64%) had National Health Research Ethics Committees. As in Latin America, African RECs were hampered by poor training[31,] infrastructure, poor operational mechanisms, irregular meetings, poor funding and weak monitoring systems[9,31-33.] African Professionals trained in research ethics at the Bloomberg's school of Public Health, Johns Hopkins, Baltimore, funded by the Fogarty International Center of the National Institutes of Health (FIC/NIH) pointed out

that the greatest challenges facing African RECs were inadequate training, funding and the tendency to virtually approve international protocols to gain funding[31]. In a resource-need assessment survey of African RECs, 97% opined that African RECs lacked adequate training in ethics and HIV vaccine trials while 83% believed that they were also poorly trained in health research ethics[34.] In another survey involving 31 RECs across 18 African countries, 38% of members were noted to have had no form of training in health research ethics[35]. A Tanzanian study also revealed poor training in ethics of REC members limiting their capacity to review protocols[36.] In South Africa, the National Health Act of 2003 established the National Health Research Ethics Council (NHREC)[37] to provide guidelines, register, monitor and enforce disciplinary measures on local RECs in South Africa. The South African Good Clinical Practice guidelines prescribed that the membership be representative of various race, gender and occupation[38].

Health research and clinical ethics over the years have been neglected in Nigeria, and are sparingly included in medical students' curricula[39]. However, RECs have existed in Nigeria since the early 1980s, but have been largely dormant. They were re-invigorated by the revitalisation of the National Health Research Ethics Committee and the introduction of the National Code for Health Research Ethics in 2007[40] to ensure good ethical principles of research, optimising benefits while minimising potential harm and undue exploitation of research participants and communities in Nigeria. The National code spells out the roles and responsibilities of the Nigerian NHREC, Institutional REC, health researchers and research sponsors aimed at protecting human rights and research participants. It further details the composition of such bodies to be at least five

members with diverse professional calling, age, gender, religion and socio-cultural backgrounds, but to include at least a member who is sensitive to community issues, one whose primary field is science and another, with primarily a non-scientific interest. It may also include a legal practitioner. All members of the REC are expected to complete NHREC approved training in research ethics[40]. The code also provides guidelines for Institutional REC registration, operations and regular audit. The NHREC accredits, registers and audits institutional RECs. It is also involved in the review of multi-centre studies (more than three centres) in the country.

Renewed interest in international collaborative research in Nigeria also led to increasing interest in Research Ethics[39]. Currently there are programmes in Nigeria aimed at developing the capacity of ethicists, clinicians, researchers and REC members. The United States FIC/NIH funded West African Bioethics Initiative of Nigeria (WABIN)* also aimed at capacity building is based at the University of Ibadan, Nigeria. Furthermore, the Association for Good Clinical Practice[+] has also started with the aim of developing the health research industry in the country[39]. Many studies that have evaluated RECs in Nigeria have been dominated by foreign investigators, but none has focused particularly on Southeast Nigeria to examine the composition, operation and training needs in that region - home to over 20 million Nigerians[41].

*http://www.westafricanbioethics.net

[+]http://www.agcpn.org

RESEARCH QUESTION.

What are the composition, organisational structure and operations of RECs in Southeast Nigeria?

MATERIALS AND METHODS.

STUDY BACKGROUND

Nigeria is the most populous nation of black people worldwide. Her 36 administrative units (States) are grouped into six geo- political regions. The Southeast region comprises five States of Abia, Anambra, Ebonyi, Enugu and Imo and is home to the Igbo ethnic group[41]. Poverty and low literacy rates are prevalent in the rural areas of this region which is served by disproportionately fewer health facilities[42]. Each of the States has two tertiary health institutions, all located within the urban centres and owned by the Government. Health indices as in other regions of Nigeria, are poor with high infant and maternal mortality rates[42]. Tertiary health centres receive referrals from the lower levels of health care. In some instances they train medical students and are approved for postgraduate medical training. They are also expected to carry out clinical research. Some of the institutions publish scientific medical journals like the *Journal of the College of Medicine, Journal of Medical Investigation and Practice* and the *Ebonyi Medical Journal**. Despite these activities, little is known about the operations of the research ethics committees in these institutions against the backdrop of the Nigerian National code for health research ethics[40].

*African Journal On Line (AJOL) – http://www.ajol.info

STUDY DESIGN.

This was a self-administered questionnaire-based cross-sectional study. The questionnaire was developed from information and themes taken from earlier studies on the same subject[9,24,28-36]. Input was also obtained from the Ethics, Law and Human Right Working Group questionnaire of the African AIDS Vaccine Programme (AAVP)[43] based at the University of KwaZulu-Natal, South Africa. The AAVP questionnaire was employed to assess the resource needs of RECs in Africa preparatory to HIV vaccine trials. This self-administered questionnaire (see appendix), comprised 68 questions divided into five sections seeking information on the establishment, organisation, operations, composition and training needs of the RECs. This tool was employed since it has been used in similar studies and will thus yield reliable and comparable data. The questionnaire also specifically sought information on the registration status of the RECs and compliance with the Nigerian National code for health research ethics, review processes, infrastructure, organisation, workload, funds, limitations and international collaboration.

Ethical approval for the study was sought from and granted by the Research Ethics committees of the University of Pretoria, RSA and the Ebonyi State University Teaching Hospital, Abakaliki, Nigeria (see Appendix). Tertiary health institutions in southeast Nigeria were contacted through a contact person to ascertain the existence of RECs in the institution, and obtain contact details of the Chairpersons of the RECs. The chairpersons of each of the target RECs were contacted by telephone and informed about the study. Thereafter, an informed consent form and a structured questionnaire were sent to them individually either directly through a research assistant or via express

surface mail. An addressed stamped envelope was included for the return mail. The questionnaire was self-administered and returned to the researcher in the prepaid envelope. Follow up telephone calls were placed to the chairmen at intervals if no reply was received. All information obtained was treated confidentially and was not specifically linked to any of the committees or their members.

DATA ANALYSIS

All information was captured and analysed using the Epidata programme and Stata 11 statistical software package. Results will be presented in simple frequency distribution tables, in the section that follows.

RESULTS

Southeast Nigeria houses five Federal Government-owned tertiary institutions and another five, owned by the respective State governments that constitute the region.

There were five other privately owned tertiary institutions with health facilities but these were in their infancy and had no committees responsible for ethics and research. Nine of the ten (90%) institutions responded to inquiries on the existence of committees responsible for ethics and research in their respective institutions. One did not respond; workers in that institution – a State government-owned facility have been on industrial action for over six months. Of the nine, two (22.2%), all State government-owned, had no Research Ethics Committees. This analysis therefore involves seven of the ten centres contacted for the survey.

