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LAGOS STATE UNIVERSITY

FOR TRUTH AND SERVICE

LAGOS STATE UNIVERSITY, OJO

RESEARCH ETHICS POLICY

LAGOS STATE UNIVERSITY, OJO

RESEARCH ETHICS POLICY

A publication of Lagos State University
P.M.B. 0001, LASU,
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Nigeria

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LASU Anthem

There's a citadel founded with great vision,
Where character and learning's the mission.
It's a fountain for all who thirst for knowledge;
The human race so to fledge.

Refrain:
Shine with your light, our great citadel,
In truth and service; in truth and service
Lagos State University
Blaze forth, shine for humanity
Together, lift high our banner
Joining hands, every thought to garner
In radiance, barring every cloud
We are LASU and we are proud!
We are LASU and we are proud!

We are blessed with culture, art, tradition,
Displayed in the Eyo Masquerade
With compelling and great aquatic splendour,
For total life and learning.

Refrain:
Shine with your light, our great citadel,
In truth and service; in truth and service
Lagos State University
Blaze forth, shine for humanity
Together, lift high our banner
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FOREWORD

The Lagos State University Research Ethics Policy is a document that seeks to guide the research enterprise to higher ethical standards.

The conduct of research is often faced with ethical questions, including engagement with vulnerable and disadvantaged groups. The literature abounds with instances of unethical research which must be avoided all the time. Learned journals often requires authors and researcher to show proof of ethics approval prior to consideration of manuscript for publication.

The Lagos State University Research Ethics Policy has a wide scope dealing with research in humans, animals, plants and technology. All researchers at our university are now required to seek ethical approval where relevant prior to commencing their studies and to maintain the highest level of ethics at all stages in the conduct of their research. This will ensure that tremendous benefit is available to all involved in the research process and that no harm comes to anyone.

Professor Olanrewaju Adigun Fagbohun, Ph.D, SAN, NPOM
Vice-Chancellor, LASU

PREFACE

Research is crucial and fundamental to the proper functioning of world-class universities such as Lagos State University. As a first step, we developed Lagos State University Research Policy in 2019. In furtherance to deepening our research culture, we have now developed the Lagos State University Research Ethics Policy.

This policy is to provide guidance and standards that will ensure the research at Lagos State University is not only of high standards but also ethical. The Research Ethics Policy sets out the systems, structures and processes for ethics reviews at our university. The roles and responsibilities of stakeholders and our University are clearly stated in the documents.

It is a policy document that commits us all to high standards and ethical conduct of research in Lagos State University. It should be read and complied with by all researchers.

Professor Olumuyiwa O. Odusanya
Director, Directorate of Research Management & Innovation
Lagos State University

ACKNOWLEDGEMENT

This research Ethics Policy is to further deepen the quality of research that emanates from Lagos State University. Ethical considerations in research are very important to improved research standard. Therefore, this initiative to develop a Research Ethics Policy is in line with current research trends.

We acknowledge with thanks the Vice-Chancellor Professor Olanrewaju Fagbohun Ph.D, SAN, NPOM for this initiative and his constant support for the Directorate of Research Management and Innovation.

We thank all those who have contributed to the fine-tuning of the document.

Our appreciation goes to Professor Olumuyiwa Odusanya, Director, Directorate of Research Management & Innovation and Dr. Temitope Yerokun-Oloko, Assistant Director, Directorate of Research Management & Innovation for their hard work and invaluable contribution in spearheading the development of the Research Ethics Policy.

ACRONYMS

APREC	-	Animal and Plants Research Ethics Committee
BSREC	-	Bio-safety Research Ethics Committee
ETREC	-	Engineering and Technology Research Ethics Committee
HREC	-	Health Research Ethics Committee
IRB	-	Institutional Review Board
REC	-	Research Ethics Committee
SHREC	-	Social and Humanities Research Ethics Committee
SREC	-	Science Research Ethics Committee

Background

Research integrity and good conduct are a crucial aspect of research at the Lagos State University and a core part of a sustainable research culture. The University is fully committed to ensuring the good conduct of all research undertaken by its staff and students, and through its engagement with external research collaborators and stakeholders. High standards and good research practices are of central importance to our commitment to research. It is the responsibility of all members of staff engaged in research activity (hereinafter referred to as 'researchers') to maintain professional standards.

The key principle underlying the Research Ethics Policy is that researchers should reflect on the ethical issues that are raised by their research and be able to justify, in ethical terms, the practices and procedures that they intend to adopt during their research. Matters of research ethics are often not clear and there is no single approach to it. This Policy therefore aims to set a clear framework and guiding principles to assist researchers in addressing the ethical issues that may arise in the course of their research.

