FEDERAL NEUROPSYCHIATRIC HOSPITAL, ARO, ABEOKUTA

HOSPITAL RESEARCH ETHICS COMMITTEE

INSTRUCTIONS TO INVESTIGATORS

Version 3 – June 21, 2018

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ACRONYMS

NCHRE	National Code of Health Research Ethics
FNPHA	Federal Neuropsychiatric Hospital, Abeokuta
HREC	Hospital Research Ethics Committee.

INTRODUCTION

This guideline is derived from the National Code of Health Research Ethics (NCHRE) of Nigeria[1], specifically from Sections B, C (sub-section f, paragraphs 1 and 2), E (sub-sections f, g, h, and s) and F, which are relevant to the investigators and reviewers. It is recommended that Investigators should be familiar with the complete national code[2], which is freely available online, in addition to the content of this guide.

The NCHRE applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria.

Health Research Ethics Committee (HREC) of the Federal Neuropsychiatric Hospital, Aro, Abeokuta (FNPHA) accepts for ethics review ONLY health research involving human participants, conducted, supported or otherwise subject to regulation by the FNPHA. The scope of the FNPHA HREC, is limited to

1. research to be done in FNPHA by anyone.
2. research to be done by permanent staff of FNPHA outside the hospital
3. research to be done by a permanent member of staff of another institution (within Ogun state or the South West geopolitical zone) which has valid collaborative agreement with FNPHA as endorsed by the NHREC (Ref. Code Section C [e & f]).
4. any research proposal to be reviewed by the instruction and on behalf of the National Health Research Ethics Committee (NHREC)

Research here is defined as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. It may consist of:

a) Therapeutic procedures – interventions administered with the intent of providing direct benefit to the research participants.
b) Non-therapeutic procedures – interventions that are not administered with therapeutic intent and are only intended to answer the scientific question of the study

Activities which meet this definition constitute research by the definition of NHREC, whether or not they are conducted or supported under a program which is considered to be research for other purposes; for example, some demonstrations and service programs may include research activities.

[1] http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf

TYPES OF APPLICATION TO THE HREC

There are 4 types of application that can be made to HREC for ethical review. An investigator may indicate any of them at the point of submission. They are:

1. *Exemption from review*: - This review exempts a proposal from full ethics review.
2. *Expedited review*: - This review subjects a proposal to full ethical review but does not have to wait for the next regular meeting of HREC before approval is granted.
3. *Full review*: - This review subjects a proposal to the full ethical review process which usually terminates at the decision during HREC meeting. The review covers both *scientific* and *ethical* acceptability of the proposed study.

Exemption from review

Characteristics of a proposal that qualifies for exemption are listed and explained in Appendix 1. An investigator who wishes to apply for exemption from ethics review shall complete the checklist in Appendix 2. If the total score on the checklist is zero, the proposal likely qualifies for the exemption. The final determination of the qualification for exemption rests with the HREC.

All exemptions shall be determined by the Health Research Ethics Committee (HREC). Applicants for exemption shall submit the ***proposal*** with ***enough information for determination to be made***, to the HREC. The HREC Chairperson or his designee, in consultation with the HREC Administrative Officer, shall decide whether the research proposal qualities for exemption from full review process. Where the Chairperson is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal shall be referred to HREC. All applications for exemption shall be brought to the notice of HREC at its regular meeting for discussion and ratification.

Expedited review

Characteristics of a proposal that qualifies for expedited review are listed and explained in Appendix 3. An investigator who wishes to apply for expedited review shall complete the checklist in Appendix 4. If the total score on the checklist (4) is zero, the proposal likely qualifies for expedited review. The final determination of the qualification for expedited review rests with the HREC.

A proposal eligible for expedited review is subjected to the process of ethical review except that it does not have to wait for the next regular meeting of the HREC before approval is granted..

Amendment of research proposal

Under no circumstance shall a researcher deviate from approved protocol, except such as is necessary to eliminate immediate hazard to research participants. The researcher shall notify the Chairman of HREC within 24 hours of such changes.

HREC requires that applicants apply for permission to amend protocols in any of the following circumstances:

i. Where there are changes in any part of the research protocol that alters the risk benefit ratio of the research.
ii. Where there are changes in the named members of the team conducting the research.
iii. Where there are changes in research sites.
iv. Where there are changes in sponsorship, institutional guidelines, institutional structure, HREC requirements, national laws or exigencies that impact on the ethical conduct of research.