RESEARCH ETHICS COMMITTEES

Health/clinical research was conducted actively, in all the institutions, and in all of these, investigations must be approved by the Research and Ethics Committees (REC) before commencement. Such committees were referred to as Research and Ethics Committees (REC) or Committee on Research and Ethics (CORE) but none was referred to as Institutional Review Board (IRB). Three of these (42.9%) were five years or less in existence, another three, six to ten years old, while only one, (14.3%) had functioned for over ten years. All the committees were local in outlook (i.e. served local institutional needs) and were instituted via the instruments of their respective institutions. Even though all the chairpersons of the committees were aware of the existence of the National Health Research and Ethics Committee (NHREC) at the

national level, only one committee was registered with the NHREC, and none, with the OHRP, nor had a Federal-Wide Assurance of the United States.

ORGANISATIONAL STRUCTURE

Only one of the seven (14.3%) committees had a dedicated office for its activities and meetings. The rest met at other sites within the hospital, including hospital's board rooms 42.9%, office of the chairpersons 28.6% and consulting rooms 14.3%. As a result, six of them had no dedicated essential equipment including filing cabinets, computers/laptops, printer, telephones, fax machines, photocopiers and office furniture. The only one with dedicated office space had a filing cabinet, office furniture and stationery. All the committees had administrative staff (28.6%) or secretaries (71.4%), three of whom were on full-time basis and the rest part-time. Funding for the committees mainly came from charges on protocols (71.4%); one did not charge for protocol review. Support from the institutions came in the form of sitting allowances, subvention for day-to-day running of the committees and remuneration of the administrative staff/secretaries.

COMPOSITION

In all the institutions, members of the REC were appointed at the discretion of the hospital's management. These members, in five institutions represent various interest groups/units in the hospital. Only in two institutions were individuals appointed also on merit. Five of the committees had membership strength of seven, while two had nine members. All the committees had female and male members but males predominated in all cases and there was no fixed ratio for male/female representation. Females

constituted only 28.3% of all members. The majority of members in each committee (88.7%) were affiliated to the host institutions. However, all but one also had community representatives who made up 11.3% of the total membership. Each of the committees was headed by a specialist medical doctor in different specialties. There were at least three medical doctors in all the committees and they accounted for 43.4% of the total membership strength. Nurses constituted 13.2% (see Table 1). Only one of the committees had a legal expert, who became a member in his capacity as the Head of Medical Records unit of the institution. Only two chairpersons were trained in health research ethics prior to their appointment into the committee. Three however were trained in research ethics after their appointment. The two chairpersons knowledgeable in research ethics prior to appointment had such training for a cumulative period of about three months and also had a post- appointment cumulative training of two to four weeks. Three of the chairpersons with training post-appointment had training ranging from five days to four weeks. The administrative staff/secretaries in five institutions had training lasting five days to 14 days after their appointment. Twenty-seven of the 53 (50.9%), total committee members in the Southeast region of Nigeria, also received some training in research ethics after appointment, ranging from three days to 14 days. A member in one of the institutions had ten-month training in health research ethics before appointment and serves as a vice chairman to that committee. The tenure for each member was not fixed and headship was not rotational in any of the committees. Six of the institutions afforded members of the committee a sitting allowance.

Table 1.

Membership composition of RECs in Southeast Nigeria.

Members	**Number**	**Percentage (%)**
Medical Doctors	23	43.4
Nurses	7	13.2
Medical Records personnel	7	13.2
Community members	6	11.3
Laboratory scientists	5	9.4
Pharmacists	4	7.4
Social workers	1	1.9
TOTAL	**53**	**100.0**

OPERATIONS

Evaluating the operations of the RECs in Southeast Nigeria shows that all the committees primarily reviewed study protocols, five of whom (71.4%) modify such protocols before approval where applicable. None monitored the research process or progress post-approval nor ensured research findings were adequately disseminated at the end. Training of committee members or local researchers was not part of the details for any of the committees (Table 2). Five of the committees had standard operating procedures, two of which have been operational for more than five years, the rest have

existed for less than five years. Only one of the five (20%) had had its SOP revised since inception. The Declaration of Helsinki was the most commonly available document for committee members (42.9%). One other, in addition, had the CIOMS guidelines. The rest had no such documents. Seventy-one point four percent of the committees did not have fixed schedules for meetings. Meetings were determined by availability of protocols for review or were called arbitrarily. All but one of the committees had an average of 11 to 50 protocols for review annually. One committee, which incidentally was the oldest, had an average of 51 to 100 annually for review. Two committees had been involved in review of clinical trials which formed less than 10% of their reviewed protocols. The rest had never reviewed clinical trials. The main foci of the committees reviewing protocols were primarily the scientific design and ethical considerations (71.4%), including budget in another 28.6%. In ethical analysis of the study protocol, the committees evaluated social value of the study, scientific validity, risk/benefit analysis, informed consent and respect for persons (100%). Others included fair participant selection (42.9%) and collaborative partnership with the community (28.6%) (Table 3). All the committees subjectively rated their committee as truly independent and their capacity to review protocols as good. The perceived threats to their independence were mainly in terms of pressures from principal investigators (28.6%) and pressure from the host institution (14.3%). Two of the committees rejected about 50% of protocols submitted to them for review while the rest (five) did reject less than a third of submitted protocols. The common reasons for rejection were methodological/ ethical issues (100%), limited capacity to implement protocol (42.9%) and limited funding (28.6%).

The average time from submission to final decision on a protocol was one to three months for six of the committees and three to six months for the remainder. Decisions were usually arrived at through consensus (100%). Deliberations of one of the committees but not the final decision-making process, was open to observers. Six of the committees invite input and clarification from investigators during meetings before final decision. A flat fee was charged per non-sponsored protocol by six of the committees while rates varied for fees charged sponsored protocols of investigation. One committee did not charge for protocol review.

Table 2.

Activities and foci of RECs in southeast Nigeria

Activities	**Number**	**Percentage (%)**
Review and approve protocols	7	100.0
Modify protocols	5	71.4
Monitor research process and progress	-	-
Train personnel in research ethics	-	-
Train researchers in research ethics	-	-
Ensure dissemination of research findings	-	-
Main focus of protocol review		
Science, ethics & budget	2	28.6
Science & ethics only	5	71.4
Primarily science	-	-
Primarily ethics	-	-

Table 3.

Main ethical considerations during protocol review by RECs in Southeast Nigeria.

Issues	Number	Percentage (%)
Social value of study	7	100.0
Scientific validity	7	100.0
Risk: benefit analysis	7	100.0
Informed consent	7	100.0
Respect for participants	7	100.0
Independent review	7	100.0
Fair participants' selection	3	42.9
Collaborative partnership with community	2	28.6

TRAINING NEEDS

Training in basic health research ethics, basic protocol review process and the informed consent process ranked foremost as the most pressing training needs (100%). Other most pressing needs were, training in clinical trial protocol review process and protection of vulnerable populations (71.4%); good clinical practice, fair subject selection, risk/ benefit analysis and monitoring and oversight function of REC (57.1%); privacy and confidentiality issues (28.6%).

Table 4.

Training needs of RECs in Southeast Nigeria.