1.0. PURPOSE

This document sets out ethical and responsible provisions regarding ethical review and approval, that ensure research and teaching practices within a comprehensive ethical framework to reflect the **Lagos State University** (herein referred to as **The University**) values while advancing the frontiers of knowledge for the benefit of humankind. The objectives of the policy are also highlighted, while the University expects that staff, students and visitors should be aware of ethical considerations and conduct their projects and studies to the highest ethical standards with clear understanding of the ethical review process operated by the University.

This policy is based on the Vision and Mission Statement of the Lagos State University(LASU).

1.1. Our Vision:

The vision of Lagos State University is:

To provide Lagos State with the required human capital for the sustenance of her position as the commercial and industrial hub of the Federal Republic of Nigeria and the strategic transformation of the industrial capacity of the state in particular, as well as the country in general.

1.2. Our Mission:

The mission of Lagos State University is:

To provide qualitative education to the large populace of Lagos State in particular and Nigeria as a whole by preparing them for the challenges of managing the public and private sectors of the State.

2.0. SCOPE

a. This Policy applies to all staff and students of the University engaged in studies or research as well as to visitors, individuals, collaborators, or agents conducting research or other studies in the name of or at the University and/or engaged to conduct research by the University. This also specifically includes research undertaken by non-academic departments of the University, and administrative research undertaken within academic departments or faculties.

b. Ethics approval is **not** required:

If the project does not involve human participants, either directly (e.g. through use of interviews, questionnaires or indirectly (e.g. through provision of, or access to, personal data or tissue material). It is also not required if the proposed study does not have ethical issues involving the use of animals, plants, micro-organisms, materials or technology that have impact on the environment, human beings or the society. This includes: projects which will only use publicly available anonymised data, population or other official statistical data or projects which will only use existing clinical or research data that has been robustly anonymised such that it no longer constitutes personal data, such as artistic works, plays, novels, films, paintings, sculptures, building designs, judicial pronouncement, news stock, newspaper cuttings and as well as census and public literature.

3.0. DEFINITIONS

Child: A child is defined as any persons under the age of 18 years.

Committee refers to the University Research and Ethics Committees.

Confidentiality: refers to the state of research processes and procedure being kept secret or private unless the participant gives consent permitting disclosure. When disclosure is to be done, the results of research should be communicated in such a way as to protect the confidentiality of participants. Researchers are required to ensure confidentiality of the participant's identity and data throughout the conduct and reporting of the research.

Ethics Review is the formal evaluation of the moral grounding of a proposed academic or research project before it is begun. The review is an attempt to

ensure that the research will treat its subjects fairly and safely, without exposing them or society at large to undue risk.

Harm physical (including sexual abuse); psychological (fear, alarm, or distress, or negatively affecting self-esteem); or some other actions which adversely affects someone else's property, rights, or interests.

Humanities: Academic discipline that include Education, Arts, Social and Management Sciences and Law.

Human material means any material extracted from living or deceased humans including human cadavers, tissue, body parts, body fluids, embryos and organs.

Human subject means any living person from which a researcher obtains data through an interaction or is identifiable through private data, either as an experimental subject or as a control.

Informed Consent is a process in which a researcher educates the participant about the risks, benefits, and alternatives of a given procedure or intervention including providing potential participants in advance, any features of the research that might reasonably be expected to influence their willingness to take part in the study.

Lay member means a member of the society, who is not employee of the University and his or her primary professional interest is not in the field of the academic discipline of the research.

Participant means an individual who has given informed consent as defined in this policy and voluntarily participates in a research, either as the recipient of a test article or as a control.

Policy refers to the Research Ethics Policy

Principal Investigator (PI) refers to the lead investigator

Co – Investigator: A member of a research team who is not leading a team.

Protection from Harm: The act of protecting participants from physical and psychological harm at all times during the investigation.

Research Fund Agency is organisation or person which provides research funding to the University or individual this include, research councils, public sector organisations, charities, non- governmental organisations, commercial and business organisations and government agencies whether located within the Nigeria or elsewhere.

Research Funding All forms of funding in support of research and enterprise activities including grants and contracts, philanthropic donations, consultancy and industrial research contracts and grants in kind.

Research means experimental or theoretical work under taken primarily to acquire new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, understandings, foundations of phenomena and observable facts.

Researcher This is an individual involved in research, including, but not limited to: staff in any of the University staff visiting from other institutions undertaking or supervising research at or for the University; undergraduate and postgraduate students (both taught and research).

Vulnerable participant means participant who is considered susceptible because of been under age, lacking capacity or individuals in a dependent or unequal relationship who are exposed to exploitation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment.

