UNIVERSITY OF ILORIN
UNIVERSITY ETHICAL REVIEW COMMITTEE

PREAMBLE

University of Ilorin established the University Ethical Review Committee (UERC) to develop and sustain a University-wide awareness of ethical issues arising from research involving human subjects and non-clinical research.

The Committee is responsible for producing guidelines for the conduct of such research and for ensuring that all University Faculties have in place appropriate procedures for the consideration and conduct of research.

The University Ethical Review Committee will also consider and give guidance on research referred to it from faculties and hear appeals on decisions made by faculties. In exceptional cases, the University Ethical Review Committee shall itself make decisions on research.

The University of Ilorin subscribes to the National Ethics and Operational Guidelines for research on Human Subjects and the various International guidelines and Principles on researches involving both human and non human subjects such as Nuremberg code (1947), the World medical Association Declaration of Helsinki (1964) and Council for International Organisation of Medical Sciences (CIOMS) guideline of 1993.

The University Ethical Review Committee has the responsibility of ensuring that research participants are handled in accordance with the national and international regulations and best practices. UERC will develop an Ethical handbook to provide guidelines on how human and non human subjects should be handled.

The University is committed to rigorous and objective inquiry and supports academics in pursuing their research in an environment that affirms academic freedom. The University also acknowledges the importance of confidentiality as a guiding principle in research involving people, human material and human data.

The University Ethical Review Committee aims at aiding and supporting researchers in maintaining exemplary ethical standards in research, and promoting a wider ethical awareness throughout the University.

The University Ethical Review Committee is concerned primarily with the general principles of natural justice, reasonableness and fairness of the decision made by the Faculty Ethical Review Committee (FERC). It also acts to ensure compliance with legal and other requirements covering researches across the entire University

1. ROLE OF THE UNIVERSITY ETHICAL REVIEW COMMITTEE

The UERC plays a primary role in Human Research Protection Programme (HRPP) through the following activities:

- Prospective and continuing review of each research protocol involving research participants, including an evaluation of the risk and benefits for the subjects
- Review the adequacy of the "Informed Consent" document as it relates to its description of the risks and benefits
- Receiving, evaluating and conducting reviews concerning reports of unanticipated problems, possible non compliance, and other information and incidents that might affect the approval of the protocol or the subjects willingness to continue to participate

OPERATION OF THE UNIVERSITY ETHICAL REVIEW COMMITTEE

2.1 Composition and Administration

There shall be a University Ethical Review Committee which will be multidisciplinary, comprising 10 – 15 members with at least two (2) members who are not directly affiliated to the University representing the community. Membership shall be drawn from Health Sciences, Applied Sciences, Social Sciences, Humanities and Central Administration and a Biostatistician.

The composition is as follows:

(i) The Chairperson of the UERC shall be a Professor and preferably a Physician, appointed by the Vice-Chancellor upon the recommendation of the Chairman, Committee of Deans.

(ii) At least 25% of the membership shall be females

(iii) No University Ethical Review Committee (UERC) shall have a member participate in the UERC initial or continuing review of any project in which the member has a conflicting interest.

(iv) If UERC wishes to review research that involves vulnerable participants, such as children, prisoners, pregnant women, physically and psychologically disabled persons, the UERC shall co-opt one or more individuals knowledgeable about and experienced in working with these participants for the review process. These individuals are not **however entitled** to vote during the UERC meeting.

(v) Each UERC member must pledge to maintain confidentiality regarding all meetings, deliberations, applications, information on research participants and related matters that shall come to his/her knowledge during service on UERC even after leaving the UERC assignment.

NOTE: That there is no time limit for this prohibition.

(vi) **Tenure** – the tenure of the Technical members of the UERC shall be two (2) years and renewable once.

(vii) **Secretariat** – the UERC Secretariat shall be located in Centre for Development and In – House Training (CREDIT)

2.2 Duties, Powers and Terms of Reference

1. The University Ethical Review Committee shall develop and sustain a University-wide awareness of ethical issues arising from all research. In carrying out its duties, it shall have particular regard to the need to protect the:

(i) rights, health, safety, dignity and privacy of research participants;

(ii) health and safety of researchers;

(iii) reputation of the University as a centre for properly conducted high-quality research.

2 The University Ethical Review Committee shall:

(i) develop and provide **policy/guidelines** for and with Faculties in relation to the conduct of researches;

(ii) ensure that all Faculties either have in place procedures for the consideration and conduct of such research or provide a written valid explanation as to why such procedures are considered unnecessary;

(iii) approve terms of reference, membership and internal reporting procedures for each **Faculty Ethical Review Committee** (FERC) that is established;

(iv) ensure the provision of appropriate training for Faculty Ethical Review Committee members with specific responsibility for ethical review;

(v) consider matters referred to it:

  (a) by Faculty Ethical Review Committees through Deans of Faculties;

  (b) which require specific consideration due to the implications they may have for broader University activities;

  (c) on applications that cannot be satisfactorily resolved at Faculty level.

(vi) consider annual reports from Faculties on the management of ethical issues in research, offering advice and making recommendations as appropriate on the operation of Faculty level procedures.

(vii) The UERC will create a database of all researches in the University

(viii) The UERC considers recommendations from the FERC for approval

3 The UERC shall, having regard to the general principles of natural justice, reasonableness and fairness of the decisions made by the Faculty Ethics Committee, in exceptional cases, and only after the local procedure for resolving difficulties has been exhausted, hear appeals against Faculty Ethics Committees' decisions and make recommendations thereon to the relevant Dean of the Faculty

3. PROCEDURES FOR FACULTIES

3.1 Under the guidance of the University Ethical Review Committee, it is recommended that each Faculty should:

(a) establish procedures for handling the ethical issues in research.