Needs	Most Pressing	Pressing	Needed	Indifferent	Not needed
Basic health research ethics	7				
Advanced health research ethics		4	2	1	
Good clinical practice	4	2	1		
Basic protocol review process	7				
Clinical trial protocol review	5	1	1		
Community engagement		1	5	1	
Malaria vaccine trial		2	2	3	
HIV vaccine trial		2	2	3	
Payments in research+		2	2	2	
Ancillary care+		2		2	1
Informed consent	7				
Fair subject selection	4	1	2		
International collaboration	1	5	1		
Post trial benefit	1	4	2		
Protection of vulnerable groups	5	2			
Monitoring and oversight functions	4	3			
Law & human rights issues	1	4	2		
Risk: benefit analysis	4	2	1		
Use of Placebo in RCT*	2	3	2		
Assessment of cultural influence			6	1	
Privacy & confidentiality	2	3	2		
Administrative issues		3	1	4	
Training on internet access	1				

+Incomplete entries

*Randomised Control Trials

Training in HIV and malaria vaccine trials were rated as pressing needs by two of the committees, needed by two others while the remaining three were indifferent. Other pressing needs were training in law and human rights issues (57.1%), international collaboration and payment in research (71.4%). Community engagement and influence of culture were ranked as needed by five and six of the committees respectively (Table 4).

CHALLENGES

Lack of sound knowledge of biomedical research ethics, research methodology, conflict of ideas, as well as poor knowledge and access to internet were cited as impediments to the effective functioning of the committees. Others included poor institutional support and funding.

SUMMARY OF MAIN FINDINGS

Seven of the nine tertiary health institutions in Southeast Nigeria have research ethics committees. Funding and institutional support for the committees are limited. Membership of the committees cuts across different professional groups and lay members. Almost half of the members have no formal training in research ethics. Most of the committees have no standard operating procedures and fix meetings arbitrarily depending on the availability of protocols. Two of them have been involved in drug trials. The committees focus mainly on scientific validity and ethical issues during protocol reviews. Oversight functions and monitoring are neglected. Average submission to approval time is one to three months. Training in basic protocol review,

basic health research ethics and informed consent process among others were their most pressing needs.

DISCUSSION

Research ethics committees (RECs), though in their infancy stages, are taking root in southeast Nigeria. Learning from the experience of the inhuman experimentation that occurred during the second world war and the consequent Nuremberg trial of the Nazi 'scientists/physicians', medical researchers globally rose to put in place, a system of self professional and social regulation through 'group consideration' (as review was referred to then)[44]. This consciousness and self scrutiny are now becoming an integral part of research system in that region of Nigeria, as implied by 77.8% of the Government owned tertiary institutions having RECs overseeing independent reviews of studies in their centres. The other two public health and the five privately owned tertiary health centres are new, with their medical schools hardly at the clinical level. The Nigerian Health Research and Ethics Committee (NHREC) demands that each health institution or agency where research is undertaken, sets up a Research and Ethics Committee (REC), or to refer to one locally to review all study proposals/protocols and ensure that ethical standards are upheld[40]. Such RECs must be registered with the NHREC at the National level. Only one of the committees, which incidentally is the oldest in that region, was registered with the NHREC. The apparent late development of such committees in southeast Nigeria, could be traceable to the NHREC, which though established in the early 1980s, remained dormant and inactive till its re-inauguration in 2005[40]. This is in sharp contrast to what obtains in the developed countries where such committees sprang up in the 1950s (United States of America)[44] and in the 1960s in the

United Kingdom[45]. By mid 1971, all 32 teaching Hospitals in the UK had RECs (93.8%) or were in the process of forming (3.1%) or reforming one (3.1%)[45]. The earliest RECs in Africa were established in South Africa between 1966[33] and 1967[31]. The oldest committee in this survey was 13 years in existence, whereas in South Africa as at 2006, 10 RECs were already more than 10 years old[33.]

Organisational structure

The nascent stages of the institutional RECs in the southeast region receive paltry institutional support and resources. All the committees but one, lacked dedicated office space, necessary equipment and office furniture. None had dedicated computers and electronic archiving systems. This sharply contrasts with the REC situation in Egypt, where half of the RECs had dedicated offices, furniture and computers[46]. Funding was also less than adequate in most cases. Teaching hospitals in Nigeria have three obligations that include teaching, services, and research. It might appear that the balance is heavily skewed toward the former two rather than the latter; hence issues of research and ethics committees still get less than optimal attention in terms of funding and infrastructure. This situation is however not restricted to the RECs surveyed. In a study involving seventeen of the twenty-two member states of the Eastern Mediterranean region of the WHO, Abou-Zeid and co investigators found that most national ethics committees lacked vital human, infrastructural and economic assets for effective functioning[47]. Kass and co workers[31] also noted the issue of scarce resources available to RECs in Africa. In India, 43% of the seven RECs examined [48] also lacked adequate financial muscle for their functions. The African Malaria Network (AMANET) in a study of 31 RECs in sub Saharan Africa found that 80.6% of them had insufficient

resources, had poor funding by their host institutions, and had no electronic data handling and archiving system[35]. Milford and co workers also found that 50% of surveyed RECs in Africa had no access to funding[34]. Traditional data capturing and storage systems involving large volumes of paper work, increases workload unnecessarily, slows down process of protocol review and communication, predisposes to data manipulation and loss, and generally impacts negatively on the output of the concerned RECs. On the other hand, poor funding and institutional support means that RECs' capacity to carry out certain functions effectively may be impaired. Such functions may include training for REC personnel and local researchers as well as carrying out oversight functions of project monitoring. This was evident in this study where the committees mainly restricted themselves to protocol review, modification and approval. The other functions as listed above, as well as, ensuring dissemination of research findings at the end of investigations were not undertaken by any of the committee.

Composition

RECs in southeast Nigeria had an average of 7.6 members, five having membership strength of seven while two had nine members. The NHREC recommends at least five members for any REC in Nigeria[40]. The Department of Health in South Africa recommends at least nine members for each committee[49]. In a study in South Africa, there were seven to twenty-nine members in RECs with a median of sixteen[33]. In Egypt the mean membership was 10.3, with a range of seven to nineteen[46]. In a case study of 12 RECs in Africa, Kass and co authors found a range of nine to thirty-one members in nine African countries[31]. The average membership of 7.6 of RECs in southeast Nigeria,

is above the five recommended by the United States DHHS[50] in the common rule, but fell short of the average of eleven (range of three to twenty-one) documented by AMANET in the survey of thirty-one RECs in sub Saharan Africa[35]. The reason is not immediately clear, but may range from hospital policy, disinterest by staff members, attitude to ethics, and research to low volume of research/investigations in the institutions. Mirroring typical hospital settings, physicians and nurses were part of all the committees (100%). Laboratory scientists and pharmacists were found in 71.4% and 57.1% of the committees respectively. By the virtue of their professions, they could all be taken to be primarily interested in the science of the protocol. Non scientific membership came in the form of staff from the medical records units in all the institutions (100%), a legal expert and a social worker in only one of the committees. Six committees had community members as part of the committees. In an Indian study, 100% of the committees had medical professionals, at least one female member and a legal expert; 86% had non medical members but none had a community representative[48]. Critical analysis of total membership of the committees in this survey reveals an unhealthy balance in favour of scientific membership (73.6%), with physicians maintaining a domineering strength of 42.9% (four of seven members) to 44.4% (four of nine members) and an average of 43.4%. In all the committees, nurses comprised 13.2 %. All the committees had female members. In South Africa[33] Health scientists/physicians also dominated (56%) committees, while nurses, pharmacists, lawyers, community representatives and statisticians made up, 6%, 5%, 8%, 8% and 1% of REC membership respectively. This predominance of medical scientists was also noted in the Eastern Mediterranean region[47] the United States of America[51] and

Egypt[46]. This pattern of membership may be related to the nature of protocols and investigations going on in the institutions, which, primarily may be health/clinical in design, hence the need to have enough expertise in the committee to scrutinise the scientific details.

