RIVERS STATE UNIVERSITY

RESEARCH ETHICS POLICY

CONTENTS

CHAPTER ONE

INTRODUCTION

1.1 About Rivers State University (RSU)

The Rivers State University started as Rivers State University of Science and Technology in October 1980 being the first University of Science and Technology in the country. Its mission is anchored on the need to ensure that students develop the skills and knowledge required to achieve professional and personal goals in local and global communities. Drawing from an enactment by the Rivers State House of Assembly in 2017 (**Enactment of the Rivers State University Law, Supplement to Rivers State of Nigeria Official Gazette, No. 4 Volume 53, Part A**) the Rivers State University was made a successor to the Rivers State University of Science and Technology. This change was made to accord the University a conventional outlook thereby increasing the number and form of programmes in its offering. It is located at Nkpolu- Oroworukwo in Port Harcourt, the capital of Rivers State, Nigeria. The motto of the University is "**excellence and creativity"** with English as the language of instruction. It is indeed a University of choice and was rated **"University of the Year, 2021."**

1.2 Mandate of the Rivers State University

The Rivers State University was established to:

i) produce scientific and technical manpower of various levels needed for essential development;

ii) produce technical and science teachers for developmental programmes;

iii) assist in the industrial and other developmental programmes through consultancy services, special project centres, and related activities;

iv) encourage the advancement of learning to all persons without distinction or race, creed, sex or political conviction the opportunity of acquiring a higher and liberal education;

v) provide courses of instruction and other facilities for the pursuit of learning in all the faculties and institutes, and to make facilities available on proper terms of such persons as are equipped to benefit from them;

vi) encourage and promote scholarship and conduct research in all fields of learning and human endeavour;

vii) relate its activities to the social, cultural, and economic needs of the people of Nigeria; and

viii) undertake any other activities appropriate for a University of the highest standard.

1.3 Research Ethics Policy Thrust of RSU

In a world of fast eroding value systems, ethics come to the rescue. With a high rise in the incidence of academic fraud in our tertiary institutions including those in Nigeria, research ethics provide illumination for knowledge pathways. Practices that fall within the purview of research ethics are often referred to as best practices knowing that they hold standardized applications across geography and demography.

The focus is to instill or rather re-instill confidence in the knowledge value chain. Interestingly it must be seen by many, accepted by all, and acculturated across facets. It is indeed the golden rule.

A document on research ethics must definitely serve as a legacy through which others can be shown right and acceptable practices in contradistinction to wrong and unacceptable practices. It must be explicit on the correct way to act and behave given certain conditions.

As a rule, the conspectus covers and is not limited to:

i. Risk and potential benefits
ii. Selection and recruitment of participants
iii. Inducements and financial benefits
iv. Protection of research participants
v. Privacy and confidentiality
vi. Community considerations
vii. Innovation and proprietorship
viii. Conflict of interests and lots more

Since value can only be demonstrated through appropriate behaviour, the thrust is to ensure widespread adherence and compliance with inherent benefits of incontrovertible proportions. It is not in doubt that having a clear statement about the integrity required of research is one sure way of mainstreaming consciousness on global best practices.

Enduring advancements can only be borne on the wings of research with attributes of verifiability, replicability, modifiability, and applicability. If research ethics are properly integrated into processes and procedures, the attributes so listed become second index.

Ours is a University that is anchored on excellence and creativity. Research emanating here from must be embedded in excellence with innovativeness as a hallmark. Herein lies the

premise that promises to galvanize growth and development on a most sustainable pedestal. The thrust of the research ethics policy therefore is to ensure research and publication integrity as bed rocked within the ultimate goal of promoting high ethical standards.

The Senate Research Ethics Committee (REC) of RSU has been established to ensure compliance with the highest ethical standards in the conduct of research.

The Senate REC of RSU shall operate under the office of the Director, Research and Development and shall have oversight over research involving animals, plants and conservation, science and technology, social sciences, and humanities and in humans, as well as ethics of professional conduct related to research.

The Animal Care and Use Research Ethics ensure compliance to all laws, regulation and policy governing the care and use of animals for research, teaching, and testing.

Plant use and conservation research ethics ensure ethical guidelines on plant use and biodiversity conservation in addition to maintaining other ethical principles of government guiding plant use.

Science and Technology research ethics including the social sciences and humanities ensures compliance with all laws, regulations and policies governing scientific and technological research in the University with respect to a researcher, other researchers, and the public.

Health Research ethics guide research involving humans and follow guidelines provided in the Nigerian National Health Research Ethics Code, the World Medical Association Declaration of Helsinki, WHO Operational Guidelines for ethics committees that review biomedical research, the Nuremberg Code, the Belmont Report, the Council for International

Organizations of Medical Sciences (CIOMS), International Ethical guidelines for Biomedical Research involving human subjects and the 45 CFR 46. These guidelines are based on four ethical principles of autonomy (respect for human dignity), beneficence (obligation to 'do good' to participants/community), non-maleficence (obligation to avoid harm to participants/community), and justice (distributing benefit and burdens fairly).

Each department shall develop and enforce written policies and procedures for compliance with good laboratory/ non laboratory practice during research, and ensure a safe environment for the conduct of any form of research with no injury to participants.

1.4 The Philosophy of Research Ethics in RSU

The philosophy of the RSU research ethics is to uphold best practices in research by expanding capacities for analyzing complex problems and issues geared towards advancing the cause of society and humanity while ensuring objectivity, transparency, and accountability in practices, procedures, and processes. This is underscored by the fact that a knowledge driven society at its best can engender egalitarianism.

1.5 Aim and Objectives of the REC

The essence is to enthrone appropriate ethical standards in line with best practices while ensuring strict adherence and compliance. The specific objectives are to:

1. ensure safety and protection of researchers and participants while obviating risks and harmful practices;
2. guard against the manipulation and falsification of data; primary or secondary by also shunning inducements, financial or otherwise;

3. ensure the confidentiality of sources/participants/respondents by allowing for informed consent;
4. accord transparency, integrity and accountability to research procedures and processes by ensuring that the recruitment of participants/respondents follows duly elected procedures;
5. strengthen the fabric of knowledge driven research within the ambit of regulations and regulatory agencies;
6. certify that researches emanating from our space follow recommended, conventional, and well tested procedures so as to convey potential and real benefits for our immediate and extended socio-economic/cultural/political environment; and
7. make researches solution driven by contextualizing them within the conspectus of SDGs and other global visions with clear cut delineations.