The application for amendment shall pass through expedited review if there are only minor changes to previously approved research during the period for which approval is authorized.

The HREC shall require that researcher submit an application for original research approval where in its opinion, the proposed amendments are substantial, such as but not limited to, change(s) in inclusion or exclusion criteria, randomization, interventions and outcome measures, in which case, the researcher shall stop the research and the HREC shall conduct a thorough review of the research before authorizing suspension, continuation or modifications to the research.

Full review

The decisions on research proposals for full review are reached during the regular ordinary meetings of the HREC, after due review process. The full review focuses on two aspects of the proposal as contained in the National Code of Health Research Ethics:

1. **Scientific validity**:- Clarity of scientific objective(s), use of valid methodology, adequate sample size (well powered), equipoise (for clinical studies), adequate operationalizing plans within the

context of the environment where research would be conducted, plausible data analysis plan (including a specific role for a Data and Safety Monitoring Board [DSMB] in clinical trials), and valid measurement(s) of outcome(s) that mitigates bias.

(**NB**: Review for scientific validity does not cover all the dimensions of *full scientific and grammatical / language* review of proposal, which is beyond the scope of HREC and better left to the academic bodies to handle.)

2. **Ethical principles**: - To protect the rights and justifiable interests of the research ***participants***, ***community*** in which the study takes place, ***researcher*** and ***research sponsor***.

REVIEW PROCESS

Application

- Access the online review page: www.review.neuroaro.gov.ng
- Create a user account if none exists.
- Be familiar with the instructions to investigators and the National Code of Health Research Ethics
- Pay the specified applicable fee online and obtain electronic receipt via remita payment gateway.
- Upload the proposal and other documents as applicable below:
    1. One-page plain language summary of the research including the title of the study, research design, methodology, principal exposure and outcome variables but must not contain information about the investigator/sponsor.
    2. The proposal without the cover page and without the consent form (anonymity)
    3. The consent form with all required information to identify the researcher/sponsor/affiliation
    4. The consent form with all required information to identify the researcher/sponsor/affiliation ***replaced with XXXXXXXX (to ensure anonymity)***.
    5. Cover page (as a separate file) that shows the following
        - Title of research, Full Names, qualifications of investigators, and e-mail Addresses
        - Names of Sponsors (where applicable),
        - Other Collaborating Institutions and Investigators (where applicable),
        - Corresponding Investigator, who must be the Project Principal Investigator (PI) or Local PI of the research and bears legal responsibility for the research.
    6. Supervisor's attestation statement. (Where applicable – in student's research, for example).
    7. Receipt for due payment
    8. Completed application form
    9. Completed principal investigator's CV in NIH (biosketch) format (maximum 2 pages, containing enough information to judge the ability of the PI to conduct the research)
    10. Evidence of completed ethics training on either of the two acceptable websites (www.citiprogram.org, OR www.elearning.trree.org)
    11. Application letter for ethics review addressed to the Chairman, HPHA Research Ethics Committee, Neuropsychiatric Hospital, Aro, Abeokuta, Ogun state, Nigeria.

12. Co-Investigators attestation statement. (Where applicable) or Copy of letter(s) of support from co-investigator(s), laboratories and sources of required resources (where the researcher indicates that s/he will be collaborating with others.
13. Sponsor's attestation statement i.e. letter of sponsorship. (Where applicable)
14. Materials Transfer Agreement (MTA - Where samples will be shipped out of Nigeria – see prototype on the NHREC website for guidance)
15. Clinical Trial Agreement (CTA – Where the research is being conducted on behalf of a sponsor) and any other agreement that may have been signed and is relevant to the participants in the research.

Protocol review rates

A. NPHA Staff
   a. Student Nurses - 2,000
   b. Undergraduates - 2,500
   c. Resident Doctors/MSc Students - 4,00
   d. Consultants/PhD Students - 6,000
B. Non-NPHA Staff
   a. Student Nurses - 3,000
   b. Working Class Undergraduates - 4,00
   c. Resident Doctors/MSc Students - 5,000
   d. Consultants/PhD Students - 10,000
C. Self-Funded Research by Nigerians in Diaspora - 15,000
D. Self-Funded Research by Foreigners - 30, 000
E. Nationally Funded Research - 25,000
F. Internationally Funded Research - 50,000