(b) appoint a named member of staff to act as the designated Officer with responsibility for the ethical review of research, who should be a Professor, who can provide support, information and advice to all members of that Faculty

(c) through the Chairperson FERC, conduct an annual review of procedures within the Faculty, report to the University Ethical Review Committee on the findings and keep ethical issues in research under continuous review;

(d) maintain and disseminate awareness of the views of relevant external expert and/or professional bodies;

(e) The FERC will recommend approval or otherwise of a proposal to UERC

(f) refer cases to the UERC that require advice or an opinion from that Committee. It is expected that referral to the UERC for an appeal will be in exceptional circumstances only. The UERC normally will not interfere with a Faculty Ethical Review Committee decision;

(g) introduce mechanisms that allow the rapid review and, where appropriate, the accelerated consideration of research proposals in order not to jeopardise any attempts at gaining external funding, **or delay** commencement of work on projects;

(h) ensure that all staff and students are aware of the ethical issues and potential repercussions surrounding their work and are adequately supported in meeting their obligations to the research, any participants, care-providers and other interested parties, and the School's ethical procedures.

3.2 All Faculty procedures shall be reviewed on a yearly basis.

4. BASIS OF APPROVAL BY FACULTY AND UNIVERSITY ETHICAL REVIEW COMMITTEES

4.1 A decision by a Faculty Ethical Review Committee (or, in exceptional cases, the University's Ethical Review Committee) to recommend a research project should not be taken to imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved; nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research that they carry out and for its effects on the research participants involved. All ethics committees **must** address themselves to ethical matters and are dependent upon information supplied by the researcher. It is the responsibility of each individual researcher to ensure that this information is properly researched, full, truthful and accurate.

4.2 A decision by any of the University's Research Ethics Committees to approve a research project does not constitute precedence and each application will be judged on its own merits and in the light of present circumstances. For that reason, a decision may be made to approve research of a kind not previously approved. Equally a decision may be made not to approve research of a kind that was previously approved. In neither case does this imply that the UERC decision, nor its decision-making process is flawed since proper ethical review cannot be reduced to a mechanical or formulaic approach.

4.3 A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate ethical approval that has been given. However, researchers are expected to make themselves aware of changes in policies or procedures and to adopt them as necessary.

4.4 The University and its Faculties have the responsibility for ensuring that:

- ethical principles are explicitly communicated to staff and students;
- ethical practices are followed by all researchers using research participants

PENALTY

Failure to follow the University's guidance on ethical review of research may result in disciplinary action.

5. Training

5.1 The University Ethical Review Committee will work with Faculties in sharing best practice through:

- dissemination of information of best practice

- assisting with organising briefing meetings, workshops, conferences etc
- requesting information and responding to feedback on best practice from Faculties and from external bodies

6. Monitoring and Auditing Procedures

6.1 The University Ethical Review Committee recognises that the definition and perceived significance of ethical problems may be subject to change and differences of opinion. In this light Faculties, through their designated Chairperson FERC, must conduct an annual review of their position and report to the University Ethical Review Committee.
The University Ethical Review Committee will consider these reports, offering advice and recommendations as appropriate and report to the Senate Research Committee.

6.2 Detailed audit of the operation of Faculty's ethics procedures will be part of the annual review process for all Faculties. Advice will be given on documentation and potential audit trails. UERC should see the minutes and individual applications at any time and will require a list of all submissions and the decision taken in respect of them.

6.3 **Failure to follow the University's policy and guidance for the ethical review and approval of research will lead to suspension of the research. Where a Faculty Ethical Review Committee or the UERC becomes aware of research being conducted in breach of these policies and procedures or of researchers who are not complying with them, the matter may be resolved by informal discussion with the researchers and remedial action being taken by them. However, where necessary, UERC may refer the matter to the Vice-Chancellor for further investigation.**

7.0 The Involvement of Children in Research

7.1 Where children are involved in research, extreme care should be taken over ethical procedures and explicit authorisation for participation of children should always be obtained from the Faculty Ethical Review Committee.

7.2 The Dean of Faculty and the designated Chairperson FERC must ensure that there are appropriate mechanisms to bring to the attention of any staff or students for whom the Faculty is responsible and whose work involves research with children that they must

check and comply with any legal requirements, such as vetting procedures, before they proceed with such work. Of necessity, the responsibility for checking and complying with such legal requirements remains that of the researcher and this point must be specifically considered in all research involving children.

8.0 CONFIDENTIALITY

8.1 Statement on Confidentiality

The University is committed to rigorous and objective inquiry and supports academics in pursuing their research in an environment that affirms academic freedom. The University also acknowledges the importance of **confidentiality** as a guiding principle in research.

8.2 Duty of Confidentiality

A duty of confidentiality will exist between researchers and participants such that confidential information revealed by a participant to a researcher can only be disclosed to others if the party providing the information has given specific authorisation or the researcher is under a legal obligation to disclose it. In some cases researchers may be under a professional obligation to disclose information to third parties. Whether information is confidential will depend on the circumstances but the key factor is whether or not the provider of the information would have considered it as confidential and would expect it to be treated as such. If the answer to both questions is "yes", then the duty of confidentiality will arise. The duty also arises when the researcher has volunteered to keep confidential the information and/or the identity of the provider.

As a result of this duty there is a need for researchers to be aware of any circumstances, such as professional codes of practice, that preclude them from being able to give absolute assurances of confidentiality.