In Nigeria, there may be another feature to the membership pattern but remains to be proven. Paramedical professionals including nurses, pharmacists, laboratory scientists among others, have persistently engaged in leadership tussle with doctors. The doctors on the other hand have consistently maintained and insist on headship positions in almost all areas of hospital and clinical management, probably including committees on research and ethics. The doctors may also argue that majority of the principal investigators in the institutional settings are clinicians. The competition is intense. This is however anecdotal.

Nevertheless, the United States OHRP recommends that the membership of Institutional review boards (IRB), as RECs are referred to in the US, should not necessarily be limited to five, but should include professionals and members of varied background in terms of race, gender and culture and with enough experience and skill to adequately review proposals and address issues arising , aimed at safeguarding the rights and interests of human participants[50]. It states that no IRB (REC) may comprise exclusively members of one profession and each IRB shall include at least one member whose major concerns are in scientific aspects and at least one member whose prime concerns are in non-scientific areas. All the RECs in southeast Nigeria had a good mix of scientific members (health scientists/clinicians) and non scientific members (medical record personnel) as well as community members in five of the committees. This is

particularly important to examine protocols not just in terms of their scientific merit, but also in terms of its social, community and cultural impacts as appreciated by lay and/or community members. The National Bioethics Advisory Commission (USA) recommends that non-scientists make up at least 25% of the IRBs' membership[52], while in the United Kingdom, community representatives are to constitute a third of the members[53]. In a survey of 12 RECs in Africa, ten (83.3%) had lay members[31]. In Egypt, 13.4% of the members were lay people[46]. Community representatives are members not really involved in the medical, legal and/or scientific analysis and are, if possible from the community[38]. They are not same as, and should not be confused with lay members[54]. Lay members are often highly educated members and may come from other professions like law, social services and even the clergy but not from health or allied professions. The RECs in this survey were diverse in outlook. Within the clinicians, the major departments in medical practice including, internal medicine, surgery, paediatrics and obstetrics and gynaecology, were often represented in the committees. Other notable medical specialties involved included pathology and radiology. Such distribution of medical specialists means that the committees might be comfortable assessing the scientific and clinical merits of most health related study protocols. Where this is not so, several authorities[40,50,54] suggest that input from relevant experts be enlisted for an in-depth review. This practice was however not the routine for the RECs surveyed in this study. However, very big RECs may be disadvantageous if, inherent personality differences and interests among members, become an impediment to protecting human research participants[55].

Other salient concerns in the composition of RECs are gender representation and institutional affiliation of members. Section 46.107 (b) of the US common rule (45CFR46)[50] among others, states that "Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender"[50]. All the committees in this survey had male and female members but males dominated in all cases. Women comprised 28.3% of the total membership in that region and ranged from 14.3% to 33.3% for individual committees. There was no fixed male: female ratio in all the committees. This gender imbalance was also noted among African RECs[31]. The upper limit of 33.3% was similar to that found in the AMANET's appraisal of thirty-one RECs in sub Saharan Africa[35]. In South African RECs, males also outnumbered females with a mean proportion of males cited as 63%[33]. One limitation of the present survey is its lack of inquiry into the underpinning dynamics or politics informing the appointment of persons into RECs in southeast Nigeria. It appears that in Nigeria, the medical/clinical profession is male dominated, hence on the basis of *pro re nata*, males will often surpass females in medical committees. This might be true, but one needs to consider the fact that the nursing profession in southeast Nigeria, on the other hand is almost exclusively female. Issues of gender balance become very important in Africa generally, and Nigeria particularly, where male dominance is maintained in every facet of life and society. Decisions during REC meetings are known to be influenced by culture and value systems[56]. The male-female dynamics in Africa may therefore impact on deliberations during ethics review. There may be a need to cushion this effect by striving for a better

gender balance in every REC. This is more so, when six of the seven committees had men as chairpersons. Only the oldest REC in the region was headed by a woman.

The US office for the protection of human research participants (OHRP) recommends that each IRB includes at least one member who has no affiliation with the institution and who is not part of the immediate family of someone affiliated with the organisation[50]. This requirement is also emphasised by the Nigerian NHREC[40]. The South African Department of Health also prescribes that membership of RECs include at least two individuals not affiliated to the institution[49]. Five of the committees in this study (71.4%) had members (all community representatives) who were not affiliated with the host institution. One REC had two such members while two RECs had all members affiliated to their institution. In general, non-affiliated members made up only 11.3% of the total membership strength of RECs in southeast Nigeria. In the AMANET review, ten of the 31 RECs had all members affiliated to the institutions[35]. In a 2006 survey of 12 RECs in South Africa, Moodley and Myer reported that two RECs had all their members independent or not affiliated with the institutions, while another two had all their members affiliated with their host establishment; the remaining eight had less than 50% of their members autonomous of the institutions[33]. Non-affiliated members are necessary to ensure neutrality of ethical reviews and protect the REC from institutional demands. In this study, all the non-affiliated members were community representatives and might not have attained the same educational and training heights as the institutionally affiliated members. Consequently, they might feel intimidated by the power differential between them and the clinicians/scientists[56]. This may not be very productive for the committees. Non-affiliated members can also be clinicians, scientists,

statisticians or other highly educated members from outside the institutions, at par educationally with their affiliated counterparts; in order to engender more power balanced deliberations and decisions. It has been argued that REC composition, power differentials, group dynamics, institutional policies and guidelines, all bear on the deliberation of RECs and consequently influence decisions[56.]