CHAPTER TWO

ETHICAL CONSIDERATIONS

All research activities conducted at/or involving the Rivers State University must conform to ethical standards guiding research and publications as detailed below:

2.1 Ethical Considerations in Research

a) **Voluntary Participation**

Researchers must ensure that participation in studies is voluntary; without any coercion or pressure. Participants should voluntarily choose to take part in a study. The rights of persons with diminished capacity such as elderly, poorly educated, physically impaired, incarcerated, persons with mental illness and debilitating financial or social circumstances must be protected as well. Participants must also be reassured of their right to voluntarily withdraw from the research without any untoward consequences. This principle should be emphasized in the informed consent process.

b) **Informed Consent**

Obtaining the consent of individuals to participate in studies is essential. Researchers must clearly explain the purpose, procedures, risks, and benefits of the study to the participants. Participants should have the information needed to make an informed decision. This principle should be emphasized in the informed consent process by providing sufficient information to prospective participants and time to respond to their enquiries and concerns, ensuring they understand the information given and have time to freely give their consent to participate in the research after thoroughly considering all options, without undue influence or coercion. Written informed

consent is preferred to verbal. In a situation where written consent is impossible, recorded verbal consent is acceptable. This should precede recruitment of each participant. Special care must be taken when enrolling special and vulnerable populations such as children (under 18); pregnant women; human foetuses; sex workers; physically and mentally challenged persons; hospitalized patients, students; infants (under the age of one year); the elderly (ages 60 and over); illiterate persons and institutionalized persons such as prisoners. The protocol must clearly indicate the category of special population to be included as research participants.

c) **Confidentiality/ Protecting Anonymity**

Protecting the privacy of participants in studies is vital. Researchers should maintain anonymity of participants by avoiding the use of information that could identify participants in research reports. Researchers must keep participants' information confidential. No description traceable to research participants shall be done without the necessary precaution. Participants' data should be securely stored and only accessible to authorized personnel through all stages of the research. Research participants have the right to request that their own data, including recordings, be destroyed.

d) **Beneficence/non-maleficence**

Researchers should maximize the benefits of the participants and minimize any potential harm or risk to participants. Ethical research aims to prevent permanent or excessive harm, whether intentional or not. Investigators must carry out reasonable risk assessment and mitigation before implementation of their proposed research and

ensure that they are competent enough to conduct the research without causing harm to participants - physically, mentally and socially. Potential risks in the research process must be made clear to participants.

e) Justice

The principle of justice requires fairness and equity in the distribution of not only the risk, but also benefits of research. It is unethical to expose participants to risk and withhold its benefit from them; denying them this benefit is unjust. Research participants should not be selected based on race, ease of access, or their compromised positions. Research should be responsive to the needs of its participants and must therefore make any product developed from such research available to them.

f) **Results Communication**

Researchers have a responsibility to communicate study results transparently and accurately. Misrepresenting data undermines the credibility of research.

2.2 The Informed Consent process

Informed consent is a process and NOT just a form. The use of a consent form is the preferred method of documenting informed consent (see appendix 1). The Informed Consent section should be addressed in the second person singular.

Components of informed consent

The components are:

1. Information: Details provided to the participants must be comprehensive, clearly written and/or verbally explained in simple language and clear terms. It must also address ethical considerations.

2. Comprehension: The investigator must ensure that the informed consent process is clearly understood by the participant/ guardian before accepting to participate in the study.
3. Voluntariness: All study participants must volunteer
4. Competence: All study participants must have competence (except those with diminished capacity), to make informed decision to enroll or decline involvement in a study. Capacity for participation may be evaluated in terms of age, mental or physical ability among others.
5. Content of Informed Consent Form:
    a) Name and Address of Principal Investigator
    b) Person to contact for answers to questions, or in event of research related injury or emergency should be clearly stated with full address and telephone number(s)
    c) Purpose of Research must be clearly stated.
    d) Benefits expected to accrue from the research must be communicated to participants and the research community. In studies, evaluating drugs or other products, the participants should be advised as to the availability of the product after discontinuation of the study. Indicate possible cost implication or whether drug would be available to the patients free of cost.
    e) Foreseeable risks or discomforts to the participants must be explained in full. Such risks include physical injury, possible psychological, social, emotional, economic harm, discomfort, or inconvenience. If the risk is unknown, it should be so stated.
    f) The length of time a participant is expected to participate should be clearly indicated. Any new information that develops during the study that may affect the participants' willingness to continue must be communicated to them. This would apply even when

the intervention/investigation phase of the study has ended while monitoring continues.

g) Treatment for adverse events or injury because of participation in the study must be clearly stated. Should a disease condition (or a comparable social condition) be diagnosed during a study, it is the responsibility of the PI to refer the affected participant for appropriate care. All expenses for research-related adverse reactions are the responsibility of the researcher(s).

h) Researchers should indicate the estimated financial burden to be incurred by the research participant(s) while taking part in the study.

i) Signature/Thumb Print of participant and date: In case of participant's inability to append his/her signature due to the level of literacy or other considerations, a proxy must sign or thumb print as a witness.

j) Signature of researcher and date

Conditions where the principle of confidentiality can be ethically breached:

These include cases in which:

i) The professional knows or suspects that an individual is acting illegally.

ii) The researcher or professional knows or suspects that an individual is harming others.

iii) The researcher or professional knows or suspects that an individual might harm others in future.

iv) The researcher or professional knows or suspects that an individual is harming himself/herself

v) The researcher or professional knows or suspects that an individual might harm himself/herself in future.

vi) The researcher or professional knows or suspects that a minor is being exploited or abused by others.

Vii) The researcher or professional knows or suspects that a competent adult is being exploited or abused by others.

Consent and Assent from Children

Individuals under the age of 18 cannot legally consent to be involved in research. The consent of the parent(s) of the child is generally required. The consent of both parents is required for research involving greater than minimal risk unless one parent is deceased, unknown, incompetent, or not reasonably available or when only one parent has legal responsibility for the care and custody of the child. One parent may, however, consent when there is no more than minimal risk or if there is more than minimal risk but the research presents the prospect of direct benefit to the individual participants. Additionally, written assent of the participating child must also be obtained from all children with a capacity to understand the research to be done. This assent is simply an indication of agreement by the child to his or her involvement in the research after this is explained in a language the child can understand.