8.3 Obligations on Researchers:

In the light of the above paragraph, it is important that researchers:

(a) do not convey personally identifiable information obtained in the course of research work to others, except with the express permission of the research participant unless either alternative arrangements have been agreed by a research participant or where the researcher is subject to a legal obligation to disclose that information;

(b) do not give unrealistic guarantees of confidentiality and anonymity and be aware that legal challenge may prevent you from honouring such a guarantee.

(c) In some circumstances it may be necessary to inform research participants of obligations under law, such as the possibility that the researcher will be required to give evidence or reveal documents, which may make it impossible for certain information to be kept confidential without breaking the law. In other cases, it may be that the researcher's professional obligations would require the disclosure of information, for example, where the welfare of a child is concerned. The research participant needs to be made aware of the possibility of future disclosure in order to be able to decide whether to take part in the research. If the researcher has made it clear that information may be passed on as a result of legal or professional obligations and the participant nevertheless agrees to take part, the researcher may pass on that information even if the participant subsequently objects. However, passing on confidential information without the express permission of the participant is not to be undertaken lightly and legal and professional advice must be sought immediately if this is contemplated;

(d) Where possible, anticipate threats to the confidentiality and anonymity of research data. The identities and research records of those participating in research should be kept confidential whether or not an explicit pledge of confidentiality has been given. Researchers should also consider whether it is either necessary or appropriate to record certain kinds of sensitive information;

(e) take appropriate measures to store research data in a secure manner. Researchers should have regard to their obligations to ensure that appropriate methods for preserving the privacy of data are used while also allowing participant access to information where this is requested by a participant;

(f) take care to prevent data being published or released in a form which would permit the **actual or potential identification** of research participants. In circumstances where it is difficult to protect the anonymity of informants and research participants, they must be informed of this fact before they are asked to take part or, if the possibility of publication had not arisen at that time, they must be re-contacted and their agreement obtained;

(g) ensure that the designated Ethics Officer is informed of any research proposal that might raise questions about guaranteeing participant confidentiality. If there are significant queries about this matter they should be brought to the University Ethical Review Committee for consideration and guidance;

(h) **ensure that data collected is used only for legitimate academic purposes**;

(i) are aware of the need to limit the University's potential liability in the event of a breach of confidentiality.

8.4 Where a Faculty Ethical Review Committee or the University Ethical Review Committee become aware either of research being conducted in breach of these policies and procedures or of researchers who are not complying with them, the matter may be resolved by informal discussion with the researchers and remedial action being taken by them. ***However, where necessary (for example due to persistent non-compliance), UERC will suspend the research and refer the matter to the Vice-Chancellor for further investigation***.

RESEARCHES INVOLVING HUMAN SUBJECTS

The National Health Research Ethics Committee (NHREC) is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants in Nigeria.

Definition of Research and Coverage of Code:

Research 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 participant.

(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 for purposes of this code, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Health research that is conducted anywhere in Nigeria must comply with all sections of this code.

Exemption

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempted from health research ethics committee oversight:

(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 exempted 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 **randomization**.

(e) **Studies that are designed to evaluate or assess quality of services, programs and procedures** and formulate guidelines leading to their improvement are exempted. 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 exempted while recommending that they should be subjected to research in order 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 initiated.

Who determines exemptions?

All exemptions shall be determined by the UERC -vide infra. In summary, applicants conducting research that require exemption shall submit the proposal or a written summary that contains enough information for judgement to be made, to the UERC. The UERC Chairperson or his designee, in consultation with UERC Administrative Officer – where one exists, shall decide whether the research is exempted or not. Where the Chairperson is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to UERC. All applications for exemption must be brought to the notice of UERC at its regular meeting for discussion as may be deemed necessary by members of UERC.

UERC functions and operations

In order to fulfil the requirements of this code, each UERC shall:

(a) operate in accordance with the provisions of the current version of the National Code of Health Research Ethics issued by the NHREC. Additional guidance may be obtained from the Standard Operating Procedure (SOP) issued by the NHREC.

(b) consider research proposals at regularly convened ordinary meetings of UERC at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas, except when an expedited review procedure is used.

(c) allow electronic participation where a member cannot physically attend a meeting, and the member shall be accounted as being present if he/she can participate electronically, for example by teleconferencing for the majority of the duration of the meeting.

(d) **Process for regular research approval**

(1) UERC shall review prescribed application materials and have authority to approve, require modifications in (to secure approval) or disapprove all health research activities covered by this code.

(2) In order for research to be approved, the decision shall ordinarily be arrived at by discussion and consensus or receive the support of a simple majority of those members present at the meeting.

(3) UERC may, at its own discretion, invite representations from the applicant(s), sponsor(s), institution(s) or any other person(s) that it may consider relevant to provide information pertinent to the research during the review process.

(e) **Process for continuing oversight of research**

(1) UERC shall conduct continuing oversight of research covered by this code at intervals adjudged by UERC as being appropriate to degree of risk involved in participation in the research.

(2) UERC shall have authority to examine all aspects and documents including consent forms, questionnaires, case report forms etc. that are related to the research and necessary for the UERC to conduct its oversight function.

(3) **The examination referred to in 'para 2' above** shall be at least once a year or at least once during the lifetime of the research where the duration of the research is less than a year.

(4) UERC shall have authority to observe or cause to be observed on its behalf, the research and its consent process to ensure compliance with the highest scientific and ethical standards.

(5) UERC may initiate process of oversight of research in the event of receipt of complaints, information or data relevant to the research from any source.

(f) **Process for expedited review**

(1) UERC may expedite review of research in the following circumstances:

(a) 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) 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.

