

Factors Influencing the Functioning of Health Research Ethics Committees and Their Implications for Public Health Research in Bauchi and Sokoto States, Nigeria: Lessons Learned from a Retrospective Study

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Article History

Received: 09 / 05 / 2026

Accepted: 14 / 06 / 2026

Published: 29 / 06 / 2026

Abstract: The need for research to conform to recognized ethical standards while the dignity, rights, safety and welfare of vulnerable individual are protected necessitates the adequate functioning Health Research Ethics Committee (HREC). This study therefore investigated the factors influencing the work of HREC in Bauchi and Sokoto States, Nigeria.

The study is a cross sectional survey of ethics committee members between 2014 to 2015. In dept interview were separately conducted for each of the six active HRECs members recruited from each state in this study. Prior to the conduct of the interview, informed consent and appointment for the face to face interview were earlier sought and granted by the respondents.

Respondents admitted that there was no oversight function in the role of HREC to review and approve the research protocols. The ethical protocols take between two weeks to a month before approval. Although, members of committee showed record of good attendance but their performance was rated average while the quarterly scheduled meeting has not been consistent. More so, there has not been any rotation of the members of committee since the inception of the body. However, all the respondents agreed that they have been receiving quality training mostly sponsored by TSHIP. Despite non-financial gains respondents offered voluntary services. The challenges commonly encountered by the HREC committee includes non-availability of an office, office equipment and stationeries, challenges in the monitoring of research work and lack of budgetary allocation for the committee for refreshment during meetings.

Operations of HREC committees in Bauchi and Sokoto States have enhanced the research activities in the states. However, inclusion of more academicians as reviewers and support of state governments is very essential for the improved performances of the committees.

Keywords: *Research Ethics Committee, Bauchi, Sokoto, TSHIP.*

How to Cite in APA format: Danladi, S. E., Oguntunde, O. & Garba, A. M. (2026). Factors Influencing the Functioning of Health Research Ethics Committees and Their Implications for Public Health Research in Bauchi and Sokoto States, Nigeria: Lessons Learned from a Retrospective Study. *IRASS Journal of Multidisciplinary Studies*, 3(6), 29-33.

Introduction

The need to strengthen the research participant protection systems in developing countries has been long recognized (Kass et al., 2003; Nyika et al., 2009). This had however led to the development of research ethics committees (RECs) which either develop or adapt international ethics regulation for better local application (Hyder et al., 2004; Chima, 2006). A research ethics committee according to UK Department of Health consists of a group of people appointed to review research proposals, to assess formally if the research is ethical. This means the research must conform to recognized ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part (UK Department of Health, 2011; WHO, 2009). Protection of the rights and welfare of vulnerable individual was further emphasized in the guidelines (CIOMS and WHO, 2016). According to the international guidelines (CIOMS, 2002; World Medical Association, 2000) and several nations' laws (National Consensus Conference on Bioethics and Health Research in Uganda, 1997; ICMR, 2000), research with humans requires independent ethics committee review. Ethics committees in Nigeria have been established over the year largely in University teaching

hospitals and a few research institutes and most commonly in accordance with United States (US) regulations and the Common Rule (U.S. Department of Health & Human Services, 2009). The Office of Human Research Protection (OHRP) of the United States records that there are 39 ethics committees in Nigeria registered with it. However local experience suggests that there indeed might be more as some of these committees have been in existence for the greater part of the last decade then without any local guidance and mechanism for coordination of their activities (Medical World of Nigeria, 2015).

The National Health Research Ethics Committee, Nigeria (NREC) was established in year 2006 with the mandate which include; review of research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases. The body also facilitates grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health



research ethics committee. Hence, every institution, health agency and health establishment at which health research is conducted are mandated to establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Committee (NREC, 2016).

Prior to the intervention of the Targeted States High Impact Project (TSHIP) in establishing Health Research Ethics Committees (HREC) in 2010, there was no any ethics committee in the State Ministries of Health of Bauchi and Sokoto state. Research organizations and individuals went straight to communities and conducted research while others approached the ministries for a formal permission to carry out the research. Thus, the rights and welfare of research subjects involved in the research were not protected due to absence of institutionalized ethical body. However, the inception of committees in the state might have brought about change in conducts of health research through thorough review of research protocols to assess methodological, ethical and legal aspects of all research carried out on humans in the States. Hence, the aim of this study is to evaluate performance of research ethics committee in Bauchi and Sokoto states Nigeria in safe guarding rights and welfare of human subjects in accordance with national codes of Ethics and international standards.