Pregnancy

If women of childbearing age will be recruited as participants and pregnancy is an exclusion criterion, the protocol and consent form should state that a pregnancy test will be given prior to participants' entry into the study. It should also be stated in the consent form that if the participant becomes pregnant during the study, the participant must notify the principal investigator as soon as possible.

Communities

It may be disrespectful to seek consent from an individual without first receiving assent from leader(s) of the community or creating public acceptance of research and may harm relationships within that community or between the community and researchers. It must be noted that community consent does NOT replace individual consent.

2.3 Ethical Considerations in Publication

a) Authorship

The following criteria must be met to qualify and be listed as an author in a publication (Elsevier 2019):

i) the person must have made substantial contribution to the study conception and design, data acquisition, analysis, and interpretation.

ii) the person must have been involved in the drafting or revising the article for intellectual content.

Researchers should not engage in the following unethical practices while publishing research result:

b) Deliberate Misrepresentation of Authorship

Deliberately listing 'Acknowledged Individuals' or omission of names of 'Substantial Contributors' as authors is considered a form of misconduct. Consequently, the following types of authorship are unacceptable:

i. **Ghost Authorship**

Failure to list substantial contributors as authors (e.g., deliberate omission of names of co-researchers including students and/or co-supervisors) is fraudulent.

ii. **Gift Authorship**

Deliberately listing weak contributors as authors (e.g., deliberate listing of colleagues and/or friends who only provided financial support, advice, research space, and departmental oversight). However, such tenuous contributors must be acknowledged in the acknowledgement section.

iii. **Guest Authorship**

Deliberately listing names of influential individuals in the field of study with tenuous affiliation with the current study to increase the chances of publication.

c) **Improper Order of Authorship**

While there is no universally accepted order of authorship, the order of authorship should be collectively decided by the coauthors to avoid contentions.

d) Competing Interests

Competing interests exist when there is a personal interest or belief that could affect one's objectivity, or inappropriately influence one's actions in publication. Competing interests are mostly finance and relationship based. Others include:

i) **Direct**: employment, grants, patents, etc.

ii) **Indirect**: honoraria, consultancies to sponsoring organizations, mutual fund ownership, etc.

At all times, researchers are required to disclose any competing interests as failure to do so may be considered unethical.

e) **Plagiarism**

Plagiarism is when an author deliberately uses another author's work without permission, credit, or acknowledgment. The most common forms of plagiarism include:

i) **Literal copying** — word for word, beyond the normal occurrence of standard phrases and nomenclature in the research area.

ii) **Substantial copying** — whole or part.

iii) **Paraphrasing** — by author or generative artificial intelligence (AI).

iv) **Text-recycling** — own work (self-plagiarism).

In whatever form, plagiarism is considered a form of misconduct.

f) **Simultaneous (Multiple) Submission**

This occurs when an author deliberately submits a paper to more than one journal at the same time for publication considerations. This practice is considered a breach of publishing ethics.

g) Research Fraud

When an author publishes a set of data or draws conclusions that are not generated by experiments or observations, but by making up or manipulation of research data. There are two kinds of fraud in publication:

i) **Fabrication** — Making up research data and reporting them.

ii) **Falsification** — Changing or deliberately omitting data or results to make them fit with the desired result of a study.

Whichever form it takes, research fraud is a serious misconduct because it results in a misleading scientific record.

h) Salami Slicing

This is the breaking up or segmenting research data from a single study with the same hypothesis, objective, sample size and population, and materials and method, to create different manuscripts for publication. Slicing of research in the shape and form afore listed is an unacceptable practice in research and publication.

CHAPTER THREE

THE SENATE RESEARCH ETHICS COMMITTEE

3.1 Functions of the Research Ethics Committee (REC)

The primary functions of the REC shall be to:

i) coordinate and regulate all matters pertaining to research ethics and integrity;

ii) ensure best practices in research activities;

iii) oversee the activities of faculty ethical review committees;

iv) report all adverse events and serious non-compliance to the Vice-Chancellor and Senate;

v) ensure training and retraining of all staff, students, and visitors on research matters;

vi) advise Senate on policies and matters relating to research ethics and integrity; and

vii) prepare and submit annual reports to Senate through the Vice-Chancellor.

3.2 Membership

The membership of the REC shall be as follows:

i) Director of Research and Development - Chairman
ii) One Representative of each College/ Faculty
iii) One lay person(religious or secular) from the public
iv) Head of the Legal Unit of RSU
v) A Deputy Registrar – Secretary

**Of utmost importance is the need for gender balance in the composition of the Senate REC.*

All members of the REC must be adequately trained and re-trained to ensure that they perform their functions appropriately, including review, education of the researchers and

monitoring of approved research reports. The Senate REC should register with the National Health Research Ethics Committee (NHREC) as well as other affiliate and statutory bodies.

3.3 Tenureship

The tenure of the Senate REC shall be two (2) years, renewable once thereafter. All appointments shall be made from the office of the Vice-Chancellor upon approval by the Senate of RSU.

3.4 Accountability

The Research Ethics Committees should be adequately funded by the University with an annual subvention and other funding as necessary. Infrastructure such as computers, scanners, printers, and telephones as well as office spaces should be provided.

The policy document should be widely distributed using existing channels of communication. The University Management should put modalities in place for trainings, seminars and workshops towards dissemination, increased sensitization, and implementation of the RE policy. The Research Ethics policy should be made easily accessible on the University's website. Appropriate sanctions should be employed using existing channels such as the Staff and Students Disciplinary Committees to ensure compliance.

Faculty Ethics Committees should be empowered to review undergraduate projects. This will facilitate research and provide the time required for attention to more complex projects.

The RSU Biosafety and Biosecurity committee should monitor and encourage the use of personal protective equipment and safety equipment in laboratories as well as appropriate

disposal of chemical, biological and radiological waste. A standard incinerator should be installed for proper disposal of infectious waste.

Emergency Response protocols indicating contact details should be made available in every laboratory in case of emergencies.