(b) Research does not involve vulnerable populations such as **children, prisoners, pregnant women** etc

(c) Research does not contain serious methodological or ethical flaws

(d) Minor changes in previously approved research during the period for which approval is authorized.

(2) Expedited review may be carried out by the UERC Chairperson or his designee from among members of UERC. In reviewing the research, the reviewer(s) shall exercise all the authorities of UERC except that the reviewer(s) **cannot** disapprove the research.

(3) The Chairman of UERC shall bring all research reviewed expeditiously to the next meeting of UERC for notice, discussion and ratification.

AMENDMENT OF RESEARCH

(g) **Process for amendment of research**

(1) UERC shall require that applicants apply for permission to amend protocols in any of the following circumstances:

(a) Where there are changes in any part of the research protocol that alters the risk benefit ratio of the research.

(b) Where there are changes in the named members of the team conducting the research.

(c) Where there are changes in research sites.

(d) Where there are changes in sponsorship, institutional guidelines, institutional structure, UERC requirements, national laws or exigencies that impact on the ethical conduct of research.

(2) UERC 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

(3) 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 UERC within 24 hours of such changes.

(4) In such circumstances as described in section (3) above, the researcher shall stop the research and the UERC shall conduct a thorough review of the research before authorizing suspension, continuation or modifications to the research.

EXEMPTION

(h) **Process for exemption**

(1) UERC may grant exemptions from review in any of the conditions enumerated above

(2) Applicants seeking exemptions shall submit the proposed research or adequate information about it to the UERCC, sufficient, in UERC judgment, to make a determination.

(3) Exemptions may be granted by the UERC Chairperson or his designee from among members of the UERC, in consultation with the UERC Administrative Officer – where one exists.

(4) In granting exemptions, the reviewer(s) shall exercise **all the** authorities of the UERC except that the reviewer(s) may not disapprove the research.

(5) Where the reviewer is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to the UERC.

(6) The Chairman of UERC shall bring all exempted research to the next meeting of UERC for notice, discussion and ratification.

SUSPENSION OF RESEARCH

(i) **Process for Suspension of research**

(1) UERC shall have authority to suspend research that is not being conducted:

(a) In accordance with UERC requirements or

(b) **In accordance with existing legislation guiding the conduct of the research in question or**

(c) In accordance with existing institutional guidelines; or

(d) Where research is associated with unexpected serious harm to participants, and

(e) **where items (a-d) have all been breached in relation to the research**

(2) Any suspension of research shall include a statement of the reason(s) for the UERC action and shall be reported within 2 weeks to the researcher(s), institution(s), sponsor(s) and NHREC.

(3) Researcher(s), institution(s) or sponsor(s) shall be entitled to ask for a reconsideration of the decision of UERC to suspend research within 2 weeks of receipt of notification.

REVERSAL OF SUSPENSION

(j) **Process for revision of suspension**

(1) UERC may reverse its decision to suspend research if the precipitant(s) of the action is resolved to UERC satisfaction

(2) The UERC will determine the case at its next regular meeting and **shall demand that the researcher enter into an undertaking with** UERC on its finding(s) and agreed remedial measure(s).

(3) Where UERC allows resumption of research, an oversight review of the research shall be carried out within 6 months or at least once during the lifetime of the research if it is shorter than 6 months.

(k) **Process for termination of research**

(1) Where the researcher(s), sponsor(s) or institution(s) is unable to offer or the UERC is unable to ascertain or enforce satisfactory remediation of the precipitant, UERC shall terminate the research.

(2) UERCC shall indicate the reason(s) for the termination of research in writing within 2 weeks to the researcher(s), institution(s), sponsor(s) and the NHREC. (3) Researcher(s), institution(s) or sponsor(s) shall be entitled to appeal the decision of UERC to terminate research to the NHREC within 2 weeks of receipt of notification.

APPEAL AGAINST TERMINATION OF RESEARCH

(l) **Process for appeal of UERC decision to terminate research**

(1) Upon receipt of an appeal of the decision of a UERC to terminate research, NHREC may, at its discretion, take up such an appeal.

(2) Where the appeal is sustained,

a. NHREC may with reasons and in consultation with the institutional UERC, direct the institutional UERC to approve the research.

b. NHREC may with reasons and in consultation with the institutional UERC mandate modifications, which if undertaken, can allow the research to proceed or resume as the case may be.

c. Where NHREC mandates restoration of the research, the institutional UREC shall have powers of continuing oversight as outlined in relevant sections of this code.

(3) NHREC may sustain the decision of the UERC and dismiss the appeal.

REVIEW OF MULTI-INSTITUTIONAL RESEARCH

(m) **Process for Review of Multi-Institutional Research**

In the conduct of multi-institutional research, each institution is responsible for safeguarding the rights and welfare of human participants in its institution and for complying with this code.

(1) **Where there are no more than 3 Nigerian research sites**:

(a) The principal investigator at each research site may apply to the institutional UERC for review.

(b) UERC may, at its own discretion, adopt the approval of research by another HREC rather than conduct a fresh review and approve the research thereafter.

(c) Where the outcome of review is discordant (that is, some UERC approve while others disapprove the research), the applicant shall submit the comments from the different HREC to their institutional UERC for consideration and possible reconciliation.

(d) Where the outcome of review by different institutional HREC is favourable but different modifications are requested, the applicant shall submit the comments of their institutional HREC for reconciliation.

(e) UERC shall, as much as possible, consult with others in order to resolve discordant reviews and generate consistent single response to multi-site research.