4.0. PHILOSOPHY OF ETHICS IN RESEARCH

Researchers must abide with the following principles at all stages of the research lifecycle. This includes the planning stage, applying for funding, the conduct and later stages of the project, such as dissemination and impact activities.

a. Studies and research should be designed, reviewed and undertaken to ensure integrity, quality and transparency that provide benefits that outweigh potential risk or harm.

b. Researchers have an obligation to protect research participants wherever and as much as possible from significant harm consequent upon the research.

c. Participants must be fully informed about the research or study they are invited to participate in and their consent to take part must be made voluntarily, freely and without any coercion. Consents should be recorded, ideally in writing.

d. Researchers must respect the rights, interests, dignity of participants and related persons in research.

e. The confidentiality of information supplied by research participants and any agreement to grant anonymity to respondents should be respected.

f. The principal investigator must obtain ethical approval for the research and be responsible for determining what ethical issues emerge from the

proposed project and for obtaining ethical approval of the project.

g. Researchers are responsible for ensuring the project is undertaken as approved by the University research ethics approval process and in compliance with any legal or organisational requirements. Any major divergence from the approved project must be subject to further ethical approval and the researcher is responsible for acquiring further ethics approval before continuing with the research.

h. Care must be taken with collecting, handling and storing sensitive, classified and/or personal data. Such data should be kept securely and protected from unauthorised access. Particular care should be taken to ensure that human data cannot be linked back to individuals unless by authorised persons. It is essential that all sensitive, classified and /or personal data are disposed of appropriately in line with legal and funder requirements.

i. The same high ethical standards shall apply wherever in the world the research is being undertaken.

4.1. Guiding Standards

The University Procedure is based on the following guiding standards:

a. **Quality**: Refers to the minimum bench mark as contained in the Research Ethics Policy including competent and consistent decision-making by relevant ethics review committee.

b. **Efficiency & Effectiveness**: Ethical Review Committee will apply care, skilfulness and avoid waste of time in treating applications and must be clear with guidelines for submission, and processes for its decisions.

c. **Transparency**: Applicants should receive sufficient detailed, critical and constructive feedback from reviewers to explain the decision made; this should also be able to satisfy the requirements of external scrutiny, if ever required.

d. **Independence**: Ethics reviewers must not have any conflict of interest with respect to any application they review

e. **Ease of application**: The procedure should be designed to be as simple and prompt as possible.

f. **Proportionality**: The detail and depth of the ethics review of any particular project should be in proportion to the estimated level of risk posed to prospective participants.

4.2. Commitment of the University

a. The University shall undertake to communicate ethical standards and policies to staff through education and training, publication of this and related policies, and through this Ethics Policy and the process for the ethical review of research and studies.

5.0. INSTITUTIONAL REVIEW BOARD (IRB) AND RESEARCH ETHICS COMMITTEES

The University will have an Institutional Review Board. The Central Board will be composed of the following ethics committees to deal with following specialised areas:

a. Animal and Plants Research Ethics Committee
b. Bio-safety Research Ethics Committee
c. Engineering and Technology Research Ethics Committee
d. Health Research Ethics Committee

e. Science Research Ethics Committee
f. Social and Humanities Research Ethics Committee

5.1. GUIDELINE FOR SELECTION:

In accordance with the federal regulations, an IRB must consist of at least five members, including:

- at least one member whose primary concerns are in non- scientific areas
- at least one member whose primary concerns are in scientific area
- at least one member who is not otherwise affiliated with the institution (and who is not part of the immediate family of a person who is affiliated with the institution)
- One member can represent more than one role (such as, clergyman who may fill the roles of both the unaffiliated member and non-scientist).

5.2. COMPOSITION OF ETHICS COMMITTEES

An ethics committee is an independent body of people from diverse backgrounds, professions and values chosen from a community to oversee or enhance the ethical conduct of biomedical research within that community or jurisdiction. Members must be diverse in race, gender, and cultural background, and be sensitive to local community issues (Protection of Human Subjects 2017).

5.3. Composition of IRB

The IRB membership shall comprise of the following people who are to be appointed by the Vice- Chancellor:

a. Chairperson of the IRB
b. Director, Research Management and Innovation/his or her nominee
c. Chairs of the various Ethics Committee established in section 5.0 above
d. Head of the Legal Unit
e. One lay person from the public
f. Principal Assistant Registrar- Secretary (To be nominated by the Registrar)

5.4. Terms of Appointment

a. Members must be knowledgeable in ethics and have up to date certification from a recognised Ethics Training body such as the National Health Research Ethics Committee.
b. The tenure of the Chairs of the IRB and the RECs is a three- year term renewable once.

5.5. Functions of the IRB

The functions of the IRB are to:

a. Regulate and coordinate all matters pertaining to research ethics and integrity at the Lagos State University.
b. Advise Senate on policies and matters relating to research ethics and integrity.
c. Prepare appropriate forms for ethics review of research proposals.
d. Ensure that humans involved in research are treated with dignity and that their well-being is not compromised and that animals involved in research are treated compassionately.
e. Review ethical aspects of research proposals and protocols that meet university, national and international criteria set out for researchers, and ensure that the research will be in the spirit of advancing knowledge and promoting the health, safety and wellbeing of the

society.
f. Ratify approved proposals from the Research Ethics Committees.
g. Serve as an appellate body where there are issues arising from the Research Ethics Committees.
h. Monitor approved proposals to ensure compliance with the guiding ethical standards.
i. Oversee the activities of its Research Ethics Committees.
j. Prepare and submit annual reports to Senate through the Vice-Chancellor.

5.6. Composition and Functions of Research Ethics Committees

The composition and functions of each of the Research Ethics Committee are as outlined:

a. Animal and Plants Research Ethics Committee (APREC)

Composition of the APREC

The membership of the APREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor of relevant discipline as Chair;
- Two experienced scientists from each of the Faculties of: Agriculture and Sciences;
- Two community representatives (lay persons: one male and one female);
- One statistician;
- One lawyer;
- Representative of Director, Research Management and Innovation.

Functions of the APREC

The principal functions of the APREC are to:

- Receive research proposals involving the use of animals and plants and review all associated ethical and scientific issues with

the use of animals and plants in research;

- Approve or take a decision on research proposals submitted for ethical clearance in the area of Animals and Plants
- Submit ethical approval granted to the IRB for ratification
- Ensure compliance with all regulations, policies and standards to protect animals and plants;
- Monitor the implementation of approved research to ensure that it is carried out ethically;
- Conduct inspections of all areas where animals and plants are housed and used;
- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to Senate through the IRB.

b. Bio-safety Research Ethics Committee (BREC)

Composition of the BREC

The membership of the BREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor from a relevant discipline as Chair;
- Two experienced scientists from each of the relevant Faculties;
- Two community representatives (lay persons: one male and one; female);
- One statistician;
- One lawyer;
- Representative of Director Research Management and Innovation.

Functions of the BREC

The principal functions of the BREC are to:

- Receive research proposals involving the use of animals and plants and other materials that involve bio-safety, and review all associated ethical and scientific issues;
- Approve or take a decision on research proposals submitted for ethical clearance in the area of Bio-safety
- Submit ethics approval granted to the IRB for ratification
- Ensure compliance with all regulations, policies and standards to protect animals and plants and other materials with bio-safety importance including proper storage and disposal;
- Monitor the implementation of approved research to ensure that it is carried out ethically;
- Conduct inspections of all areas where animals and plants are housed and used;
- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to Senate through the IRB.

c. Engineering &Technology Research Ethics Committee

Composition of the ETREC

The membership of the TREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor of Engineering, as Chair;
- Two experienced engineers from the Faculty of Engineering;
- A representative the Faculty of Science;
- A statistician;

- One lawyer;
- Two community representatives (lay persons: one male and one female);
- Representative of Director Research Management and Innovation.

Functions of ETREC

The principal functions of the TREC are to:

- Receive and review research proposals in the area of Engineering and Technology, and review all associated ethical and scientific issues;
- Approve or take a decision on research proposals submitted for ethical clearance in the area of Engineering & Technology
- Submit ethics approval granted to the IRB for ratification
- Ensure the protection, safety, dignity, rights and wellbeing of potential and actual research participants.
- Monitor the implementation of approved research to ensure ethical compliance.
- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to the IRB.

d. Health Research Ethics Committee (HREC)

Composition of the HREC

The membership of the HREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor of Medicine as Chair;
- Two experienced scientists from each of the Faculties of the College of Medicine;

- Two community representatives (lay persons: one male and one female);
- One statistician;
- One lawyer;
- Assistant Director Research Management and Innovation.

Functions of the HREC

The principal functions of the HREC are to:

- Receive research proposals involving the use of humans and invasive procedures and associate health facilities, and review all associated ethical and scientific issues;
- Approve or take a decision on research proposals submitted for ethical clearance in the area of Health.
- Submit ethics approval granted to the IRB for ratification
- Ensure the protection of the safety, dignity, rights and well-being of potential and actual research participants;
- Monitor the implementation of approved research to ensure that it is carried out ethically;
- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to the IRB.

e. Science Research Ethics Committee (SREC)

Composition of the SREC

The membership of the SREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor from the Faculty of Science, as Chair;
- Two experienced scientists from the Faculty of Science;
- A representative from the Faculty of Engineering
- A statistician;
- One lawyer;
- Two community representatives (lay persons: one male and one female);
- Representative of Director Research Management and Innovation.

Functions of the SREC

The principal functions of the SREC are to:

- Receive and review research proposals in the areas of Science at the University, and review all associated ethical and scientific issues;
- Approve or take a decision on research proposals submitted for ethical clearance in the area of Science
- Submit ethics approval granted to the IRB for ratification
- Ensure the protection, safety, dignity, rights and well-being of potential and actual research participants;
- Monitor the implementation of approved research to ensure ethical compliance.
- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to the IRB.

f. Social and Humanities Research Ethics Committee (SHREC)

Composition of the SHREC

The membership of the SHREC shall comprise of the following members who are to be appointed by the Vice- Chancellor:

- A professor from the humanities or law, as Chair;
- Two experienced behavioural scientists from each of the Faculties of: Arts, Education, Law, Management Sciences and Social Sciences;
- One statistician;
- One lawyer;
- Two community representatives (lay persons; 1 male and 1 female);
- Assistant Director Research Management and Innovation.

Functions of the SHREC

The principal functions of the SHREC are to:

- Receive research proposals involving the use of humans for such purposes as behavioural observations/recordings, non-invasive physiological recordings, evaluation of behavioural/social interventions, educational assessments, interviews, surveys, and cognitive tests, and review all associated ethical issues;
- Approve or take a decision on research proposals submitted for ethical clearance in the area Social and Humanities
- Submit Ethics approval granted to the IRB for ratification
- Ensure the protection of the safety, dignity, rights and well- being of potential and actual research participants;
- Monitor the implementation of approved research to ensure that it is carried out ethically;

- Make recommendations as appropriate to the IRB
- Prepare and submit annual reports to the IRB.

5.7. Requirements for Ethical Research Practice

a. Researchers must comply with relevant codes, guidelines, policies and directives on ethical and safe practices in research;
b. All proposals for research in the University must be submitted for ethical approval by the relevant research ethics committee depending on the nature of the research.
c. Best practices ensuring that international and national guidance are followed in the constitution of committees and the preparation of their operational guidelines.

5.8. Training and certification of Ethics Committee members

a. Training will be provided for all new members of IRB and Ethic Committee.
b. All members of the proposed IRB and Ethic Committee must have completed approved training programs in research ethics. Additional training in research methodology and research administration is recommended and must be taken during their first year of membership.
c. Training workshops on research ethics, funding and grants will be held at least once each year for members of IRB and Sub-Ethics Committee to stay abreast with the current trends in research ethics.
d. The Directorate of Research Management and Innovation shall organise, sponsor and support such training on behalf of the University.
e. Training validity is for 2 years

6.0. ETHICS REVIEW PROCESS AND APPLICATION

6.1. Procedures for Ethical Review

a. The lead researcher is responsible for deciding which ethics review procedure is applicable. Ethics approval can be obtained via standard routes, which are outlined in this section. It should be noted that for certain types of research there are also specific legal, regulatory and governance requirements that must be considered alongside the requirements for ethical review (e.g. requirements that apply to health care research, human tissue research, and clinical trials of investigational medicinal products or medical devices).
b. Review applies to:
   i. Research led by LASU staff or students which is conducted within or outside Nigeria; or Research in which University staff or students may be involved, but which is led by another university or research organisation (which may be conducted either within or outside Nigeria).
   ii. This applies to all administrative research (i.e. research which does not form part of the standard academic research that is undertaken within departments and research disciplines). It may be undertaken by, or on behalf of, professional service departments, or the professional service functions within academic departments or faculties.
   iii. The University Procedure has been designed to take into account the differences between disciplines, and aims to achieve an appropriate balance between carrying out the ethical review of research projects in a sufficiently rigorous way to effectively protect the welfare, dignity

and rights of human participants, whilst also being risk-aware, flexible and as user friendly as possible in order to facilitate research within departments.

c. The **MINIMUM** ethics review required for all research is set out as follows:

i. Ethics review process is first based upon the soundness of the research proposal in its discipline. Proposals of poor quality that do not meet this criterion will not be subjected to Ethics consideration.

ii. All proposals must be referred to the appropriate Research Ethics Committee for review

iii. Reviewers must not have any conflict of interest with the proposed study and are required to state so or decline review, should this be significant

iv. Where a member of the IRB or Research Ethics Committee is involved in a proposed study, they must recuse themselves from the review process and meetings where such proposals are reviewed and approved.

v. All applicants must be received on a designed protocol/form approved by the Research Ethics Committee

vi. Exempted category of approval can be granted if there is no known risk to the participants and can be granted by the Chairman of the appropriate Research Ethics Committee and such exemption is to be ratified at a full meeting of the Committee.

vii. Expedited review refers to a process where there is an urgent need usually arising fro institutional purposes to accelerate the process of review. This must be done after at least one review by an expert.

viii. A full review requires that at least two experts review the proposal as is the usual process.