Members' training in ethics and research is an important ingredient for pro active and productive REC in terms of reviews, deliberations and decisions on proposals. The NHREC requires that all members of REC in Nigeria before registration must have completed an NHREC approved course in ethics. The six yet to be registered RECs in southeast Nigeria currently fall short of this requirement and this may hamper their registration. The importance of such training has also been emphasised by other regulatory bodies and authors[31,35,49 50 56]. About half of the members of the RECs in this study had no training in research ethics. This challenge is not limited to these RECs, but has been noted elsewhere. Rivera's review of RECs in Latin America showed that members had limited training[30]. In Tanzania, 45% of the members had no training[36], similar proportion (46%) was noted in the 2006 South African survey[33]. In that same survey, two of the RECs had no trained members, while only 25% of members of seven RECs assessed had formal training in India[48]. In Egypt, Sleem recorded a higher percentage of trained members (75%) and 100% of chairpersons[46]. The AMANET survey showed that training was limited in Africa and that 38% of members in the 31 RECs studied in Sub Saharan Africa also had no training[35]. Similarly, the RECs in Africa survey preparatory to HIV vaccine trials also revealed that only about 40% of REC members were trained in ethics before appointment into the committee[34]. The

importance of training in research ethics and/or methodology for REC members cannot be over emphasised. Members would need in-depth knowledge, skill and capacity to be able to contribute meaningfully to ethical reviews and debates[57]. The relevance of training of REC members in Nigeria becomes more relevant considering the limited access to training in the country. Weak social, economic and health infrastructure militate against such training, so also is the non-inclusion of research ethics in the curricula of medical schools in Nigeria[39,58]. Recently, participants at a training workshop in health research ethics posited that lack of such training is inimical to quality ethics review, monitoring of approved protocols, understanding the role of REC and the informed consent process[58]. This study established that all the chairpersons were aware of the existence of web based courses on research and ethics. This knowledge should be systematically made available to other members, who should be encouraged to undertake such courses. NHREC approved courses are also available online (http://www.citiprogram.org). These resources can go a long way in ameliorating the situation. A weak REC in terms of knowledgeable members can compromise protection of participants and delay review, hence impeding advancement of research in an institution and the society[56]. Host institutions should therefore help in this regard and the target should be 100%, such that each member is adequately equipped for the details of ethics review[57]. Nigeria and Africa need virile RECs in the quest to address the 10/90 gap[24 35].

OPERATIONS

Details of the RECs' operations revealed that all were largely involved in protocol review and approval only, and five do offer suggestions for protocol modification before eventual approval. These are fundamental duties of any REC in order to safeguard human participants. Another essential function is monitoring of research progress by the RECs[40,50,59]. All the committees examined were deficient in this latter task. This contrasted with the finding in a survey of seven RECs in India, where 57.1% of them monitored research progress[48]. Poor institutional support, funding and lack of necessary materials including vehicles and necessary logistics could be responsible for this. This does not enhance protection of human participants in research. Inadequate resources had been identified earlier by AMANET as militating against this oversight function of RECs in Africa[35]. Monitoring of projects at regular intervals, or at intervals corresponding to the scale of risk involved, but not less than once a year, is prescribed by most regulatory bodies[40,49 50,60]. Approval of a protocol by a committee including the informed consent process is not a one-stop affair but an enduring process that entails continuing IRB/REC oversight[59]. Many workers have noted that lack of resources for project monitoring in developing countries, seriously threatens the protection of research participants[32,61-63]. Further means of enhancing participants' safety and welfare in research, is by training researchers in research ethics and good clinical practice in general. In his examination of RECs in central and eastern Europe, Coker found that of the ten countries with national ethics committees, only three offered training in research ethics[64]. This point is highlighted by the NHREC for RECs in Nigeria. Section G subsection a of the Nigerian National Code for Health Research Ethics, states "HREC

shall organize, cause to be organized on its behalf, sponsor, support or associate with training and educational programs for biomedical, social and behavioural sciences' researchers[40]. Only one of the RECs surveyed undertook such trainings at intervals. The paucity of trained personnel on such RECs as well as poor funding and institutional support may well also be responsible. Many workers have earlier advocated strengthening of institutional support to enable RECs undertake these oversight functions[65-67]. In instances, institutional authorities have pointed to the fact that fees charged by RECs for protocol review, should be ploughed back into training of members. This would have been ideal, but for the low yield from such charges in resource-limited settings especially with paucity of sponsored investigations. Six committees charged fees for their review at a flat rate for non-sponsored protocols; rates for sponsor-driven protocols varied. This is in tandem with the NHREC regulation (NHREC) which allows RECs to charge fees at the institution's discretion[40]. In India, only one of the seven committees charged fees, and that applied to industry-sponsored protocols[48]. Two-thirds of the RECs in South Africa as at 2006 charged fees for review[33]. Authors have however called for the optimisation of such funds to decrease financial dependence on host institution[35].

Five of the RECs studied had Standard Operating Procedures (SOP) documents. Only one however had been revised in the last five years. SOPs are a prime requisite to regulate the activities of the committee to ensure fairness and effectiveness. This operational guideline should be such that the main objectives of the REC, (protection of research participants and respect for human dignity) are achieved in a transparent and research-friendly fashion. This is essential for quality control and reliability in the review

of ethical contents of research in a timely and independent manner[2]. The WHO guidelines of 2000[68] and other National authorities[40,60] spell out necessary ingredients to be included in SOPs. Among these are the composition requirements, functions and duties, terms and conditions of appointment, recruitment of independent consultants/experts, available offices and structure of the secretariat. It must also define its internal procedures from meeting schedules, agenda and minutes, quorum requirements, process of review and decision-making, maintenance of confidentiality of protocols to administrative procedures including financial transactions. The modality for application for review of protocols, required documentation including informed consent, protocol presentation, and process of amendment, complaints process and methods of communication with researchers should also be included in the SOP and be adequately publicised. Monitoring of research projects is an important part of REC functions. The SOP therefore should also incorporate the methods of regular research monitoring, monitoring of the informed consent and create access to members by research participants and communities for any complaints (including report of adverse events) or clarifications during the research. Furthermore, it should create an avenue for post-trial review and publication of research findings among the research participants/communities as well as global dissemination through journal publication. SOPs should also indicate the process of internal auditing of REC's activities and report to the National body for evaluation. It must be noted that a good SOP which is made available to the researching public goes a long way in dispelling the skepticism surrounding REC processes and procedures bred by the perceived secrecy of such committees[5,69]. In previous surveys, 45% of RECs in Latin America had SOP[30], 57% in

India[48], and 83.3% in South Africa [33]. The southeast Nigeria figure is comparable with these.