(2) **Where there are more than 3 Nigerian research sites**:

(a) Applicant(s) may follow the steps outlined above or (b) Applicant(s) may apply to NHREC directly.

(3) **In international collaborative research**

(a) Only applicant(s) with qualification(s) and background sufficient to serve as Principal Investigator(s) and based in a registered institution in Nigeria that is capable of carrying out the proposed research shall apply for review of research.

(b) UERC may adopt the approval of another HREC or that of any other local or international ethics review committee (to the degree that such approvals comply with the requirements of the code and take account of local circumstances) and approve the research.

(c) Where the outcome of review is discordant, the applicant shall submit the comments from the different HREC or ethics committees to UERC for consideration and possible reconciliation.

(d) Where the outcome of review is favourable but different modifications are requested, the applicant shall submit the comments from the different HREC or ethics committees to UERC for consideration and possible reconciliation.

(e) UERC and ethics committees shall, as much as possible, consult with each other in order to resolve discordant reviews and generate consistent single.

(4) UERC shall notify investigator(s) in writing of its decision to approve, disapprove or require modifications of the research activity.

(5) UERC shall have a maximum of 3 months from the date of receipt of a valid application to give its decision to the applicant. An application shall be considered valid only after receipt of all materials required by UERC to give a determination.

(6) Where UERC considers an application of such complexity that it cannot conclude the review, the application shall be referred to NHREC and the applicant duly informed within the stipulated 3 months.

(7) Where UERC does not conclude its review in 3 months and has not referred the case to the NHREC, 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.

(8) Where UERC decides to disapprove 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.

(9) Where UERC has received representation from the applicant in response to an existing decision, UERC may decide to uphold or modify its previous decision and shall communicate this decision to the applicant within 3 months of the representation.

(10) UERC is mandated to keep all records related to its decision(s) for a minimum of 10 years after completion of the research activity.

PROTECTION OF PARTICIPANTS IN THE RESEARCH ENTERPRISE

UERC must protect the rights of researcher(s)

(1) **UERC shall protect the right of researcher(s) to publish their research**.

(a) In certain situations, this will require the submission of an agreement between sponsor(s), institution(s) and researcher(s) allowing researcher(s) to use the outcome of research in manner consistent with current practice within the research community.

(b) UERC shall evaluate whether such agreement is necessary when the research is being reviewed and if found necessary, request same before approval is given.

(2) **HREC shall protect researchers from exploitation**.

(a) In certain situations, this will require the submission of an agreement between sponsor(s), institution(s) and researcher(s) **indicating right to, ownership of and** right of access to data, resources, intellectual property and infrastructure generated in the course of the research.

(b) UERC shall evaluate whether such agreement is necessary when the research is being reviewed and if found necessary, request same before approval is given.

(3) **HREC shall protect communities participating in research from exploitation**.

(a) In certain situations, this will require the submission of an agreement between sponsor(s), institution(s), researcher(s) and the community indicating adequate community consultation and agreement with the proposed research.

(b) UERC **shall** evaluate whether such agreement is necessary when the research is being reviewed and if found necessary, request same before approval is given. This implies that UERC has ordinarily found the study approvable but requires that the community should be engaged and their assent sought before research is allowed to proceed. In this circumstance, the UERC cannot change its decision on the approval status of the research once the community engagement process has commenced. If the community engagement fails, then the research cannot proceed in that community.

(c) Where applicable, such community assent or engagement efforts shall be documented and evidence of same submitted to UERC during the research review process.

(d) In some instances, it will be necessary to set up a Community Advisory Board (CAB). Such boards may be established by the study investigators in consultation with the community.

(e) Members of **CAB** shall be selected by the community through their usual consultative process and it shall include broad representation of community members based on age, sex, religion and other community parameters that may be relevant to the study. It may include relatively more representation from population of interest to the study. It may include representatives from the research group and other non-community members whose special

knowledge or expertise may be considered necessary for effective functioning of the community advisory group. In all instances, members of the community must constitute a simple majority of the CAB.

(f) The function of the CAB is to provide community members opportunity to share their views about ethical issues that proposed research raises for individual community members, community as a whole, neighbouring communities and their region/nation. The CAB also provides a forum for dissemination of pre, intra and post-research information to the community. Members of CAB may provide advice and support as needed for the successful implementation of research.

(g) The definition of community shall vary with research and shall be based on application of the best scientific principles.

(4) **UERC must protect researcher(s) from undue pressure from sponsor(s), institution(s), participant(s)** or any other source by ensuring that no researcher enters into an agreement or is subjected to circumstances that limits his/her legal rights, freedoms and obligations under Nigerian law to pursue his/her research activities.

Ethical Principles and Guidelines for UERC approval of research

In order to approve research covered by this code the UERC, shall determine a balance between the various principles guiding the ethical conduct of research, some of which are outlined below. Since some of these will inevitably conflict, judgement and consensus are essential in determining whether a research should be conducted.

(a) Research must have **social or scientific value** to either participants, the population they represent, the local community, the host country or the world, in order to justify the use of finite resources and risk exposure of some participants to harm. Research should evaluate issues that lead to improvements in health and contribute to meaningful knowledge. Such knowledge should be disseminated to all relevant stakeholders during and after the conduct of research. In certain instances, for example in some international collaborative studies, research should be integrated with comprehensive capacity building, technology transfer and health care delivery strategies that address significant local health problems and add value to local participants of research, including researchers, institutions, communities and the country.