ix. A minimum of three ethics reviewers appointed by the appropriate Research Review Committee is required to undertake an ethics review of a potentially 'high risk' research application.

x. All applicants will be given the opportunity to respond to ethics issues raised during the review process and modify their proposals as necessary

xi. If there is a significant, fundamental difference of opinion between ethics reviewers about the ethics of a proposal, the appropriate Research Ethics Committee may refer the proposed study to no more than two experts to advise it on the decision to take.

xii. If members of the appropriate Research Ethics Committee, cannot reach a consensus within **one month** the matter is to be referred to the IRB to undertake an ethics review of the application. If the matter is urgent this may be done through the Chairman's action, in consultation with other committee members within 5 (five) working days.

xiii. All final approvals are to be made by IRB and they last for 12 months which could be renewed on annual basis subject to applications and satisfactory conduct oversight functions of IRB and relevant Ethics committee.

6.2. Appeal

a. If an application is not approved as a result of an initial ethics review by a Research Ethics Committee, an appeal may be made to the IRB through the Research Ethics Committee to which the initial application was submitted. If the matter is urgent, this applicant may inform the Chair of the IRB. An expedited review process may be used. The IRB's decision is final.

6.3. Time Frame

a. The length of time for approval of projects should be relatively straightforward; the ethics review will be approximately one month. However, delays can occur if a research ethics application form is not fully completed, if the ethics reviewers request more information, if an application is judged contentious, or if the applicant appeals against the ethics decision.

b. Appointed ethics reviewers should make every effort to complete reviews within the deadline set by the Research Ethics Committee, in order to avoid unnecessary delays to colleagues' and students' research. If a reviewer is unable to perform a review within the defined period, they should inform the Research Ethics Committee promptly so that alternative arrangements can be made.

7.0. ROLES AND RESPONSIBILITIES

a. Deans, Heads of Departments, Directors are responsible for the conduct of the research that is undertaken in their departments, Centres, Directorate or Units. They are therefore responsible for ensuring that researchers undertake appropriate ethics review procedures for research activities that require ethics approval.

b. They are also responsible for ensuring that all staff and students are familiar with the contents of the Policy and that appropriate training and guidance is made available.

c. In everyday research practice, however, the first responsibility for considering, respecting and safeguarding the dignity, rights, safety and well-being of human participants involved in research lies with the lead researcher (e.g. the principal investigator or supervisor). However, this does not absolve more junior, or more senior, staff, or students, from personal responsibility in this respect, or from their responsibility to disclose any failure to meet the principles of conduct required by the Policy.

d. The Research Ethics Committees will also keep under review relevant University policies and guidance and will report its actions to the Institutional Review Board.

e. The overall responsibility for the development, implementation and monitoring of research ethics policies lies with the Institutional Review Board.

f. The Institutional Review Board will maintain a watching brief on emerging ethical issues relating to research and if necessary will report to the Vice-Chancellor.

8.0 RESEARCH MISCONDUCT

Failure to comply with ethical standard contained in this the approved University policy or failure to apply reasonable care in assessing the likely ethical implications of a research project may constitute research misconduct. Research misconduct includes the following, whether deliberate, reckless or negligent:

i. Unethical behaviour in the conduct of research.
ii. Failure to obtain appropriate permission to conduct research
iii. Deception in relation to research proposals.
iv. Fabrication, falsification or corruption of research data
v. Dishonest misinterpretation of results
vi. Distortion of research outcomes, by distortion or omission of data that do not fit expected results
vii. Unauthorised use of information which was acquired confidentially
viii. Deviation from good research practice, where this results in unreasonable risk of harm to humans, other animals or the environment
ix. Publication of data known or believed to be false or misleading
x. Plagiarism, or dishonest use of unacknowledged sources
xi. Misquotation or misrepresentation of other authors
xii. Inappropriate attribution of authorship
xiii. Fraud or other misuse of research funds or research equipment
xiv. Attempting, planning or conspiring to be involved in research misconduct

xv. Inciting others to be involved in research misconduct
xvi. Collusion in or concealment of research misconduct by others
xvii. Failure to comply with relevant legislation, including that relating to health and safety, data protection, intellectual property and animal experimentation.

The above list is not exhaustive and other misconduct specifically related to research activity may be dealt with under this procedure.