How to pay the fees online

- Visit: https://www.remita.net/
- Click "Pay FGN and State TSA
- Select Federal Government of Nigeria
- Name of MDA: FEDERAL NEURO-PSYCHIATRIC HOSPITAL ABEOKUTA - 1000035
- Name of Service/Purpose: ETHICAL REVIEW FEE
- Description of Payment: Title of your research proposal
- Amount to Pay: put in the appropriate fee as show above
- Complete the rest of the form and pay through any of the payment options available in Remita.
- The remita receipt will be sent to your email.
- You should upload the receipt during the submission process along with other required documents

The review

The uploaded proposal passes through online review and can be tracked by the investigator. The NPHA HREC has set a benchmark of 4-6 weeks to conclude each review and notify the applicant of the outcome. When a submission is assigned to a review, 2 weeks are allowed for the response to accept or reject to review. Four weeks from the time of acceptance is allowed for the reviewer to complete the review and submit report. Automated reminder is sent to the reviewer a day after the due date for acceptance/rejection and report submission respectively.

HREC has a maximum of 3 months from the date of receipt of a valid application to conclude the review and notify investigator(s) in writing of its decision to *approve*, decline approval or *require modifications* of the proposed research activity. (An application shall be considered valid only after receipt of all materials required by HREC to give a determination.)

Where HREC decides to decline approval of a health research activity, it shall include in its written notification, a statement of the reason(s) for its decision and give the applicant an opportunity to respond in person or in writing within 3 months of receipt of the notification.

Where HREC has received representation from the applicant in response to an existing decision, HREC may decide to uphold or modify its previous decision and shall communicate its decision to the investigator within 3 months of the representation. The benchmark here is 2 weeks for NPHA HREC.

Where HREC does not notify the applicant of its decision within three months of application or of response to an existing decision of HREC, the applicant shall have the right to complain to NHREC with the possibility of reallocation of the proposal to another HREC and sanction of the concerned HREC.

ETHICAL PRINCIPLES AND GUIDELINES FOR HREC APPROVAL OF RESEARCH

To approve research covered by this code, the HREC shall determine a balance between the various principles guiding the ethical conduct of research, the core of which are contained in the NCHRE and outlined in the checklist in Appendix 5. Since some of these will inevitably conflict, judgement and consensus among HREC members are essential in determining whether a research should be conducted.

To increase the chances of the research proposal being approved at the first review (or at all), the investigators should ensure that it contains enough information to allow the committee judge the scientific validity and ethical aspects of the research. Therefore, the following sections may be considered in the proposal (*NB – the arrangement and the names of the sections and sub-sections do not matter as much at the information provided to make review decision*):

A. **Background of Study** - Describing current knowledge about the research.
    a. Rationale for the study
    b. Objectives of the study

B. Research Methods

    a. Study design - stating clearly the nature of the study (descriptive, drug trial, experimental)
    b. Study site / setting.
    c. Sample size determination
    d. Sampling strategy/Interview including inclusion/exclusion criteria/frequency of interviews
    e. Measures
    f. Instruments – scoring, interpretation, psychometric properties.
    g. Data collection procedure
    h. Statement on invasive sampling (blood, tissue etc) inclusion/exclusion criteria and frequency of (invasive) sampling
    i. Physical examination procedure if indicated
    j. Follow up details if required
    k. Laboratory procedure to be used

l. Intervention to be used

m. Data analysis method to be used

C. **Ethical considerations** - This may be a sub-section of Research methods or a separate entity. In this section, researcher is to clearly identify the potential ethical problems that may arise in the research and address these. For example, if conducting research on prisoner, the issues of vulnerability and diminished autonomy are important, and the researcher should address these concerns in the protocol. The scope of details required in this section depends on the nature of the study (see relevant items in Appendix 5). At the **minimum**, the following subheadings should be itemized and explained in the protocol:

a. Confidentiality of data;

b. Translation of protocol to the local language;

c. Beneficence to participants;

d. Non –maleficence to participants;

e. Voluntariness

In addition, there should be a copy of *consent form* as an attachment / appendix to the proposal. A prototype of the consent form is available for free download.