(b) For research to be ethical, it must be have **scientific validity**. Research lacking clear scientific objective(s); using invalid methodology; that is underpowered; lacking equipoise (for clinical studies); whose operationalizing plans are inadequate within the context of the environment where research would be conducted; lacks plausible data analysis plan (including a specific role for a **Data and Safety Monitoring Board [DSMB]** in clinical trials) and research with biased measurement(s) of outcome(s) is unethical.

(c) Ethical research must ensure **fair selection of participants based on the scientific objective(s) of the research** while minimizing risk. 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). **Regardless of this requirement, participants who are at excessively increased risk of harm should be excluded.** Children, pregnant women, socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged groups, groups with constrained autonomy and other vulnerable populations should not be excluded from research without explicit reasons for doing so; particularly from studies that can advance their health and well being. However specific safeguards should be included to protect the vulnerable, appropriate to degree of risk. Groups, communities, participants and researchers who bear the burden of research should share in the benefits.

(d) All research involve risks; to be ethical therefore, there must be **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.

(1) Where the risks outweigh the benefits to the participants, other criteria outlined in this code must justify such risks.
(2) Risks and benefits should be considered at the level of individual research participants and at the community, whenever appropriate.
(3) Comprehensive delineation of risks and benefits should be done for participants during the research, the population hosting the research and for both participants and population after completion of research
(4) **Therapeutic procedures must 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.
(5) **The risks associated with non-therapeutic procedures must be minimized** by:
(a) Procedures consistent with sound research designs
(b) Procedures that do not expose participants to undue risk
(c) Using procedures already being performed on participants for diagnostic or therapeutic purposes, whenever appropriate
(d) Applying risk-knowledge calculus to ensure that risks are reasonable compared to the knowledge to be gained from the study.
(e) For research to be ethical, it must undergo **independent review**. Research participants, researcher(s), sponsor(s) and institution(s) have multiple and overlapping interests which can generate conflicts and distort judgements. Independent review, through a system of ethical review and oversight of such systems assures society that reasonable attempts have been made to minimize the potential impacts of these conflicting interests and ensure balanced judgements.
(f) **Informed consent** is a *sine qua non* for ethical conduct of research. **In order for consent to be valid, it must have the following components**:
(1) Adequate information must be provided at the educational level no higher than that of individuals with at most 9 years of education in Nigeria.
(2) The design of the consent process must be appropriate for the type of research, expected participants, risks anticipated and the research context.
(3) Consent forms shall not be longer than 8 pages in order to ensure comprehensibility and enhance recall of pertinent information. Unnecessary verbiage, legalisms, jargons and truth-

dumping are to be avoided. The recommended format for 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

(4) Where indicated, additional information can be provided on supplementary information sheets.

(5) **The informed consent document shall contain the following aspects**:

i. Title of the research

ii. Name(s) and affiliation(s) of researcher(s) of 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

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.

(6) Research participants are entitled to retain a copy of the consent form.
(7) Where appropriate, researcher(s) may be required to undertake a re-consenting process during the course of research as determined by the UERC.
(8) Where, in ordinary circumstances, participant(s) are unable to provide written consent, researcher(s) must propose 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 UERC before the research commences.
(9) UERC may require that all or some types of consent process be witnessed.
(10) Researcher(s) must keep all copies of consent form and make them available for examination by participant(s), sponsor(s), institution(s), UERC and NHREC.
(11) Where appropriate, UERC may require researchers to provide **translations of consent processes appropriate to the socio-cultural characteristics** of the population to be studied.
(12) All consent activities must be documented.
(13) Consent in other situations, including research involving children, persons with diminished autonomy, vulnerable populations and other extraordinary situations, including waiver of consent, are described in other guidance documents issued by NHREC.
(g) For research to be ethical there must be **respect for potential and enrolled participants**. This implies that potential participants should be treated with respect from the moment they are approached to the conclusion of the research should they choose to participate. Their right to privacy may not be needlessly compromised.
Participants must know that their involvement is voluntary and that they can withdraw at any time without penalties. However, data, samples, etc. already contributed to the research up to that point may not needlessly be withdrawn as this may jeopardize the scientific validity of the research, unjust to those who remain in the study and all or part of their sample or data may have been used or modified into different form(s), including presentation at meetings or publications by the researchers. Respect entails that participants must be treated as partners in the research enterprise with every opportunity taken to inform them of the progress of the research and any new finding that may have potential impact on their health and well being, and on their continued participation in the research. It also entails protection of the welfare of research participants. This means that the process of research must be carefully monitored to

ensure that participants are not exposed to excessive risk and all adverse events are examined in details and promptly. Such adverse events must also be reported to UERC and efforts made to prevent future occurrences. Full medical care must be provided to participants who have suffered such adverse events and where warranted compensations paid. The requirement to respect both enrolled and potential participants means that researchers should engage with communities where research is being conducted whenever this is appropriate. In certain instances, community consultation or assent may have to precede research activities in order to engender community buy-in and to respect the socio-cultural values of the community and its institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and well being, and the outcome of the research.

(h) For research to be ethical, nothing must be done to undermine the **trust relationship** that is at the heart of the researcher(s)-participant(s) relationships. This requires that there is transparency in all matters relating to the research enterprise including clear description of goals, risks, benefits, alternatives to participation and voluntariness. It is also necessary to determine the social value of the research and engage in creative approaches for effective representations and involvement of researchers and communities in the entire enterprise. Strategies for dynamic and reciprocal collaboration that leads to transformation of essential relationships based on reciprocity are also essential. This trust principle encourages the engagement of individual participants and communities, respects local socio-cultural values and encourages the provision of relevant and timely feedback to communities.