The Declaration of Helsinki was available to all members of three RECs, In addition, one other REC had the CIOMS guidelines available to its members. They all however had copies of the Nigerian National Code for Health Research Ethics (NCHRE). These are important documents guiding ethical research involving humans and it is pertinent that all REC members and researchers be conversant with them. Both the declaration of Helsinki and the CIOMS guidelines are the two most commonly employed documents by RECs globally[46]. For most RECs in southeast Nigeria (71.4%), meeting schedules were not fixed, but depended on the availability of proposals for review, i.e. on demand. This was not surprising, as six of the committees had about 50 or fewer protocols to review annually; and submission of these proposals might also have been investigator/sponsor-dependent and irregular. Two of them sat monthly and this included the one that reported between fifty and a hundred protocols to review each year. In the WHO African region, most RECs met monthly, and some, quarterly[36]. This finding was similar to that of Kass et al also surveying RECs in Africa, 58.3% met monthly and 16.7% met irregularly based on number of protocols available[31]. In the survey by Milford et al[34], 34% of RECs met monthly, while 25% met on *ad hoc* basis. The Nigerian National Code allows RECs to schedule their meetings according to needs, what is important is that the meetings be widely and timely circularized, to ensure scheduled meetings are quorate. Such schedules should be available to researchers to guide their submissions. The average workload for the RECs is low compared with that of some South African RECs with an average of four to thirty

protocols per meeting[33]. This might be a reflection of poor research culture in Southeast Nigeria. More worrisome is that only two of the committees had been involved in clinical trial protocol review. One limitation here, was that it was not evident from this survey how many such protocols were approved, and actually did take place. However, this may suggest that clinical trials and sponsored investigations are relatively few in this region which is home to over 20 million Nigerians[41] with high disease burden which might be ameliorated with simple cost-effective interventions[9]. Weak REC and ethical review systems might also be a possible reason for this.

All the committees reached decisions mainly by consensus or discussions - modalities approved by the NHREC[40]. This makes it more important that such committees be adequately constituted to enhance free and equal contributions from members – male, female, scientific, lay and community representatives alike.

All the RECs rated themselves as independent and thus able to arrive at decisions free from external encumbrances. This differs from the Milford et al survey where only 65% of RECs considered themselves truly independent[34]. Investigators are afforded the opportunity for input and clarifications by six of the committees but only one sought opinions from experts in fields in which the committee lacked expertise. Outsourcing of experts is an additional safeguard[40,49,50] to further protect research participants. They assist in reviews but do not vote with the committees. Such external experts may further enhance the independence of the REC. Independence of REC is important to arrive at unprejudiced decision aimed at safeguarding participants and avoiding the pressure to approve protocols to attract funds, infrastructure and employment[58].

The primary concerns of majority of the RECs were science and ethics. A few also did consider budget. It is necessary for each REC also to consider budgetary provisions of any research. Good investigations with sound scientific and ethical design and content may be rendered unethical, if available resources will not get it to operational conclusion, rendering participation of subjects futile.

The emphasis on ethics is to be expected since the major function of any REC/IRB is to promote ethics in research aimed at protecting participants. Consideration of the scientific design is also very important. Valid conclusions may only be informed by scientifically sound and properly designed investigations. Poor science in research exposes participants to risk for no just cause and tantamount to bad ethics[70,71]. The REC ideally analyses all aspects of a protocol (the objective and procedures designed to achieve the objective) as well as consider the investigator's qualification and competence, to take up responsibility for proper conduct of the research[71-73] and protection of human participants[68].

Scientific validity was one of the aspects evaluated before approval of a protocol by all the RECs in southeast Nigeria. Others included social value, informed consent procedure, risk/benefit analysis and respect for participants (100%). Some but not all also considered fair participant selection, independent review and collaborative community partnership. These eight items guarantee the ethics of a study especially in developing countries[74] and should be really evaluated by all RECs in all protocols before granting approval. They ensure that only necessary and relevant investigations, beneficial to the participants and community, are undertaken without undue risks to the

participants, while maintaining the highest ethical standards. The fact that they were not all considered by all committees, underscores the need for further training of REC members in southeast Nigeria. Nevertheless, flaws in methodological and ethical contents were the commonest reasons for rejection of proposals submitted by researchers. Two of the committees, on the average rejected about half of the proposals sent in for review. This high rejection rate and reasons for rejection may denote a deficiency in research methodology and ethics training among researchers in that region. It may also connote that researchers are not aware of the requirements or criteria for approval adopted by their local REC. Correction of this deficiency through ethics training falls within the ambits of RECs, which have been largely neglected for limited capacity and paucity of funds. This high rejection defers markedly from the Indian experience where only two percent of proposals were rejected[48], as well as in South Africa where the reported rejection rate varies from zero to ten percent, with a mean of 4.5%[33]. This difference may reflect differences in the skills of the researchers in protocol drafting, or the rejection criteria adopted by the RECs in the different countries.

Average time between submission of a proposal and final decision, varied between one month and three months for six of the seven RECs evaluated. For the last, this period ranged from three to six months. However, three of the committees reviewed protocols within a month of receipt, and all gave feedback to the investigators within a month of the initial meeting/decision. The average time for submission to decision in South Africa was five weeks (range 10 days to 10 weeks)[33]. Keeping this process open and timely will make operations of REC appreciated by investigators, who otherwise, deem the process of ethics review as burdensome and as such hinders clinical research[75]. The

NHREC stipulates a maximum of three months from receipt of proposal to final decision[40]. None of the committees received final project reports before dissemination. It is possible that some studies end up not being published. Putting participants through an investigation without dissemination of final results or the participants debriefed is unethical[3,74], an issue RECs should insist on. The situation was a bit different in India where four of the seven committees did receive final project reports[48].

The early developmental phase of the RECs in southeast informed their training needs. Unlike more advanced RECs as seen in Egypt[46] and South Africa[33] and some other African countries[35], where training needs related more to placebo controlled trials, determination and minimisation of risks and scientific design issues in clinical trials[33-35, 48]; training in basic protocol review, research methodology and informed consent process were all denoted as most pressing training needs by all the RECs in southeast Nigeria. Other pressing training needs were: training in clinical trial protocols, protection of vulnerable populations, good clinical practice, risk/benefit analysis, fair subject selection and monitoring/oversight functions of the REC. All the issues listed above are requisite knowledge for effective functioning of the RECs[58]. International collaboration was marked as pressing by five committees. This is important in the face of increasing foreign sponsored investigations in Africa[61,62]. RECs in southeast Nigeria must be versed in the intricacies of foreign investigations vis-a-vis the cultural inheritance of the local population, their vulnerability in the face of poverty and heavy disease burden, post-trial benefits amongst others, to protect the participants from exploitation[9]. Concerns have been raised by many stakeholders about increasing research activities in developing countries, without parallel boost in ethics review capacity[32,76,77]. It is

known that adequately constituted IRB/RECs and OHRP registration and Federal Wide Assurance are a *sine-qua-non* for US-Federally sponsored research[78]. RECs in southeast Nigeria should strive for this. None had OHRP and FWA registration. As at 2006, eight of the 12 RECs assessed in South Africa by Moodley& Myer[33] had Federal Wide Assurance numbers.

Training in Malaria and HIV vaccine research were also rated as pressing by some of the RECs. Such training is fundamental considering the devastation to health, economy and society by the two conditions.