CHAPTER FOUR

STANDARD OPERATING PROCEDURES (SOPs)

4.1 Procedure for submission of applications

All submissions for ethical approval shall be submitted in the following format:

1. An application letter addressed to:

   The Chairman,
   Senate Research Ethics Committee,
   Rivers State University
   Nkpolu-Oroworukwo

2. Study Proposal with the following components

   i) A cover page specifying the title, full name(s), qualifications, sponsors, collaborating institutions of investigators, corresponding investigator, the PI of the protocol who bears responsibility for the research.

   ii) Background of the Study: A description of previous related research and current knowledge must be provided

   iii) Rationale for the study

   iv) Aim and Objectives of the study

   v) Methodology

   a) Study design - clearly stating the nature of the study (descriptive, drug trial, case-control, longitudinal, correlational, experimental etc.)

   b) Sample size determination

   c) Sampling technique to be used to select participants, detailing inclusion/exclusion criteria & frequency of sampling.

d) Data collection procedure - How the data/samples will be obtained, and the purposes for which they will be used should be adequately discussed. Instrument for data collection e.g. questionnaire to be administered must be included in the protocol, Describe the instrument including standardization, procedure and pilot testing, Physical examination procedure or Laboratory procedures to be used. Follow up details if required. How long the data/samples will be kept and any other parties to whom the data or samples will be shared should be adequately described.

e) Data analysis package to be used (Name and version)

f) Ethical Considerations: In a separate section, each of the following issues must be addressed briefly in order to convey to the REC how the PI intends to tackle this while executing his/her research: Confidentiality of Data, Translation of Protocol to local language/ simple language, compensation and/or Direct Benefits to Participants, Non-Maleficence to Participants, issues of Equity and Justice in Participant Selection, Right to Decline/Withdrawal from Study without Loss of Benefits.

vi) References

vii) Appendixes

i) Attach Informed Consent Form (where research involves human participants)

ii) Attach Data collection form/ proforma.

Important notes:

Where necessary, the questionnaire & Informed Consent form should be translated to the Local language of participants to facilitate clear understanding.

The protocol should be typed and paginated, including references. Three hard copies of the protocol/ proposal and one soft copy should be submitted to the REC Office.

4.2 Procedure for Review

The primary role of an Ethics Committee lies in the review of proposals with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. The Committee shall meet once a month for proposal reviews and approvals. A minimum of two reviewers (three or more preferably) shall review any proposal submitted.

The review shall focus on scientific design, recruitment of research participants, care and protection of research participants, protection of research participants' confidentiality, informed consent process, and community considerations.

Types of Reviews: Three types of reviews shall be conducted by the Senate REC as follows:

i) **Exempt Review**: Exemption is provided to research proposals in which there is virtually no risk to the participants.

ii) **Expedited Review**: This type of review involves research with minimal risk, or request for minor changes in already approved proposals. CHAIR/Designee can review outside of formal monthly review.

iii) **Full Review**: This category of review involves research in which there is more than minimal risk to participants, invasive procedures, selection of participants, informed consent procedures. Examples of more than minimal risk include research involving invasive procedures such as blood sampling, tissue biopsy etc.

Following review of a protocol, the committee shall assign an approval status which shall be one of the following: -

i) Approved - The investigator may begin the research as proposed in the protocol/ proposal.

ii) Pending-Conditional – This indicates that modifications in the protocol and/or consent form are required before research commences. No research may be started until all conditions have been met and formal approval has been obtained from the Committee.

iii) Pending-Deferral– A deferred protocol must be revised as recommended by the reviewers and resubmitted. No research may be started until all conditions have been met and formal approval has been obtained from the REC.

iv) Rejection – A protocol may be rejected by the Committee if it has been deferred several times and the Committee feels that the problems have not been adequately addressed, or if the protocol is not justified and poses severe or unnecessary risk to the participants.

Conditions for Approval

i) Approval is given initially for a specified period of one year. If the project takes longer than the specified period to complete, a request for an extension of the ethics clearance should be sought on the submission of an annual progress report.

ii) That any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being effected.

iii) That a copy of the final report of the research project is lodged with the senate REC for its information and record.

iv) Researchers must agree to notify the Review Committee if and when a project is curtailed, terminated or completed by sponsors or other regulating authorities of the project.

v) Approval is given for therapeutic trials on condition that the Principal Investigator notifies the Review Committee within seven (7) days of any adverse event or occurrence and violations that take place during that trial.

vi) Research could be audited by the Committee during the research period to ensure compliance with guidelines.

4.2.1- The Procedure

By administration, all Departments and Faculties should set up Research Ethics Committees to ensure compliance. The Faculty Research Ethics Committees must exercise oversight over the Departmental Research Ethics committees while the Senate REC exercises oversight over the Faculty Research Ethics Committees. It is standard practice for a member of the Senate REC to attend Faculty Research Ethics Committee meetings. Matters emanating from the Departmental Research Ethics Committees go to the Faculty Research Ethics Committee. Postgraduate Research reports (Dissertations and Theses) must pass through the Faculty Research Ethics Committee. Researches seeking ethical approval from the Senate REC must be those that are:

1) Multi –institutional
2) International
3) Grant based
4) Inbound and outbound

4.3 Procedure for Notification of Decision

The principal investigator will be communicated in writing of the decision of the Senate REC. If approved, a unique **alphanumeric reference code** will be assigned and should be quoted on all publications from that research. Below is a sample of the Ethical Approval number:

RSU- REC/20xx/Fx/00xx

Where RSU – REC represents Rivers State University Research Ethics Committee
20xx represents year of approval
Fx represents faculty ie FE would mean Faculty of Engineering (A list of faculty abbreviations is enclosed as Annexure)
00xx represents the four digit serial numbering

4.4 Procedure for Suspension of Research

The Ethics Committee shall have power to suspend any research that is not being conducted:

i) Where research conduct is not in accordance with sound ethical principles
ii) Where research conduct is not in accordance with the existing RSU REC policy and guidelines
iii) Where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the decision and shall be reported within FOURTEEN (14) days to the researcher(s), institution, sponsor(s), and Vice-Chancellor. The researcher(s), institution, or sponsor(s) shall be entitled to ask for a reconsideration of the decision of the Ethics Committee to suspend research within fourteen (14) days of receipt of notification.

Process for Revision of Suspension

i) The Ethics Committee may reverse its decision to suspend research if the areas of controversy are resolved to the satisfaction of REC.

ii) The committee will determine the case at its next regular meeting and may require that the researcher sign an agreement with the committee on its finding(s) and agree remedial measure(s).

iii) Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY DAYS (180) days. Process for Termination of Research

iv) Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation of the precipitant, the committee shall terminate the research. The committee shall indicate the reason(s) for the termination of the research in writing within fourteen (14) days to the researcher(s) and sponsor(s)

v) There shall be no appeal on the decision of the REC to terminate research.