(i) For research to be ethical, the interest of participants, researchers, sponsors and communities must be protected. This will ensure that the research has lasting impact, transfers technology where appropriate, contributes to capacity building and demonstrates respect for socio-cultural and other differences. Risks, benefits and responsibilities of research must be shared during the development, planning, conduct, dissemination of results. Intellectual property, indigenous knowledge and contributions of all parties must be taken into consideration, adequately protected and compensated particularly where research leads to tangible or intangible benefits. Satisfactory parameter(s) that shall determine sharing of commercial and other benefits should be clearly articulated and where indicated, benefit sharing agreements, materials transfer agreements, patent rights, intellectual property and royalties' distribution agreements should be signed before initiation of research.

(j) For research to be ethical, it must be conducted in accordance with the principles of good clinical and laboratory practices. These are international standards for designing, conducting, and reporting clinical trials that involve human participants. Compliance with these standards is additional assurance that the rights, safety and well-being of trial participants are protected in a manner that is consistent with the highest ethical and scientific standards.

UNIVERSITY OF ILORIN, ILORIN, NIGERIA
FACULTY RESEARCH POLICY

1. It is the responsibility of the researcher/research team to decide whether a project is ethically sensitive and should be subjected to either a speedy review or full Research Ethical Committee approval.

2. The forms and procedures for submitting applications for review can be obtained from the University Ethical Review Committee website.

3. Where required by the funding agency, grant applications must provide a statement by the proposers that they have given proper consideration to any ethical matters which the proposal raises. Where an ethics review is yet to be undertaken, this should be stated. Where the proposers regard ethics review as unnecessary, a statement that justifies this view is needed.

4. Researchers must address ethical consideration explicitly in their proposal where these arise in the design or conduct of the proposed research.

5. Research should be designed, reviewed and undertaken in a way that ensures its integrity and quality.

6. Where the study does not involve the use of deception, research staff and subjects must be fully informed about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved.

7. The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.

8. Research participants must participate in a voluntary way, free from any coercion.
9. Harm to research participants must be avoided.

10. The independence and impartiality of researchers must be clear, and any conflict of interest or partiality must be explicit.

11. Researcher should be guided in their research by appropriate standard guiding the conduct of research.

12. Researchers are expected to consider fully the ethical implications of their research and their means of resolving any ethical issues.

13. Funding agency for the research should be acknowledged where applicable.

14. Research must be conducted in accordance with human rights.

15. Research must be conducted in accordance with sustainable development and respect for the environment.

16. Research must promote peace.

17. The researcher and the research institution are responsible for exercising honest research practices.

18. The researcher is individually responsible for the activities, subject matter and method of his or her research, as well as for the quality of the results.

19. The researcher must respect the contributions of other researchers and follow standards for authorship and cooperation.

20. When conducting research, the researcher must follow national and international regulations on ethics and safety.

21. The researcher must clarify the degree of certainty and precision that characterizes the research results. In particular, the researcher must take care to clarify the relative extent of the results' certainty and validity, as well as indicate any elements of risk or uncertainty that may be significant for possible uses of the research results

22. In cases where plausible, yet uncertain information exists that the use of technology or the development of a certain research field might lead to ethically unacceptable consequences for health, society or the environment, researchers within the given field must strive to provide information that is relevant for using the Precautionary Principle.

23. The researcher must respect the demand for informed consent.

24. Research must secure the privacy of the research subjects.

25. The researcher must show due care and respect for animal welfare in the preparation and execution of animal experiments, and must account for the experiment's necessity to the relevant authorities.

26. The researcher must accommodate his or her research so that the use of research results are not contrary to the fundamental demands of animal welfare.

27. When questions are raised concerning a researcher's use of animals testing on the basis of ethical considerations, the researcher must ask an independent ethics committee for their assessment.

28. The researcher must, whenever natural, seek to incorporate alternative sources of knowledge, such as traditional knowledge.

29. The researcher should, whenever relevant, seek to use participatory methods.

30. The researcher is responsible for ensuring openness and scientific quality in contract research.

31. The researcher is obliged to be open about possible conflicts of interest.

32. Research institutions should have in place clear routines that reward researchers who popularize research and participate in research-related public debate

PROCEDURES FOR INSTITUTIONAL MONITORING

1. It is the responsibility of the Principal Investigator to monitor the conduct of research which has received ethical approval. The Principal Investigator must ensure that there is an appropriate continuing review of the research, taking into account any possible changes that may occur over the duration of the research project. It is the responsibility of the Principal Investigator to alert the Departmental Representative of the Faculty Ethical Review Committee (DRFERC) if any further ethical implications arise. It is the responsibility of the Principal Investigator to ensure that data are securely held and preserved.

2. Where significant concerns have been raised about the ethical conduct of the study, the Departmental representative in FERC **must** request a full and detailed account of the research for full ethical review.

3. Where the Departmental representative in FERC considers that a study is being conducted in a way which is not in accord with the conditions of its original approval it should consider withdrawal of its approval and require that the research be suspended or discontinued. It is the duty of the Departmental representative to inform the appropriate funding body that ethical approval has been revoked.

COMPLAINTS/APPEALS PROCEDURE

1. Where a decision has gone against a proposal or requires significant revisions to its conduct, the Principal Investigator has the right to request that the decision is reconsidered. Where the decision under appeal was made by the FERC, the Ethics Appeals Panel should convene to consider the matter. Any concerns should be reported to University Ethical Review Committee.

2. A Principal Investigator wishing to make a formal complaint or appeal should raise the issue in writing to the Chairman/ Chairperson of the Faculty Ethical Review Committee setting out his/her causes for concern. This letter should contain sufficient information to allow his/her grounds for appeal to be understood and should demonstrate clearly the basis of the complaint/appeal.