Challenges

Committees charged with ethics review globally are faced with challenges[51] but these challenges tend to be more acute in developing nations[31]. In their survey of RECs in sub Saharan Africa, Kass and co workers as well as Milford et al recorded that most RECs faced the challenges of inadequate training/expertise, poor funding/resources and weak monitoring systems[31,34]. Similarly, Nyika et al in the AMANET survey also of 31 RECs in the same region, noted similar constraints, in addition to lack of active and consistent participation by members during meetings[35]. Other challenges recorded elsewhere include, poor financial/institutional support in India[48]; inadequate diversity of members in South Africa[33] and absence of national ethics guidelines and standards for RECs in Egypt[46]. These challenges were similarly voiced by the majority of the RECs in southeast Nigeria, particularly limited institutional support, funding, expertise, and training for members and researchers.

Limitations of this study.

This study was based on a self-administered questionnaire completed by chairpersons of the various RECs. Their responses might not have aptly reflected the views of the other members of their committees, especially if they were not consulted before completing the questionnaire. Moreover, being a form of self appraisal, there might have been the tendency to emphasise strengths while underreporting the weaknesses. Over emphasising capacity shortfall and training needs may be in attempt to secure funding[34]. Being a quantitative study, the study could not ascertain in depth, certain dynamics at play during committee meetings and decision making process. A further qualitative assessment through in-depth interviews of members and chairpersons to further evaluate the internal workings of RECs in southeast Nigeria is recommended. Any other weaknesses might have arisen from unreliability of the data collecting instrument.

Conclusion and Recommendations.

Research ethics committees in southeast Nigeria are in relatively early developmental stages with different degrees of unmet needs regarding their composition, training, operations, funding and registration with national and international registering authorities. With increasing international research activities in Africa, there is need for more investment in targeted capacity development for RECs. To ensure effectiveness, RECs should be independent of any political, institutional, professional and economic influence. This can be ensured by lay members of the committee, public accountability, audit and control of conflict of interest[3.] Institutional support in terms of finances,

administrative staff, office space and equipment are needed. Access to travel funds and vehicles and sundry logistics should also be provided, as these are essential for project monitoring. It is recommended that the Nigerian Ministry of Health – the parent body of the NHREC, goes a step further by detailing the forms of mandatory institutional support necessary to provide financial and logistic wherewithal for the REC to carry out such functions, like training of personnel and researchers, as well as research monitoring.

RECs should be able to build capacity within the population by training and re training programmes to the benefit of both the REC members and local investigators. However it must be recognised that any systematic training should require adaptation to the local context as well as economic and infrastructural support[3]. Ethics of biomedical research is becoming increasingly complex and members of RECs must keep abreast of the issues involved to ensure safety of the local population and distributive justice. There is a need for increasing partnership with funders within and outside the African continent for investment in capacity development to ensure that human participant protections keep pace with the complexity and volume of health research being conducted in Africa.

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Appendix.

Informed Consent form and the questionnaire.

ORGANISATIONAL STRUCTURE, OPERATIONS AND TRAINING NEEDS OF RESEARCH ETHICS COMMITTEES IN SOUTH EAST NIGERIA.

INFORMED CONSENT FORM.

Dear Sir/Madam,

I am currently an MPH student at the University of Pretoria, South Africa with special interest in Research Ethics. Apart from serving as my research project for the MPH degree, this survey will evaluate the organisational structure and function of research ethics committees (REC), within the Southeastern region of Nigeria, with a view to identifying their strengths, weaknesses, and possible training needs. Depending on the results, there is a possibility that institutions in the region may be viewed negatively by research funders and sponsors. A potential benefit however, is that it may be used to make case for further training and capacity building, for RECs in the region, hence enhancing their standards, and thereby attracting further international collaborative studies in the long run.

The questionnaire will take between 15 and 25 minutes to complete. All information will be treated confidentially and will not specifically be linked with your institution. Individual reports analyzing your specific response superimposed on the regional findings will be made available to you ONLY. Responses from all the centres would be used to describe the general trends across the region, this would be made public.

Participation in this survey is voluntary and you are at liberty to decline to participate or withdraw your information at anytime without offering any reason. I am also sending an electronic copy of this survey as an e mail attachment. I will be grateful if you could fill the questionnaire and return it to me through the enclosed self addressed envelope or if you prefer the electronic form, return it to me at oujair@yahoo.com.

The study has been ethically approved by the RECs of the Ebonyi State University Teaching Hospital (EBSUTH), Nigeria and the Faculty of Health Sciences, University of Pretoria, Republic of South Africa and they can be contacted at chinedunwigwe@yahoo.com, or +234 8035792970 and manda@up.ac.za or (Tel) +27 123541330 & (Fax) +27 123541367 respectively. Should you have any inquiries, please feel free to contact me at anytime via e mail at oujair@yahoo.com or by phone +234 8039558074 or +27834049650. Your assistance would be much appreciated.

Yours Sincerely,

Dr. OUJ Umeora

By signing here, you consent to participating in this survey

_____ _____ _____

NAME SIGN DATE

A QUESTIONNAIRE ON ORGANISATIONAL STRUCTURE, OPERATIONS AND TRAINING NEEDS OF RESEARCH ETHICS COMMITTEES IN SOUTH EAST NIGERIA.

SECTION A: GENERAL INFORMATION

1. Institution (Optional)_____
2. What is the name of your ethics committee? (optional)

   _____
3. Do research activities go on in your institution? No [ ] Yes [ ]
4. Do you have a research ethics committee (REC) or Institutional Review Board (IRB)?

   No [ ] Yes [ ]
5. If Yes, When was the Committee established? (dd/mm/yyyy) ____/____/_____
6. What is the source of legal instrument establishing your committee?

   Hospital/Institutional Board [ ] Government edict/law [ ]

   Legislative Act [ ] None [ ]
7. Are you aware of the existence of the National Health Research Ethics Council (NHREC)

   No [ ] Yes [ ]
8. Is the committee registered with the NHREC No [ ] Yes [ ]
9. How would you describe your committee local [ ] Regional [ ] National [ ]
10. Is the REC/IRB accredited by OHRP/FWA? No [ ] Yes [ ]
11. If Yes, give FWA number_____

SECTION B: ORGANISATIONAL STRUCTURE

12. Has the committee got office space for its own use? No [ ] Yes [ ]
13. If not, where do its meetings take place?_____
14. How many full time administrative staff works for the committee?_____
15. How many part time administrative staff works for the committee?_____
16. Please list the designations of the Admin. Staff _____

_____

_____

_____

17. Please list resources/office equipment available to the committee

Filing cabinet [ ] Computer/laptop [ ] Printer [ ]

Telephone [ ] Fax machine [ ] Photocopier [ ]

Office furniture [ ] Stationery [ ] Typewriter [ ]

E mail [ ] Internet access [ ] Library [ ]

Electronic data archiving system [ ] Bank account [ ]

18. What is your source of funding (check as many as are applicable)

Subvention from Government/Institution [ ]

Foreign agency [ ]

Charges from reviews [ ]

None [ ]

19. Is Ethics review compulsory for all studies in your institution? No [ ] Yes [ ]

20. What kind of support do you get from the Institution's management?

Funding [ ]

Infrastructure [ ]

Remuneration for administrative/secretariat staff [ ]

None [ ]