4.5 Responsibilities of stakeholders

a) The Institution

i) Shall establish, nurture and maintain the REC

ii) Facilitate funding and support for the committee secretariat and Staff

iii) Share burden of protection of Human Participants and that of the investigator

iv) Educate staff and students about emerging ethical issues affecting human participants.

b) Research Ethics Committee:

i) Understand and apply the rules/guidelines

ii) Review, approve, disapprove and modify proposals

iii) Conduct continuing review of approved projects

iv) Observe the consent process and verify changes

v) Suspend or revoke approval where applicable. Ethics committees are not under any obligation to place themselves under pressure to accept the sponsor's opinion regarding submitted protocol.

vi) Train/educate investigators to ensure that they develop ethically sound protocols

vii) Provide effective communication of the decisions of the committee to investigators

viii) Report all adverse events and serious non-compliance to the Vice-Chancellor and senate

c) The Researcher(s):

i) Is/are accountable for the consequences of his/her research.

ii) Is/are accountable to their professions, the University, staff and students involved in the project and project sponsors.

iii) Must be professionally competent

iv) Must use sound methodology

v) Must provide full information about the study to the Ethics Committee and Human Participants.

d) Participants:

They are expected to request for information in order to have a clear understanding of the study and clarify all doubts before accepting to participate in the study.

e) Communities

i) Permission from a leader(s) of the community is required before any research is discussed with the community or individuals.

ii) The leader of the community is considered to have the authority to encourage enrolment of participants in research.

f).Sponsors

i) It is mandatory that sponsored research protocols be subject to independent ethics review in both the site where the research will be conducted (in this case, RSU) as well as the sponsor(s') country(ies).

ii) Ensure that the funds are being used in a manner that is ethically acceptable.

iii) In the event of circumstances where the RSU REC is asked to review research before it is reviewed in the country of the sponsor, there should an assurance that after the review process, if such studies are no longer sponsored, a reimbursement of funds used by the REC shall be made.

iv) If the RSU REC does not approve the research, then the research cannot be conducted within that country despite approval from the sponsor's country.

CHAPTER FIVE

RESPONSIBLE INNOVATION

5.1 Introduction

Responsible Innovation seeks to promote creativity and opportunities for research and innovation that are socially acceptable and undertaken in the public interest. Innovation often raises questions, and the potential impact can sometimes be unpredictable.

All researchers of the University are expected to conduct their research taking into consideration the following:

1. Interactive
2. Ethics
3. Social responsibility
4. Environmental responsibility
5. Future-oriented goals
6. Sustainability
7. Societal desirability
8. Desirability
9. Acceptance
10. Involvement of relevant stakeholders

In achieving the above factors, the University will engage the following:

i) **Public Engagement**: Researchers, industry, policymakers and civil society and their joint participation in the R&D process;

ii) **Gender Equality**: All actors –women and men –are on board in R &D;

iii) **Science Education**: Increase number of researchers and align the educational system to provide future researchers with knowledge of RRI;

iv) **Ethics**: In order to adequately respond to societal challenges, researchers of the University must respect fundamental rights and the highest ethical standards;

v) **Open Access**: Give free online access to the results of publicly- funded research (publications and data);

vi) **Governance**: As an umbrella for all the others: policy makers also

vii) **Anticipation**: Analyse those intended and potentially unintended impact that might arise; be these economic, social, environmental or otherwise.

viii) **Reflexivity**: Reflect on values and beliefs during R&I

ix) **Deliberation**: Inclusively open up visions, purposes, questions and dilemmas to broad, collective deliberation through processes of dialogue, engagement and debate, inviting and listening to wider perspectives from publics and diverse stakeholders.

x) **Responsiveness**: Change routines, structures and systems to adapt to changing circumstances and new insights.

5.2 Staff Behavioural Principles

Principle One Research and Innovation for Social Value
Core Principle Our Research and innovation considers value in a more holistic way- social, ethical, environmental, cultural and economic benefit.

Specific Principles

i) Stated innovation aspirations and strategy must begin with social and environmental problem solving, not simply academic or commercial goals.

ii) More rounded benefit assessment and mapping processes are used to generate a deeper understanding in relation to current or alternative solutions.

iii) Benefit and effectiveness claims are evaluated and underpinned by clear evidence - using science, social science and stakeholder involvement to demonstrate benefit parameters and residual concerns.

iv) Processes which involve wider groups of stakeholders are undertaken. These are to co-create solutions with stakeholders, to listen to their views or to explore any concerns they may have.

Principle Two

Explore Potential Impact

Core Principle

Consider, assess and effectively prioritize the potential social, ethical, environmental, cultural, and economic implications/ impact–in- use and misuse, from research to reuse.

Specific Principle

i) Process design which includes collaborative initiatives - partnerships and community or charitable projects or stakeholder involvement - that specifically wield wider impact.

ii) Openness about results of such collaborations and priorities and decision making in this regard

iii) Development of evaluation processes or impact metrics

iv) Clear commitments on EHS and wider impacts arising from impact assessment processes Ongoing, 'self-critical' monitoring programmes of innovation in use

Principle Three

Involvement of Stakeholders

Core Principle

The values, concerns and issues raised by stakeholders are respected and responded to and they are proactively involved innovation process and their governance. They are themselves mindful of the public good.

Specific Principles

i) A clear stakeholder mapping and involvement strategy and plan

ii) Stakeholder involvement processes at key stages in the research and innovation process

iii) Demonstration that stakeholder concerns and considerations have been considered and responded to in the research and development process

iv) Continued responsiveness to stakeholders in governance and through monitoring of the innovation in use and beyond

PrincipleFour

Governance and Radical Transparency

Core Principle

Demonstrating trustworthiness is at the heart of governance. Exercise oversight, anticipate,and effectively manage opportunities and problems geared towards adapting and responding quickly to changing knowledge and circumstances.

Specific Principles

i) There must be clearly stated commitments to strong governance and transparency

ii) The senior management team is accountable for managing innovation strategy and for these commitments. They have the necessary understanding and training to allow them to do so effectively.

iii) Aspirations are backed up by evidence - (E.g., may include among others: openness about the use of a technology; sharing negative and positive research findings; Open Access to full research findings; back up of benefit, effectiveness and safety claims with evidence; openness about the priorities around wider impact; transparency about issues around regulation and lobbying.

iv) Stakeholder involvement processes are undertaken at key stages, including honesty about management of conflicts in stakeholder views and the impact on strategy.

v) Ongoing monitoring, with feedback loops, into the positive and negative impact of innovation decisions. These are fed into senior management decision making.