3. The appeal/complaint will be received by the Ethics Appeals Panel as written. The Ethics Appeals Panel will consist of the following:
   i. The Chairman/Chairperson of the Faculty Ethical Review Committee. (The Chairman / Chairperson have the right to appoint another senior member of academic staff in his absence).
   ii. At least 2/3rd of the Departmental representatives as members.

4. If the Panel agrees, the appeal can be upheld without a hearing. Where there is a disagreement, or a lack of clarity, the Ethics Appeals Panel will invite the applicant to meet with them. If additional expertise is required, the **Chairman** may invite up to two members of staff with relevant expertise but who have not been involved in the initial decision to join the panel. After the hearing, the Panel will determine whether the applicant is successful. It is the duty of the Research Ethics Appeal Panel to provide

clear justification for its decision regarding whether an appeal has been successful or unsuccessful.

5. Any complaints received from external organizations will be considered by the Chairman/Chairperson in the first instance and referred to the Ethics Appeals Panel if considered necessary. For external complaints the same procedures detailed above will be implemented.

RESEARCH STUDENTS AND THE ETHICS POLICY

1. It is the responsibility of the University to make sure their students are aware of the contents of the University Research Ethics Policy. Student awareness of the ethical research policy should further be reinforced by supervisors/ lecturers at departmental level.

2. In most cases the ethical review of student research will be administered at departmental level (e.g. through the FERC or by the Research Supervisor). If a department feels that a full review is warranted then the matter should be referred to the Chairperson of Faculty Ethical Review Committee.

RESEARCH CONDUCTED OUTSIDE NIGERIA

1. Where research is to be conducted outside Nigeria, the FERC should establish whether local ethical review is required by the host country and,

2. If not, how the principles of the Research Ethics Policy can be followed in developing and undertaking the research.

Avoiding Duplication of Submission

- Duplicate submission of proposal for ethic reviews should be avoided.

Legal and data requirements

- It will remain the responsibility of the Principal Investigator to ensure that arrangements are in place to maintain the integrity and security of research data.

Health and social care studies

- **While the University Research Ethics Policy aims to be as inclusive as possible.**

- **NOTE: That for health-related studies NO additional ethics approval may be required.**

CODE OF CONDUCT FOR RESEARCH

1. Researchers should **ensure** that research projects are ethically sound and have received the approval of the University Ethics Committee(s) before they commence.
2. Ensuring the safety of all who are involved in the research process.
3. Ensuring that research is conducted in suitable environment with appropriate facilities.
4. Undertaking professional development appropriate to the research
5. Ensuring maintenance of all personal records of research progress and zero falsification of results
6. Maintenance of strict confidentiality to achieve protection of intellectual properties
7. Avoiding harm to subjects and minimizing any adverse effect that the research may have on people, animals and the natural environment.
8. Ensuring that **the** research findings are suitably disseminated.

UNIVERSITY OPEN ACCESS POLICY TO RESEARCH PUBLICATION

1. All research papers, where copyright allows, should be made available in an open access Form upon publication.
2. All research papers where copyright allows should be uploaded in the university website upon publication.
3. In view of availability, researchers should take advantage of opportunity to publish in an open access form offered by journal publishers and can make use of research grants in order to pay open access publication fees.
4. The University should provide fund for publication of research findings in journals.

ETHICS OF PUBLICATIONS

1. Researchers are encouraged to disseminate their research and research findings in an appropriate form, usually as papers in refereed journals.
2. A publication must contain appropriate reference to the contributions made by all participants in the relevant research. Any person who has not participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research is not to be included as an author of a publication derived from that research.
3. In addition to meeting the requirements of the points above, an author must ensure that the work of research students, research assistants, research officers, and technical officers is recognized in all publications derived from research to which they have made a contribution;
4. A publication which is substantially similar to other publications derived from the same research must contain appropriate reference to the other publications.
5. A researcher who submits substantially similar work to more than one other publisher should disclose that fact to the publishers at the time of submission.
6. Publication and dissemination of work electronically or on the Web should be treated with the same degree of integrity as every other form of publication.

INTELLECTUAL PROPERTY (IP)

- If a researcher has generated IP during the course of his/her research, it is the responsibility of the University IP office to assess and determine whether or not to protect and commercialize the IP.

SUPERVISION

- All supervisors and researchers must observe and undertake the responsibility set out from time to time in accordance with the requirement prescribed by the University Senate as specified in the guidelines manual for staff and student.

CONFLICTS OF INTEREST

- It should be noted that external work, whether or not remunerated, has to be regulated in order to ensure that it either does not create a conflict of interest or, if necessary, it has received formal sanction from the University.

ADVERSE EVENTS

- Researchers shall be responsible for monitoring and reporting any adverse events occurring in the course of the research and each School must have systems in place to ensure that all such adverse events are recorded and, if appropriate, investigated.

INSURANCE ON RESEARCH

- There should be insurance for researchers as well as the subjects.

PROCEDURES FOR DEALING WITH ALLEGATION OF RESEARCH MISCONDUCT

- Research misconduct such as fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting progress or results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research breach the code of conduct of the research whether it causes harm or not.

RESEARCH ETHICS OATH

I will conduct my activities as a researcher with integrity and honesty; I will use my scientific knowledge and skills for the benefit of humanity and for sustainable development; I will show respect for animals and nature; I will act in accordance with research ethics, and I will not allow considerations based on ideology, religion, ethnicity, prejudices or material advantages to overshadow my ethical responsibility as a researcher.

Student Signature:

Date: