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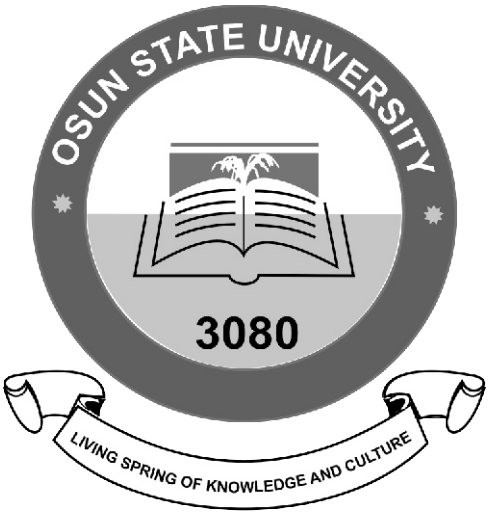
OSUN STATE
UNIVERSITY
OSOGBO, NIGERIA

POLICY ON RESEARCH ETHICS



OSUN STATE UNIVERSITY POLICY ON RESEARCH ETHICS

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ACRONYMS

ACUREC	-	Animal Care and Use Research Ethics Committee
ADR	-	Adverse Drug Reactions (ADRs)
AE	-	Adverse Event
CBD	-	Convention on Biological Diversity
CERC	-	College Ethics Review Committee
CIOMS	-	Council for International Organisations of Medical Sciences
CRF	-	Case Report Forms
CMAC	-	Chairman Medical Advisory Committee
CoI	-	Conflicts of Interest
COAREC	-	College of Agriculture Research Ethics Committee
COEREC	-	College of Education Research Ethics Committee
CHCREC	-	College of Humanities and Culture Research Ethics Committee
COLREC	-	College of Law Research Ethics Committee
CMSSREC	-	College of Management and Social Sciences Research Ethics Committee
CT	-	Clinical Trials
DRA	-	Drug Regulatory Agencies
DVC ARIP	-	Deputy Vice-Chancellor, Academic, Research, Innovations & Partnership
EC	-	Ethics Committee
EHCS	-	Environmental Health and Chemical Safety
EHS	-	Environmental Health and Safety
EPC	-	Ethics of Professional Conduct
ERC	-	Ethics Review Committee
ERRB	-	Ethical Research Review Board
ETL	-	Ethics of Teaching and Learning
FDA	-	Food and Drugs Act
FE	-	Food Effect
FERC	-	Faculty Ethics Review Committee
GCP	-	Good Clinical Practice
GMO	-	Genetically Modified Organisms
GMP	-	Good Manufacturing Practice
HIV	-	Human Immunodeficiency Virus
HREC	-	Health Research Ethics Committee
IACUC	-	Institutional Animal Care and Use Committee (IACUC)
ICT	-	Information and Communication Technologies
IPR	-	Intellectual Property Rights
IRB	-	Institutional Review Board
M&E	-	Monitoring and Evaluation

MAD	-	Multiple Ascending Dose
MT	-	Monitoring Team
MTA	-	Materials Transfer Agreement
MTD	-	Maximum Tolerated Dose
NAFDAC	-	National Agency for Food and Drug Administration and Control
NASENI	-	National Agency for Science and Engineering Infrastructure
NHREC	-	National Health Research Ethics Code
NSE	-	Nigeria Society of Engineers
NUC	-	National Universities Commission
ORIM	-	Office of Research and Innovation Management
PI	-	Principal Investigator
PHD	-	Doctor of Philosophy
PMS	-	Post Marketing Surveillance (PMS)
PUCREC	-	Plant Use and Conservation Research Ethics Committee
QTLP	-	Quality Teaching and Learning Practice
RCT	-	Randomized Controlled Trials
RUSU	-	Radiation Use and Safety Unit
SAD	-	Single Ascending Dose
SON	-	Standard Organisation of Nigeria
SOP	-	Standard Operating Procedure
SSHREC	-	Social Sciences and Humanities Research Ethics Committee
STREC	-	Science and Technology Research Ethics Committee
UNIOSUN	-	Osun State University
UNIOSUNHREC	-	Osun State University Health Research Ethics Code
UPL	-	UNIOSUN Publishing Ltd.
USA	-	United States of America
WHO	-	World Health Organsation

FOREWORD

FOREWORD

I am delighted to present and dedicate this publication titled **Osun State University Policy on Research Ethics.** The book's publication is another fulfilment of my mission and vision for rebuilding the University for strategic growth and development. The UNIOSUN Policy on Research Ethics aims to create a conducive intellectual milieu for achieving excellence in research and training that will benefit and change society for the better. It will be a fantasy to expect a workable cycle that will generate funds for research, guarantee research infrastructure, create quality and relevant research outputs that will be commercialized without an ethics policy.