CHAPTER SIX
ENFORCEMENT AND DISSEMINATION OF RESEARCH PROCEDURES

6.1 Purpose

This Procedure describes how to responsibly publish and disseminate research results consistent with the principles and code for the conduct of research.

This Procedure applies to:

a) the dissemination of research outputs; and
b) dissemination undertaken as part of applications for research grants and forms of financial support.

6.2 Procedure

A. Background

i) Enforcement and dissemination of research is an integral part of the research process, passing on the benefits to a diverse range of potential beneficiaries of research, including other researchers, research sponsors, consumers and industry, policymakers, and the public. Procedures for dissemination continue to evolve and expand, which can assist in more efficiently reaching large audiences.

ii) The objective of this procedure is to assist researchers to understand and apply best practice in the enforcement and dissemination of research in accordance with the principles and responsibilities.

B. Dissemination of findings

i) University researchers have a responsibility to disseminate a comprehensive account of their research. The account should include (where possible) relevant negative results as well as findings that may be contrary to any stated hypothesis. Decisions about how the research will be published or disseminated should not be inappropriately influenced by the nature and direction of the results. Researchers should consider opportunities and limitations such as patents, commercial in confidence agreements and confidentiality/sensitivity. If immediate open access is desirable for research impact, associated fees (article processing charges) may be incurred via publisher agreements. Most publishers allow open access publishing without charge via institutional open access repositories. The increased costs of presenting findings to peers for critical input also needs consideration.

ii) University researchers must strive to agree with the most appropriate publisher for their work, must avoid 'predatory' or 'questionable' publishers and take active steps to ensure that the selected publisher is of good standing. The University website provides information and links to resources to assist researchers with publisher selection and choosing trusted journals.

iii) University researchers should consult the designated offices for guidance on the appropriate avenues for publication.

iv) When negotiating research or consultancy contracts, the University's Office of Research Services and researchers will seek unrestricted agreement for the full, honest and timely reporting of results, wherever possible. Any agreement to restrict, delay or limit publication should not exceed the period needed to protect intellectual

property or other relevant interests.

C. Accuracy

University researchers must take all reasonable steps to ensure that:

i) Methodology, data, findings and/or observations are reported accurately and clearly;

ii) Reporting of methodology, data, and findings is consistent with international guidelines and conventions appropriate to the relevant discipline or disciplines;

iii) Conclusions are justified by the results; and

iv) Any limitations are appropriately acknowledged.

v) Communications about research and its findings must identify the host institution(s) and all sources of support for the research.

vi) Researchers must ensure that they cite and acknowledge their own work and the work of others (whether published or unpublished) accurately, and in accordance with the Authorship Procedure and the conventions accepted within the relevant discipline(s).

vii) Researchers will cite primary sources and data to ensure that credit for research is attributed fairly and to facilitate the easy location of the origin of a work, a finding, an idea, or research data.

viii) Researchers will ensure that research findings are peer reviewed, in accordance with best practice in the discipline and the Peer Review Procedure.

ix) Researchers will ensure that the information about their research activity and track record as it appears on their research output repository curriculum vitae, job applications, grant applications, reports and public statements is accurate; specificallythe state of publication is accurately described.

D. Open access and transparency

E. Confidential and sensitive information.

i) University researchers must ensure that their enforcement and dissemination activities take account of any ethical or legal restrictions relating to intellectual property, including Indigenous Cultural and Intellectual Property. This includes any confidentiality and privacy requirements of research sponsors and participants. In event of any doubts, researchers are recommended to seek advice from the Legal Services before disseminating research or technical data which may be considered confidential or sensitive.

ii) Researchers must consider the unintended consequences and adverse outcomes of research prior to its communication therefore seek advice from the relevant business units or relevant authorities prior to any publication and/or dissemination of the findings. Research or its outputs may cause harm to human, animal or plant health or the environment, could harm national security, or be otherwise confidential or sensitive. In such situations and prior to any dissemination, researchers must complete a risk assessment to identify and manage any potential risks arising from the dissemination of the research or technical data.

F. Broad communication of research

University researchers are encouraged to communicate their findings to the widest appropriate audience in forms that are accessible to that audience. This may include research end-users, such as policy makers, government agencies, industry, not-for-profit organizations, consumers and the general public.

i) Researchers should seek communication training and support, available from the

University.

ii) Researchers anticipating media interest after the publication of research out comes will liaise with the relevant Communications Officer in their Academic Unit.

iii) Researchers will consider the following when communicating research findings publicly in any forum:

a) As a general rule, research findings should not be discussed in the public arena until they have been tested through peer review. Exceptions to this general rule include the presentation of research in progress or before publication:

b) On a public server as a preprint;

c) at professional conferences;

d) when it is in the national interest or in the context of a public health crisis;

e) when it is a requirement of research contracts or agreements that research findings are discussed prior to publication; and

f) for contract or applied research, where peer review is not required and/or appropriate.

In discussing the findings of a research project prior to peer-review, special care should be taken to explain the status of the project –e.g., whether it is still in progress or has been finalized and whether the findings have been published.

iv) Ensure research participants are provided with a summary of the research out comes prior to any wider communication in accordance with the participants' directions, excluding research projects where consent is waived or qualified.

v) To maximize understanding of research findings, researchers will promptly inform those

directly affected by the research, including interested parties. This may include providing research participants with a summary of the research results.

vi) The findings of research with a strong commercial element, certain contractual obligations, and protection (patent) requirements may have to be formally registered or presented to a stock exchange, a financial body, a sponsor or investors before any public release.

G) Correction of the public record

If University researchers become aware of any errors or misleading information in their published research outputs, they must take action to correct the record with the publisher according to relevant publisher policy in a timely manner. This includes:

i) Research manuscripts that have been made publicly available as preprints

ii) Research findings that have been misrepresented by third parties

H) Breaches of the Code

Breaches of the Code that are related to the publication and dissemination of research include, but are not limited to:

i) fabrication, falsification or misrepresentation of research data or source material in a research output or any communication, including social media and grant applications

ii) plagiarism of someone else's work, including theories, concepts, research data and source material; duplicate publication (also known as redundant or multiple publication, or self-plagiarism) without acknowledgement of the source or original publication

iii) failure to maintain records required by an export control body as a condition of

publication and dissemination

iv) failure to take active, reasonable and timely steps to correct the public record upon becoming aware of errors or misleading information in their published research outputs

v) public dissemination of research (e.g., via social media) that is yet to be tested in peer review without providing an appropriate caution or caveat

BIBLIOGRAPHY

Code, N. (1949) Trials of war criminals before the Nuremberg military tribunals under control council law. *The Nuremberg Code,10*(1949), 181-2.

European Commission (2017). Principles of responsible innovation: Building the trustworthiness of technology. Available at https://ec.europa.eu (accessed 11th December 2023)

Elsevier (2019).Ethics in Research and Publication.Directorate of Publishing Services for STM Journals at Elsevier, Amsterdam, Netherlands. Available at www.ethics.elsevier.com (accessed 27 October 2020).

General Assembly of the World Medical Association. (2014). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *The Journal of the American College of Dentists*, *81*(3), 14-18.

Interreg Central Europe: European Union Regional Development Fund (2017). Introduction to responsible research and innovation and to responsible innovation: Rosie train the trainer capacity building. Prague, 28-29 November 2017. https://programme 2014-interreg-central.eu

Miracle, V. A. (2016). The Belmont Report: The triple crown of research ethics. *Dimensions of critical care nursing*, *35*(4), 223-228.

University of Ibadan ethics policy. Available athttps://rmo.ui.edu.ng/sites/default/files/UI_ETHICS%20POLICY.pdf

vanDelden, J. J., & van der Graaf, R. (2017). Revised CIOMS international ethical guidelines for health-related research involving humans. *Jama*, *317*(2), 135-136.

APPENDIX IA: SAMPLE OF INFORMED CONSENT FORM FOR CLINICAL SCIENCES

RSU Research Ethics approval number:

This approval will elapse on: dd/mm/yyyy

Title of the research:

Name(s) and affiliation(s) of researcher(s):

Sponsor(s) of research:

Purpose(s)/Aim of research:

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research(Summary**):**

Expected duration of research and of participant(s)' involvement:

Risk(s): state any risks to participants

Costs to the participants, if any, of joining the research:

Benefit(s)of the research, if any

Confidentiality statement:

Voluntariness:

Alternatives to participation:

(For example: If you choose not to participate, this will not affect your treatment in this hospital in any way.)

Due inducement(s): state if any

Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:

Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s):

State clearly what will be done if participants suffer any injury as a result of participation in this research

What happens to research participants and communities when the research is over:

State what actions would be taken after study as it relates to participating individuals or communities, if any

Statement about sharing of benefits among researchers and whether this includes or excludes research participants:

(For example: If this research leads to commercial products, the Rivers State University shall own it. There is no plan to contact any participant now or in future about such commercial benefits.)

Any apparent or potential conflict of interest:

(For example: None of the researchers own shares in RSU Pharmaceuticals or its associated companies. We are not aware of any other information that may cause the researchers not to do their work without fear or favour

Statement of person obtaining informed consent:

I have fully explained this research and have given sufficient information, including about risks and benefits, to make an informed decision.

Signature: _____ Date: _____

Statement of person giving consent:

I have read the description of the research and have had it translated into the language I understand. I have also discussed it with the researcher to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks, and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

Signature: _____ Date: _____

Phone number: _____

Witness' (if applicable):

Name: _____ Signature: _____

In addition, if you have any question about your participation in this research, you can contact the principal investigator,

Name…….....

Department…….....

Phone…….....

Email…….....

APPENDIX IB: CONSENT FORM FOR HUMANITIES AND SOCIAL SCIENCES

DEPARTMENT:
FACULTY:

RIVERS STATE UNIVERSITY, NKPOLU-OROWORUKWO, PORT HARCOURT

Sir/Madam,

You are please requested to express willingness to participate in an interview with respect to a study titled –

The interview will be transcribed and made available for academic use. However, your confidentiality is assured.

Interview duration will not be more than sixty (60) minutes.

KINDLY COMPLETE THIS FORM

I, _____(Name of Interviewee)

knowingly and voluntarily permit the student – (Name of Student) of the Department of (Name of Department) - to fully use my responses for educational purposes.

Name and Signature: _____ (Interviewee)

Interview Location:_____

Interview Date:_____

APPENDIX II: APPLICATION FORM FOR ETHICAL APPROVAL

RIVERS STATE UNIVERSITY
APPLICATION FORM FOR ETHICAL APPROVAL

SECTION A (for researcher only)

1. **Title of Study**:

   _____

   _____

   _____

2. **Details of Principal Researcher/ Investigator**:
   A. **Name**: _____
   B. **Institution**: _____
   C. **Faculty/School**: _____
   D. **Department:** _____
   E. **Phone number:** _____
   F. **Email address:** _____
3. **Unit(s) of RSU where study will be conducted (including where participants will be contacted/ where sample processing or other study procedures will be conducted)**

   _____

   _____
4. **Nature of Study (Tick as appropriate)**
   i) Questionnaire administration
   ii) Clinical Studies
   iii) Preclinical / Pharmacokinetic study
   iv) Laboratory analysis
   v) Clinical Trial (Non-interventional)
   vi) Clinical Trial (Interventional)
   vii) Retrospective study (Use of existing data)
   viii) Qualitative research (Interviews etc.)
   ix) Others; Please Specify _____
5. **Type of Project** (Tick as appropriate)
   1) International research

2) National research
3) Local (state or regional) Research
4) Postgraduate (FWACP, FNMC, MSc, MPH. PhD, MPhil, FWACS)
5) Others Below MSc(Diploma etc.)
6) Undergraduate Projects

6. Mode of Funding (Tick as appropriate)

A) Self-Funded
B) Nationally/ Institutionally Funded
C) Government Funded
D) Internationally Funded
E) Other Sponsor (Specify): _____

7. Will study involve any invasive procedure(s) (if so, outline such procedures)?

_____

_____

_____

8. What are the possible adverse effects of the procedure/intervention?

_____

_____

_____

9. Will assent be obtained? Yes / No/ Not Applicable

10. Will written informed consent be obtained? Yes / No/ Not Applicable

11. Study Requirements

A. Biological Sampling required? Yes / No/ Not Applicable

B. If yes, which samples? (Please Specify)_____

C. Are samples going to be shipped out of Nigeria? Yes / No

D. Duration of Study:_____

12. Supervisor's details (where applicable)

Name: _____

Contact Address _____

Phone: _____

Email address: _____

Signature: _____ **Date**: _____

DECLARATION IN SUPPORT OF APPLICATION FOR ETHICAL APPROVAL

I certify that the information provided in the study protocol is true to the best of my knowledge. I agree to undertake the research according to the ethical principles described in National Code for Health Research Ethics, relevant Federal and local laws, ICH-GCP6 guidelines (where applicable), government and institutional guidelines and regulations. I understand that the Ethics Committee will provide Ethical Approval for this protocol for a specified time period not exceeding 1 year and that continuation of the research beyond this period will require renewal of the approval. I understand that the Ethics Committee may, without prior notice, observe or cause to be observed, the research for which approval has been given in order to ensure compliance with approved protocol, suspend or terminate the conduct of this research if necessary.

Name of Investigator: _____

Signature: _____ Date: _____

SECTION B (For Ethical Reviewer only)

Decision: _____ **Date:** _____

Review Comments (if any):

_____

_____

APPENDIX III ETHICAL GUIDANCE DOCUMENTS

1. THE BELMONT REPORT(1979)

Ethical Principles and Guidelines for the protection of human subjects of research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. April 18, 1979

Agency: Department of Health, Education, and Welfare.

Action: Notice of Report for Public Comment.

Summary: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behaviourals research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider:

(i) the boundaries between biomedical and behavioural research and the accepted and routine practice of medicine

(ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects

(iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78- 0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

2. COUNCIL FOR INTERNATIONAL ORGANIZATION OF MEDICAL SCIENCES

COUNCIL FOR INTERNATIONAL ORGANIZATION OF MEDICAL SCIENCES (CIOMS) serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for the ethical conduct of research, among other activities.

The International Ethical Guidelines for Biomedical Research Involving Human Subjects, sometimes informally referred to as CIOMS Guidelines, is a set of ethical principles regarding human experimentation created in 1993 by CIOMS and updated in 2002. These 21 guidelines (15 in the original report) address issues including Informed consent, standards for external review, recruitment of participants, and more. The Guidelines are general instructions and principles of ethical biomedical research.

The Council has also issued International Guiding Principles for Biomedical Research Involving Animals.

3. DECLARATION OF HELSINKI(1964)

The Declaration of Helsinki was developed by the World Medical Association (WMA), as a set of ethical principles for the medical community regarding human experimentation and is widely regarded as the cornerstone document of human research ethics. (WMA 2000, Bošnjak 2001, Tyebkhan 2003).

It is not a legally binding instrument in international law, but instead draws its authority from the degree to which it has been codified in, or influenced, national or regional legislation and

regulations (Human and Fluss 2001). Its role was described by a Brazilian forum in 2000 in these words "Even though the Declaration of Helsinki is the responsibility of the World Medical Association, the document should be considered the property of all humanity" (Human and Fluss 2001).

Principles: The Declaration is morally binding on physicians, and that obligation overrides any national or local laws or regulations, if the Declaration provides for a higher standard of protection of humans than the latter. Investigators still have to abide by local legislation but will be held to the higher standard.

Basic principles: The fundamental principle is respect for the individual (Article 8), their right to self-determination and the right to make informed decisions (Articles 20, 21 and 22) regarding participation in research, both initially and during the course of the research. The investigator's duty is solely to the patient (Articles 2, 3 and 10) or volunteer (Articles 16, 18), and while there is always a need for research (Article 6), the subject's welfare must always take precedence over the interests of science and society (Article 5), and ethical considerations must always take precedence over laws and regulations (Article 9). The recognition of the increased vulnerability of individuals and groups calls for special vigilance (Article 8). It is recognised that when the research participant is incompetent, physically or mentally incapable of giving consent, or is a minor (Articles 23, 24), then allowance should be considered for surrogate consent by an individual acting in the subject's best interest. In such cases their assent should still be obtained if at all possible (Article 25).

Operational principles: Research should be based on a thorough knowledge of the scientific background (Article 11), a careful assessment of risks and benefits (Articles 16, 17), have a

reasonable likelihood of benefit to the population studied (Article 19) and be conducted by suitably trained investigators (Article 15) using approved protocols, subject to independent ethical review and oversight by a properly convened committee (Article 13). The protocol should address the ethical issues and indicate that it is in compliance with the Declaration (Article 14). Studies should be discontinued if the available information indicates that the original considerations are no longer satisfied (Article 17). Information regarding the study should be publicly available (Article 16). Ethical publications extend to publication of the results and consideration of any potential conflict of interest (Article 27). Experimental investigations should always be compared against the best methods, but under certain circumstances a placebo or no treatment group may be utilised (Article 29). The interests of the subject after the study is completed should be part of the overall ethical assessment, including assuring their access to the best proven care (Article 30). Wherever possible, unproven methods should be tested in the context of research where there is reasonable belief of possible benefit (Article 32).

4. **NUREMBERG CODE (1947)**

i) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the

experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

ii) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

iii) The experiment should be so designed and based on the results of animal experimentation and acknowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

iv) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

v) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

vi) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

vii) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

viii) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

ix) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

x) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

APPENDIX IV: FACULTY ACRONYMS

Team	Faculty	Acronym
1	Faculty of Administrative and Management	FAM
2.	Faculty of Agriculture	FA
3.	College of Medical Sciences	COL
4.	Faculty of Communication and Media Studies	FCMS
5.	Faculty of Education	FED
6.	Faculty of Engineering	FE
7	Faculty of Entrepreneurial Studies	FENT
8.	Faculty of Environmental Science	FES
9.	Faculty of Humanities	FH
10.	Faculty of Law	FL
11.	Faculty of Medical Laboratory Science	FMLS
12.	Faculty of Science	FS
13.	Faculty of Social Sciences	FSS

MEMBERS OF THE ETHICS POLICY DRAFTING COMMITTEE

1. Prof. Victor Akujuru – Deputy Vice-Chancellor Administration
2. Prof. Godwin B. Okon- Director, Research and Development
3. Prof. Ibinabo Laura Oboro- Faculty of Basic Clinical Sciences, College of Medical Sciences
4. Engr. Prof. Reuben Okparanma - Faculty of Engineering
5. Prof. Erema Daka – Faculty of Science
6. Dr. Temple Probyne Abali - Faculty of Social Sciences
7. Dr. Richard G. Chinda - Faculty of Law
8. Dr. C. I. Chinda–Faculty of Humanities
9. Dr. (Mrs.)M.E. Ogbamgba – Deputy Registrar