D. **Mode of dissemination of the research finding**s:-

APPENDIX 1: CHARACTERISTICS OF PROPOSALS THAT QUALIFY FOR EXEMPTION

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    1. Research on regular and special education instructional strategies, or
    2. Research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:
    1. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
    2. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available (note that this refers to availability of data and not the status of the custodian of the information/data) or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
D. Studies that are meant to evaluate the outcome of procedures, programs and services are exempt because they are designed to produce information leading to improvement in delivery of procedures, programs and services. Such studies usually evaluate measures that are already in use and considered part of standard practice. They may include collection and analysis of data or collection of new data but they do not involve allocation into groups or randomisation.
E. Studies that are designed to evaluate or assess quality of services, programs and procedures and formulate guidelines leading to their improvement are exempt. Such studies may involve the collection and analysis of some data.
F. Innovative or non-validated medical treatment – treatment that is designed solely for the benefit of the patient but in which the ability of the treatment to result in the desired result is to some degree not proven. Such activities are exempt while recommending that they should be subjected to research to generate information about their efficacy as soon as possible.

G. Clinical audit, where the study is designed and conducted solely to define or judge only current care, without reference to a standard. It may involve the collection and analysis of data but there is no allocation to intervention groups or randomization and the services have been delivered before the audit is

APPENDIX 2: CHECKLIST FOR PROPOSAL MEANT FOR EXEMPTION FROM FULL ETHICAL REVIEW

Sn	Item	Scoring guide	score
1a	Is the research conducted in ***established*** or ***commonly accepted educational settings***, involving ***normal*** educational practices such as: 1. Research on regular and special education instructional strategies, or 2. Research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods?	Yes=0, No=1	
1b	Is the research conducted in ***new*** or ***uncommon educational settings***, or involving ***new or unusual*** educational practices?	Yes=1, No=0 Not applicable=X	
2a	Does the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior	Yes=0 No=1	
2b	Will the information obtained be recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants?	Yes=1 No=0 Not applicable=X	
2c	Could any disclosure of the human participants' responses outside the research reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.	Yes=1 No=0 Not applicable=X	
3a	Does the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens?	Yes=0 No=1	
3b	Are the sources of the data ***publicly available*** (to anyone for any purpose)? - NB: This refers to availability of data and not the status of the custodian of the information/data	Yes=0 No=1 Not applicable=X	
3c	Will the information be recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.	Yes=0 No=1 Not applicable=X	
4a	Is the proposed study meant to evaluate the outcome of procedures, programs and services with the view of producing information leading to improvement in delivery of procedures, programs and services?	Yes=0 No=1	
4b	Is the proposed study in **4a** to evaluate measures that are ***already in use and considered part of standard practice***?	Yes=0 No=1 Not applicable=X	
4c	Does the proposed study in **4a** involve allocation into groups or randomization.	Yes=1 No=0 Not applicable=X	
5	Is the proposed study designed to evaluate or assess quality of services, programs and procedures and formulate guidelines leading to their improvement?	Yes=0 No=X	
6	Is the application on an innovative or non-validated medical treatment that is designed solely for the benefit of the patient but in which the ability of the treatment to result in the desired result is to some degree not proven?	Yes=0 No=X	

Sn	Item	Scoring guide	score
	NB: Such activities are exempt while recommending that they should be subjected to research in order to generate information about their efficacy as soon as possible.		
7a	Is the proposal a Clinical audit – to be conducted solely to define or judge only current care (or services which have been ***delivered before*** the audit was proposed)?	Yes=0 No=X	
7b	Will the proposed clinical audit in **7a** involve reference to a standard?	Yes=1 No=0 Not applicable=X	
7c	Will the proposed clinical audit in **7a** involve allocation to intervention groups or randomization?	Yes=1 No=0 Not applicable=X	
	TOTAL (of zero suggests eligibility for exempt)		

APPENDIX 3: CHARACRITICS OF PROPOSAL ELIGIBLE FOR EXPEDITED REVIEW

The following are the eligibility criteria for expedited review:

i. Research is found to involve no more than minimal risk – meaning that the probability and magnitude of harm is no greater than that encountered in the daily lives of all (or the great majority of) persons in the population (under normal circumstances) from which research participants are to be recruited. Note that minimal risk is applicable in *non-therapeutic research only*.
ii. Research does not involve vulnerable populations such as children, prisoners, pregnant women etc.
iii. Research does not contain serious methodological or ethical flaws
iv. Minor changes in previously approved research during the period for which the approval covers