9.0 PROCEDURE FOR DEALING WITH SUSPECTED CASES OF MISCONDUCT

a. The University has a responsibility to investigate allegations of research misconduct fully and expeditiously. It also has a responsibility to protect researchers from malicious, mischievous, or frivolous allegations.

b. The procedures for dealing with alleged misconduct by staff or post-graduate research students are as follows:

i. Anyone who has good reason to suspect research misconduct should report it in confidence as appropriate to the IRB
ii. Those who raise concerns in good faith will not be penalised in any way for doing so. The safeguards for individuals raising genuine concerns are detailed in the University's administrative procedure.
iii. Allegations should normally be made in writing, accompanied by any available supporting evidence. All allegations will be dealt with under the appropriate LASU procedure for staff as stated in the Conditions of Service and for students as stated in the students' handbook.
iv. If at any stage an allegation is found to have been malicious or mischievous in nature, the matter may result in disciplinary action

being taken against those making the allegation.

v. In cases where an allegation implicates someone who is not subject to the University's procedures, the Vice-Chancellor shall bring the matter to the attention of their employer or any other appropriate body.

vi. Where the research is funded in whole or part by an outside grant, the Vice-Chancellor shall have regard to the guidance issued by the relevant funding body. The Vice-Chancellor shall ensure that any such body is given appropriate and timely information as to the instigation and progress of an investigation and any referral under disciplinary regulations.

c. In the event of a finding of misconduct, where the person responsible is subject to the regulation of a professional body such as the Medical and Dental Council of Nigeria, Council of Legal Education or other professional bodies, the Vice-Chancellor shall consider whether it is appropriate to inform the professional body of any finding.

d. Where the person responsible has published research, especially related to any research misconduct and has been if confirmed to be true, the Vice-Chancellor shall inform journal editors or others of any finding.

e. If an allegation has been made publicly, the Vice-Chancellor shall consider whether it is appropriate to make public the outcome of its investigation into the matter.

10.0. CONSIDERATION INVOLVING HUMAN RESEARCH

10.1. Principles of Health Care Ethics

a. **Autonomy** is a term used to describe a person's ability to make decisions, or speak and act on their own behalf, without interference from another party.

b. **Beneficence** is a moral obligation to act by providing and balancing benefits of others. To ensure beneficence, researchers must develop and maintain a high level of skill and knowledge, make sure that they are trained in the most current and best practices, and protect and defend the rights of others, prevent harm from occurring to others, remove conditions that will cause harm, help persons with disabilities and rescue persons in danger.

c. **Non-maleficence** means that there is an obligation not to inflict harm on others. This principle should be the end goal of all a researcher's decisions, and means that they providers must consider whether other people or society could be harmed by a decision made, even if it is made for the benefit of an individual. Such actions may include do not kill, do not cause pain or suffering, do not incapacitate, and do not cause offense.

d. **Justice** means that there should be an element of fairness in decisions that burden and benefit, as well as equal distribution of scarce resources and new treatments according to the persons share, need, effort, contribution and merit.

10.2 Use of Human Material/ Tissue

i. The use of human tissue or fluids in research must comply with all relevant statutory controls and regulations.

ii. All research projects using human tissue or fluids must undergo rigorous ethical scrutiny by the Health Research Ethics Committee

iii. Any regulatory licences, approvals or permissions required to use or store human material must be obtained prior to the work commencing and cannot be retrospective.

10.3 Involvement of Vulnerable Persons in Research

i. All research involving vulnerable adults should obtain ethical approval by the appropriate Research Ethics Committee before commencing the research.

ii. Researchers should not assume vulnerability based on single characteristics such as age, disability, appearance, behaviour, medical condition (including mental illness), communication impairments or beliefs.

iii. When conducting research involving vulnerable adults, researchers should always, without compromising the rights of the individual, consult with the person with duty of care.

iv. It should be recognised that the individual's vulnerability may be the interest of the research and the individual should be permitted to participate in the research, if the project has obtained appropriate ethical approval and if it is in the best interest of the individual.

10.4 Involvement of Children in Research

i. Research should only involve children if the relevant data cannot be obtained from adult subjects.

ii. Researchers must obtain consent from the child's legal guardian for research involving children under the age of 18, the child's assent however is also necessary where possible. The only other exception to this is research using anonymous data held previously e.g. by a school or institution.

iii. Researchers should obtain consent from at least one parent but both parents are preferable, if possible, for more invasive research, especially medical. In a disagreement of consent for a child who is not competent, where there is a divergence of consent of the two parents, it is recommended that the child should not be included in the research.

iv. Assent of the child is required if he/she is above 12 years in addition to obtaining consent of the of the parents/ legal guardian.

v. A child's refusal to participate in research must always to be respected.

vi. Should a child become distressed during the procedure/research, this must be taken as a valid refusal to participate and the child should be withdrawn from the research and/or the consent renegotiated.

vii. Researchers should avoid incentives or pressures to influence a child's participation or to influence carer's consent to volunteer the child, in the expectation of obtaining direct benefit either financially or therapeutically.

viii. Researchers must give consideration to the cumulative medical, social and psychological consequences of the child's involvement in research.

ix. Researchers should inform the participating child the of study procedures involved at each stage of their study.

x. Children have rights to privacy and confidentiality which must be respected; albeit with precedence given to child safeguarding.

xi. Researchers must ensure that children are protected from any kind of exploitation from research.

xii. Researchers must ensure that no child is disadvantaged through their involvement in research.