Methodology

Study design

This is a cross sectional study conducted among the HRECs members in Bauchi and Sokoto States between May and June, 2016. In dept interview were separately conducted for each of the six active HRECs members recruited from each state in this study. Prior to the conduct of the interview, informed consent and appointment for the face to face interview were earlier sought and granted by the respondents.

Data collection

Structured guide for in-depth interviews were used to collect primary information from the HREC members to assess their experience as well as their opinions on the barriers, suggestions and possible facilitators that would ensure sustainability of HRECs in the future. The interviews were audio recorded, later transcribed and harnessed with the information gathered by the interviewer taking notes during interviews.

Desk reviews were also conducted on HRECs' registers of the protocols to assess the availability, completeness of data, type and information of the number of protocols reviewed, average turnaround time on receiving protocols and issuing approvals.

Data processing

Data gathered were carefully placed under the relevant emerging themes from the transcripts using the process of constant comparison, in which each item was checked or compared with the rest of the data in order to establish analytical categories. Some selected typical quotes were also included in the study descriptive report in order to emphasize responses of the interviewee without losing the original context of the meaning.

Ethical considerations

Protocol was submitted to the Futures Group Ethics Committee to obtain ethical clearance and to Bauchi and Sokoto

States Ethics committee for review and ethical approvals. Informed consent was used to obtain verbal permission from respondents before commencement of the interview while confidentiality was maintained throughout the study processes.

Results

According to respondents, the major role of HREC is to review and approve the research protocol having met the criteria. Most respondents were of opinion that there was no oversight function except one who stated that the committee does monitor the research at times.

Among the functions and the role of the committee, I think the most important to me is I can say after collecting all the research approving but the mono frame of the research process should be the important aspect because the committee is suppose to periodically monitor the conduct of the research during the research process.

The ethical procedure employed by the committee involves submission of the research protocols to the committee through the commissioner who forwards it to the Permanent Secretary, through whom it would be sent to the desk officer. After assessing the protocol, the desk officer send it to reviewers or a specialist as need be otherwise, it can be approved if the noted errors are corrected and the approval communicated to the researcher through phone call.

..now the ethical process face all the research proposals for anybody who intend to carry out research should submit his proposal through the research ethic secretariat, that is through the honourable commissioner first, when the proposal is being collected, the research committee also sit and look at all the proposals and then ensure that all the guideline is been adhered to, then they will now pass this proposal for approval then the research will go on, on the process of conducting the research will also submit the report of the research to the committee, then the research will be disseminated and then use by the state.

According to most respondents, it takes an average of two weeks for a protocol to be approved while others stated that it takes up to a month if the protocol has to pass through a specialist, who may not be available at all time. The performance of the committee was rated at an average of 50% by the respondents while the frequency of their meeting scheduled quarterly was not consistent as the last meeting was held over a year past. Members of committee showed record of good attendance, as at least 80% of the total members were usually available when invited to the meeting while others were mostly unavoidably absent. Apart from a member that died and another that got another appointment, all the members from the inception were still part of the committee in Bauchi state and there has not been any rotation of the committee except replacement of members who retired from their official duty.

As regards the process against HREC standard, there was no waiver or exception. The desk officer makes copies of the protocol and shared with the HREC members after which a review was held and necessary corrections pointed out for amendment before consideration for approval which was communicated to the Permanent Secretary and the Commissioner. Some of the

respondents were of the opinion that delay in protocol approval arises as a result of the number of reviewers involved while others stated that since the committee's work is an adhoc work their primary assignments may limit the active participation in the review process. However, reaching a researcher on the feedback could be difficult in situation such where did not drop their phone numbers, thus constituting delay in the process.

If there are obstacle for delay in processing, the delay may be when an applicant submit his application if there is anything that either his application does not carry any contract phone number or all the necessary thing that you get contract with the application, that will delay, so that will be one of the obstacles, if his submission there's some gap that he is suppose to come and give more information on some certain things that will delay.

Members of the committee were always available except when preoccupied by their regular duties. All the respondents also agreed that they have been receiving quality training mostly sponsored by TSHIP.

Availability means when they call for meeting will they be always available?.....Yes, they will be available unless as I have said earlier if the member of the committee is not present, if he is already away for another assignment that is all I know but I know if he is present he will be available at the meeting

....I have been trained last time after the inauguration, the training conducted at Zaranda where TSHIP supports the training.....

Despite non financial gains and lack of a designated office for the committee's operation, respondents offered voluntary services and were motivated by the fact that they are rendering service to humanity.

.....anybody that finds himself in that committee it's a job responsibility because I know his organization nominated him (or her) to be part of this base on his own schedule of responsibility

Based on the submission of the respondents, awareness of the public of the existence of the committee's existence, committee's protection of the public, their reviewing and approval of the protocols as well as the National registration by HREC were stated as the major achievements recorded so far.

...the committee has achieved a lot of things, because all the research that is being conducted currently in the state goes through the research ethics committee and this a loudable achievement, and the committee are doing their responsibility very well and then also TSHIP is also supporting the committee intensively to see that they perform their responsibility as contend in ethics of protocols....

The challenges commonly encountered by the HREC committee includes; non-availability of an office, office equipment and stationeries, challenges in the monitoring of research work and lack of budgetary allocation for the committee for refreshment during meetings. Hence the view of the members interviewed towards the sustainability of HREC entails; the need for periodic training and retraining of both the old and new members, the need

for inclusion of more academicians that can serve as reviewers among the committee members, as well as having some administrative staff for the committee. Moreso, the respondents stated the need for state government's involvement as regards budgetary allocation, office and other facilities provision.

...Government should also try to ensure continuous funding of HREC, because that is the only way we (would) have sustainability even if the international donor partners that are supporting us are not there, the state can sustain the good things that have been already established in the state...

Discussion

The major role of (Health Research Ethics Committee) HREC as enumerated by the respondents in this study is to review and approve the research protocol having met the set criteria. This view is found in agreement with the report of Okonta and Umeora (2011) who described the role of HREC as fostering the integrity of Health Research in the country. However, HREC committee in Bauchi and Sokoto state often plays an oversight role and performs the function of a third party independent review of the research protocols submitted by researchers in the respective states. This is similar to the role plays for staff and students of the University by the University College Hospital Health Research Ethics Committee (UCH HREC) reported by Eyelade et al. (2011).

Ethical procedure employed by the committee in this study involves the deliberations of the committee on the submitted research protocol to ensure its conformity with the guideline, after which the document is sent to reviewers or specialist as the case may be. Approvals of qualified protocols are then granted when the arising issues have been resolved. This procedure consider the seven requirements proposed as necessary to make research ethical, these are; enhancement of health or knowledge, the research must be methodologically rigorous, the human subjects must be fairly selected based on the scientific objectives and not vulnerability or privilege or the potential for and distribution of risks and benefits, there must be favourable risk-benefit ratio within the context of standard clinical practice and the research protocol, an independent review by unaffiliated individuals to approve, amend, or terminate the research and an informed voluntary consent by individual participants. Also, the human subjects should have their privacy protected, well-being monitored and the opportunity to withdraw (Emanuel et al., 2000; Eyelade et al., 2011; Okonta et al. 2011). Contrary to the duration of two to four weeks in which the full review process of a submitted protocol was reported to be completed in this study, an average of 21 weeks was reported in an earlier study (Eyelade et al. 2011), whereas, NHREC guidelines stipulates a maximum period of 3 months from the date of receipt of a valid application (Beecher, 1966; NHREC, 2007).

Generally, respondents rated the performances of HREC in the two states as average. This could be due to the adequate attendance of the committee when called for meetings or review wish could be facilitated by the timely information prior the day of the meeting. According to the terms of reference of WA Country Health Service (2015), notices of the meeting are expected to be dispatched five working days in advance of the meeting date. The Committee meetings in this investigation were not consistently held quarterly as scheduled, contrary to the monthly meeting proposed. Although, inconsistencies in time of the meeting could

be justified by ability of the chairperson to cancel a meeting if there is insufficient business to warrant holding a meeting (WA Country Health Service, 2015).

All the respondents interviewed in the two states have been undergoing series of training sponsored by TSHIP, the essence of training programme especially for new members of the committee who have not had previous formal training on research ethics was further enumerated in an earlier report (West African Bioethics, 2016). Moreso, some members of the committee as observed in the study became members by the virtue of their offices. However membership of the HREC committee is voluntary as was also found in the report of Boyd et al. (2016).

The respondents were of the opinion that sustainability of HREC depends on prompt solutions to the problems presently confronting it, the chief of which is associated with inadequate funding. Similar, challenges were encountered in an institution based ethical body (West African Bioethics, 2016). Periodic training of committee members, inclusion of more academicians that can serve as reviewers in the committee and as well as financial participation of state Governments were stated as possible measures of maintaining the operations and sustaining the integrity of HREC in the Bauchi and Sokoto states.

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