APPENDIX 4: CHECKLIST FOR PROPOSAL MEANT FOR EXPEDITED REVIEW

Sn	Items	Scoring guide	score
1	The proposed research is therapeutic, that is, involves application of treatment	Yes=1, No=0	
2	The proposed research involves no more than minimal risk – meaning that the probability and magnitude of harm is no greater than that encountered in the daily lives of all (or the great majority) persons in the population (under normal circumstances) from which research participants are to be recruited.	Yes=0, No=1	
3	The proposed research involves vulnerable populations such as children, socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged groups, groups with constrained autonomy (eg prisoners) and other vulnerable populations	Yes=1 No=0	
	THE LAST TWO ITEMS ARE TO BE COMPLETED BY THE REVIEWER		
4	The proposed research contains serious ethical flaws	Yes=1 No=0	
5	The proposed research contains serious methodological flaws	Yes=1 No=0	
	TOTAL (of zero suggests eligibility for expedited review)		

APPENDIX 5: THE REVIEWER'S CHECKLIST

	Items	**Yes=Y No=N NOT APPLICABLE=NA**	**Comments of the reviewer**	**Response of the investigator**
1	The proposed research has social or scientific value to either participants, the population they represent, the local community, the host country or the world, to justify the use of finite resources and risk exposure of some participants to harm.			
2	The proposed research evaluates issue(s) that is expected to lead to improvements in health and/or contribute to meaningful knowledge.			
3	The research has clear scientific objective(s)			
4	The study design is valid for the stated objectives			
5	The sample size calculation method is appropriate			
6	The study is well powered.			
7	The instrument(s) for data collection is (are) appropriate and sufficient to generate measures to meet the objectives			
8	Each of the instruments for data collection (each) has published psychometric properties in this environment or there is a plan for a pilot study in which to determine these.			
9	Identifiable sources of biased measurement(s) of outcome(s) are adequately addressed			
10	The research has plausible data analysis plan to meet all the objectives.			
11	In case of clinical trials, the data analysis plan includes a specific role for Data and Safety Monitoring Board			
12	In case of clinical studies, the proposal has equipoise			
13	The operationalizing plans are adequate within the context of the environment where the research would be conducted.			
14	Is the proposed selection of participants fair based on the scientific objective(s) of the research? This requirement refers to both who is included and who is excluded from recruitment and the strategies employed for participants' recruitment (including choice of research sites and communities).			
15	Regardless of the requirement in item 14 above, participants who are at excessively increased risk of harm are excluded.			

	Items	Yes=Y No=N NOT APPLICABLE=NA	Comments of the reviewer	Response of the investigator
16	Children, pregnant women, socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged groups, groups with constrained autonomy and other vulnerable populations whose health could be advanced be participating in the study are excluded ***without explicit reasons*** for doing so			
17	Specific safeguards are included to protect the vulnerable, appropriate to degree of risk.			
18	Groups, communities, participants and researchers who bear the burden of research will share in the benefits.			
19	There are valid attempts to minimize risks and maximize health related benefits (as distinguished from risks and benefits of therapies that participants would be exposed to even if they were not participating in research or incidental risks or benefits) to participants in order to engender favourable risk benefit ratio within the context of where the research is being conducted.			
20	Where the risks outweigh the benefits to the participants, the other part(s) of the proposal justifies such risks.			
21	If appropriate (eg, community survey), risks and benefits is considered at the level of individual research participants and at the community.			
22	There is comprehensive delineation of risks and benefits for participants during the research, the population hosting the research and for both participants and population after the completion of research			
23	If applicable, the therapeutic procedures fulfil requirements of clinical equipoise – there must be genuine uncertainty, among at least a significant minority of unbiased acknowledged experts who are not associated with the study under consideration, about preferred treatment.			
24	Procedures for non-therapeutic procedures are consistent with sound research designs			
25	Procedures for non-therapeutic procedures do not expose participants to undue Risk			
26	Procedures for non-therapeutic procedures are those which are already being performed on participants for diagnostic or therapeutic purposes, whenever appropriate			
27	Procedures for non-therapeutic procedures applies risk-knowledge calculus to ensure that risks are reasonable compared to the knowledge to be gained from the study.			

	Items	Yes=Y No=N NOT APPLICABLE=NA	Comments of the reviewer	Response of the investigator
28	In case of a clinical trial, the proposed conduct is in accordance with the principles of good clinical and laboratory practices – following international standards for designing, conducting, and reporting clinical trials that involve human participants.			
29	The informed consent has adequate information which is provided at the educational level not higher than that of individuals with at most 9 years of (basic) education in Nigeria			
30	The design of the consent process is appropriate for the type of research, expected participants, risks anticipated and the research context.			
31	The consent form is no longer than 4 pages in order to ensure comprehensibility and enhance recall of pertinent information.			
32	Unnecessary verbiage, legalisms, jargons and truth-dumping are not in the consent form			
33	Each page of the consent form is as follows: (i) Paper size – A4; (ii) Font – Times New Roman or similar; (iii)Font Size – 12; (iv)Spacing – 1.5; (v) Margins – 2.5 cm, no gutter			
34	Where indicated, additional information is provided on supplementary information sheets.			
35	The informed consent document contains the following aspects: (i) Title of the research (ii) Name(s), qualification(s) and affiliation(s) of researcher(s) or applicant(s) (iii)Sponsor(s) of research (iv)Purpose(s) of research (v) Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research. (vi)Expected duration of research and of participant(s)' involvement. (vii) Risk(s) (viii) Costs to the participants, if any, of joining the research (ix)Benefit(s) (x) Confidentiality (xi)Voluntariness (xii) Alternatives to participation (xiii) Incentive (inducement) to participants			

	Items	Yes=Y No=N NOT APPLICABLE=NA	Comments of the reviewer	Response of the investigator
	(xiv) Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation. (xv) Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s). (xvi) What happens to research participants and communities when the research is over? (xvii) Statement about sharing of benefits among researchers and whether this includes or exclude research participants. (xviii) Any apparent or potential conflict of interest. (xix) Detailed contact information including contact address, telephone, fax, e-mail and any other contact information of researcher(s), institutional HREC and head of the institution.			
36	There is provision for the research participants to retain a copy of the consent form.			
37	Where, in ordinary circumstances, participant(s) are unable to provide written consent, the proposal contains a process of consent that adequately records participants' informed decision such as witnessed thumb-printing or witnessed audio recording. (The process proposed must be approved by the HREC before the research commences)			
38	Should HREC require that the consent process in this study be witnessed?			
39	Researcher(s) has made provision to keep all copies of consent form and make them available for examination by participant(s), sponsor(s), institution(s), HREC and NHREC.			
40	Translations of consent form and processes appropriate to the socio-cultural characteristics of the population to be studied is necessary in this study and has been done.			
41	Where appropriate, the Materials Transfer Agreement (MTA) Governing the Transfer of Samples and Biological Materials is fully completed and submitted with the proposal.			
42	Where appropriate, there is a statement that the researchers and research sponsors will provide complete medical care and commensurate compensation for all research related injuries that participants may suffer.			
43	Where appropriate, there is a statement that the researchers and research sponsors will provide evidence of insurance coverage of the research to provide adequate			

	Items	Yes=Y No=N NOT APPLICABLE=NA	Comments of the reviewer	Response of the investigator
	compensation for research related injuries, their care and compensation.			
44	There is a statement in the proposal where research participants are asked to waive their legal rights, including the right to legal redress of research related injuries and compensations. (This is unethical.)			
45	Where appropriate, there is a written agreement between sponsor(s), institution(s) and researcher(s) which allows researcher(s) to use the outcome of research in manner consistent with current practice within the research community.			
46	Where appropriate, there is a written agreement between sponsor(s), institution(s) and researcher(s) indicating rights to, ownership of and rights of access to data, resources, intellectual property and infrastructure generated during the research.			
47	Where appropriate, there is a written agreement between sponsor(s), institution(s), researcher(s) and the community indicating adequate community consultation and agreement with the proposed research. (The definition of community shall vary with research and shall be based on application of the best scientific principles.)			
48	Where appropriate, there is a statement that the researcher will not enter into an agreement or will be subjected to circumstances that limits his/her legal rights, freedoms and obligations under Nigerian law to pursue his/her research activities.			
49	Where appropriate, the investigator provides assurances that reasonable effort shall be made to ensure that the benefits of research are made available to the community where the research was conducted. Details of any arrangement to ensure this shall be worked out by the researchers, sponsors, HREC, community leaders and Community Advisory Committees			
50	Where appropriate in interventional studies, the investigator provides evidence of adequate provision to cover claims for injuries, disabilities, or death of a research participant resulting from participation in research.			
51	Where appropriate, there is a statement that the sponsor will ensure that the investigational product and any comparator products are of appropriate quality and are subject to quality assurance procedures. This information is			

	Items	Yes=Y No=N NOT APPLICABLE=NA	Comments of the reviewer	Response of the investigator
	accurate and adequate to justify the nature, scale, and duration of the clinical trial.			
	RECOMMENDATION (BY THE REVIEWER)			
	Approve			
	Approve after minor revision			
	Approve after major revision			
	Reject			