Others: Please how_____

_____

SECTION C: OPERATIONS

21. What functions have the committee carried out in the past or is currently performing?

Review and approve protocols	[ ]
Modify protocols	[ ]
Monitor research process and progress	[ ]
Train personnel in research ethics	[ ]
Train researchers in research ethics	[ ]
Ensure dissemination of research findings	[ ]

22. Do you have copies of the following and make them available to individual members?

	Have copies	Available to individual members
National code for health research ethics	[ ]	[ ]
Helsinki declaration	[ ]	[ ]
Belmont report	[ ]	[ ]
CIOMS* guidelines	[ ]	[ ]
Nuremberg code	[ ]	[ ]
Nuffield Council report	[ ]	[ ]
UNESCO Declaration	[ ]	[ ]

23. Do you have a standard operating procedure (SOP)? No [ ] Yes [ ]

24. For how long has the SOP been in existence? ≤5 years [ ] >5years [ ]

25. Has the SOP ever been revised? No [ ] Yes [ ]

26. If not confidential, how can your SOP be accessed?

_____ _____

27. How often does the committee convene for protocol review?

Weekly [ ] fortnightly [ ]

Monthly [ ] Every three months [ ]

Others: please specify _____ _____

28. If meeting schedules are not fixed, what determines when meetings are held?

Availability of protocol/proposal for review [ ]

Arbitrary [ ]

Others: specify _____

29. What is the average number of protocols reviewed annually?

Ten or less [ ] 11 – 50 [ ]

51 – 100 [ ] > 100 [ ]

30. What proportion are clinical trials?

None [ ] < 10% [ ] 10-50% [ ] >50% [ ]

31. What is the main focus of the committee in protocol review?

Science, ethics & budget [ ] Primarily science & ethics [ ]

Primarily science [ ] Primarily ethics [ ]

32. Which of these do you consider during protocol review? (check as many as are applicable).

Collaborative partnership with community [ ]

Social value of the study [ ]

Scientific validity [ ]

Risk:Benefit analysis [ ]

Independent review [ ]

Fair participants' selection [ ]

Informed consent [ ]

Respect for Participants [ ]

33. How do you rate the capacity of your committee to review research protocol?

Limited [ ] Moderate [ ]

Good [ ] Excellent [ ]

34. Has your committee been involved in ethical review of any clinical trial?

No [ ] Yes [ ]

35. How do you rate the independence of your committee?

Truly independent [ ] Partially independent [ ] Not independent [ ]

36. What are the perceived challenges to the committee's independence?

Lack of transparency of the committee [ ]

Material offers or favour to the committee [ ]

Pressure from politicians [ ]

Pressure from sponsors [ ]

Pressure from Principal investigators [ ]

Pressure from institutions [ ]

Biased committee members [ ]

Unequal treatment of applications in the review process [ ]

Others: please specify_____

37. What proportion of protocols is initially rejected?

Less than a third [ ] About Half [ ] More than half [ ]

38. If not confidential, State the commonest reasons for protocol rejection

Methodological issues [ ]

Ethical issues [ ]

Funding [ ]

Limited capacity to implement protocol [ ]

39. Please estimate the following time intervals

	< 1month	1- 3 months	3-6 months	> 6 months
Submission to Review	[ ]	[ ]	[ ]	[ ]
Review to Feedback	[ ]	[ ]	[ ]	[ ]
Feedback to final approval	[ ]	[ ]	[ ]	[ ]
Total Submission to Approval	[ ]	[ ]	[ ]	[ ]

40. How are decisions arrived at for protocol review?

Majority vote [ ] consensus [ ] Discussions [ ]

41. Are the committees' meetings open to observers? No [ ] Yes [ ]

42. Are researchers invited to the meetings for input? No [ ] Yes [ ]

43. Are fees charged per protocol? No [ ] Yes [ ]

44. Are the fees flat charges for all protocols [ ] or flexible [ ]

45. If flexible, please give rates _____

46. Are research findings presented to the committee before wider dissemination?

No [ ] Yes [ ]

47. How often are the operations of your committee reviewed/audited?

Never [ ] Annually [ ] Irregularly [ ]

SECTION D: COMPOSITION

48. How many members are there in the Ethics committee? _____

49. What is the profession of the Chairperson? _____

50. Is the headship rotational? No [ ] Yes [ ]

51. Are members co opted at instances? No [ ] Yes [ ]

52. What informs who you co opt at such instances?

Vulnerable population involved [ ]

Expert scientific opinion required [ ]

Others: Specify _____

53. How many members are males? _____ and females? _____

54.Is the male/female ratio fixed? No [ ] Yes [ ]

55. How many members are staff/affiliated to the institution? _____

56. How many members are from outside the hospital/university community?_____

57. Do you organize in-house training for members? No [ ] Yes [ ]

58. Do you know of web-based training in research ethics? No [ ] Yes [ ]

59. Are members remunerated? No [ ] Yes [ ]

60. Is the Chairperson trained in research ethics? No [ ] Yes [ ]

61. What is the tenure of members of the committee in years? _____

62. How are members appointed into the committee?

On Individual merit	[ ]
Representing various interests/departments	[ ]
Discretion of the Institution/hospital management	[ ]
Individuals volunteer	[ ]
On recommendation of the Ethics committee	[ ]
Recommended by research sponsors	[ ]

63/64.PLEASE COMPLETE THE FOLLOWING TABLE ON THE MEMBERSHIP OF THE COMMITTEE. (see attached)

SECTION E: TRAINING NEEDS

65. Please indicate the perceived training needs of your committee (using a scale of 1 – 5, rank these needs as follows: 1- Most pressing need; 2- pressing need; 3 – Needed; 4 – indifferent; 5- not needed)

Basic health research ethics	[ ]
Advanced health research ethics	[ ]
Good clinical practice	[ ]
Basic protocol review process	[ ]
Clinical trial protocol review	[ ]
Community Engagement	[ ]
Malaria Vaccine trial	[ ]
HIV Vaccine trial	[ ]

Payments in research	[ ]
Ancillary Care	[ ]
Informed Consent	[ ]
Fair subject selection	[ ]
International Collaboration	[ ]
Post trial benefits	[ ]
Protection of vulnerable groups	[ ]
Monitoring & Oversight functions of RECs	[ ]
Law & Human Right Issues	[ ]
Risk: Benefit analysis	[ ]
Use of Placebo in Randomized Controlled Trials	[ ]
Assessment of Cultural Influence	[ ]
Privacy & confidentiality	[ ]
Administrative issues	[ ]

Others: Please specify _____

_____

_____

SECTION D (CONTD): Composition

Please complete the following table (use additional sheets if necessary):

63 **Please outline the composition of your ethics committee:**

	Position on committee (eg. Chair, Administrator, Member)	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 days.	
									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_____		

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

_____

_____

****adapted from the Ethics, Law & Human Rights working group of the African AIDS Vaccine Programme (AAVP), University of KwaZulu-Natal, Pietermaritburg, Republic of South Africa.**

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