11.0. INFORMED CONSENT

a. Informed consent must be acquired before any research is undertaken.

b. Participants must be fully aware of the aims of the research and the source of funding for the research.

c. Participants must understand what participation in the study requires and what benefits may arise from the research prior to their participation. Participants must have a clear understanding of how the data is going to be used and by whom.

d. Participants must be made aware of all reasonably foreseeable risks arising from the study prior to their participation in the research.

e. Participants must be given information about alternative procedures/interventions to the proposed one in the study and be allowed to decide.

f. Use of incentives should be minimal and should not impair the judgement to give informed consent.

g. Researchers must obtain written consent where it is appropriate. In exceptional cases where it is not appropriate, researchers must adequately justify the omission of this record in their ethics application.

h. Where vulnerable participants are involved in a research, appropriate ethical and legal protocols must be adhered to.

i. Consent for foetuses used in research must be obtained from the mother or legal guardian of the mother, where the mother is legally incapable of consenting.

j. Where there are legitimate reasons not to acquire consent, prior approval must be sought from the appropriate Research Ethics Committee. For example, in covert or deception studies.

12.0 PRINCIPLES OF DATA CONFIDENTIALITY

a. The identity or any information that collectively might reveal the identity of a participant must not be released without prior consent.

b. The collection and storage of data by researchers must comply with the Nigeria Data Protection Regulation (2019) and any University data management policies.

c. Research data and methods of analysis should be transparent and open to scrutiny without prejudicing participants' rights to confidentiality.
d. Confidentiality of information collected in the course of research must respect the boundaries of Nigeria legislation, or the local legislation for projects conducted overseas.
e. Research proposals undertaken under the Official Secrets Act (1989) are not exempt from requiring ethical review.
f. In research projects where participant's personal data is collected, researchers must detail in their ethics application the date by which the identifiable personal details of participants will be destroyed.
i. Participants have the right to confidentiality under the Data Protection Act 2019 and the University's Data Protection Policy and Guidelines. Therefore, participants' confidentiality must be maintained at all times and this can be done using the following procedure:
ii. Using unique identifiers or pseudonyms instead of names where appropriate storing all data in a locked/encrypted file on a University approved data storage media.
iii. Ensure any removal storage media (e.g. USB drives or laptops) are encrypted.
iv. Storing all data in a locked/encrypted file on a University approved data storage media ensure any removal storage media (e.g. USB drives or laptops) are encrypted.

v. Carefully dispose all paper documents containing personal information in a fashion that protects the identity of participants. e.g. cross-cut shredding. Securing confidentiality statements from all researchers destroying audio and video tapes on completion of research, or as appropriate to the circumstances; transcripts with anonymized or de-identified participants should be kept.
vi. Obtaining the minimum information necessary from the subjects or participants.

13.0. CONFLICT OF INTEREST

a. All individuals involved in research must declare any potential or existing conflicts of interest throughout the entire lifespan of the research project. Such conflicts should be reported immediately to IRB or the appropriate Research Ethics Committee
b. Consideration must be given to potential conflicts of interest that may arise given the source of research funding and the nature of the research project including declaring all funding sources.
c. Conflicts of interest should be considered when researchers engage with peer review processes.
d. All funds must be managed in accordance with the University's Financial Regulations and Procedures policy.

14.0. TRAINING OF UNIVERSITY STAFF

a. All staff and students undertaking research are required in the course of their career or studies to have undertaken appropriate training or to have had significant relevant experience before embarking on any research activity.
b. Staff and students must responsibly consider whether their training or experience sufficiently qualifies them to evaluate the

ethical implications of their research. If not, they should seek appropriate advice from within their department and/or from colleagues within their discipline with specific expertise in relation to research ethics.

c. This policy should be formally incorporated into all undergraduate/postgraduate training programmes.

15.0. INSTITUTIONAL MONITORING

a. It will be the responsibility of the researcher to monitor the conduct of research that has received ethical approval (for students, in consultation with supervisors). The researcher 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.

b. Audit of research projects will be carried out periodically.

c. A full and detailed account of the research may be requested by the Institutional Review Board where significant concerns have been raised about the ethical conduct of a study.

d. Where a study is being conducted in a way which is not in accordance with the conditions of its original approval the Institutional Review Board may consider the withdrawal of its approval and require that the research be suspended or discontinued.

e. It is the duty of the Institutional Review Board to inform the appropriate funding body that ethical approval has been revoked.

f. All researchers should submit an annual report and an end of project report.