I need to put on record that efforts towards the institutionalization of ethical standards in UNIOSUN began at the College of Health Sciences HREC in 2011 when the university-sponsored a delegate to the inaugural meeting of the Forum of the Chairmen of Health Research Ethics Committees in Nigeria and Abuja on 25th November 2011 to obtain all necessary information that will enable the registration of the UNIOSUN HREC with the national body.

I, therefore, congratulate all our researchers on this book.

Research practice is outlawed it if is normal or contrary to reasonable expectations. The University Policy on Research Ethics will promote research core values and address academic dishonesty, management of conflict of interest, conference sponsorship, recruitment fees, co-authorship of the article, funding for facilities, competence of investigator, scientific integrity and misconduct, plagiarism, fabrication, intellectual property rights and disagreement between two ethics committees. The ethics policy provides the globally acceptable guidelines that will make research be carried out with honesty and integrity within the acceptable ethical framework.

I commend members of the Global Ethics Committee under the leadership of the Deputy Vice-Chancellor (Academic, Research, Innovations and Partnerships), all the representatives of Colleges and all those who worked behind the scene for their efforts in producing the policy book that will, henceforth, guide the conduct of research in all our University Colleges/Faculties as well as our Institutes. I thank you.

Labode Popoola, PhD, FFAN
Vice-Chancellor, Osun State University
Osogbo, Nigeria.

PREFACE

PREFACE

Osun State University priorities excellence in research, teaching and learning, informed by ethics. Professional conduct and prompt service delivery cannot be achieved without sound ethical standards. The Osun State University Policy on Research Ethics in an invaluable compendium of a set of guidelines about ethical principles and issues in the conduct of research, specifying the obligations of researchers, sponsors and beneficiaries of research.

This policy covers ethical issues as it affects staff, students and visitors to UNIOSUN in research, teaching and learning, and professional conduct and services, which provides guidelines for the conduct of research undertaken by staff, students and visitors. It establishes a framework for the University Review Committees, develops an acceptable standard for teaching and learning, and maintains, regulates different ethical practices and professional conduct.

To adequately implement the UNIOSUN Policy on Research Ethics, four new Research Ethics Commitees (UNIOSUNRECs) have been created and the existing UNIOSUN Health Research and Ethics Committee (UNIOSUNHREC). The newly created committees are Social Sciences and Humanities Research Ethics Committee (ACUREC), Plant Use and Conservation Research Ethics Committee (PUCREC), and Science and Technology Research Ethics Committee (STREC).

The policy includes the Ethics of Teaching and Learning (ETL) and Ethics of Professional Conduct (EPC). It makes recommendations for funding, infrastructure development and administration, capacity building of personnel, sensitization of the university community to the ethics policy, periodic review of the policy and compliance with the Policy guidelines.

On behalf of the Committee, I wish to express my appreciation to the Vice-Chancellor, Labode Popoola, PhD, FFAN, who constituted the Global Ethics Committee to develop ethics protocols to guide research with human and animal research subjects for the University. I also express my sincere gratitude to all members and representatives of all the Colleges, including the Postgraduate College, who compiled the necessary data and information for the success of this publication.

Osun State University believes in excellence in research, teaching and learning. This policy will be of invaluable benefit to all researchers, staff, students and the community.

Anthony Kola-Olusanya, PhD
Deputy Vice-Chancellor
(Academic, Research, Innovations and Partnerships)
Chairman, Global Ethics Committee
Osogbo, Nigeria.

CONTENTS

CHAPTER ONE

OSUN STATE UNIVERSITY POLICY ON RESEARCH ETHICS

1.0 INTRODUCTION

1.1 PREAMBLE

Following the approval by the National Universities Commission (NUC) on December 21, 2006, Osun State University (UNIOSUN) became the 30th State University and 80th in the Nigerian University system.

Osun State University (UNIOSUN) is set up as a conventional, multi-campus University charged with the production of high-quality, well–rounded, globally competitive and entrepreneurial graduates who are catalysts for rapid and sustainable socio-economic development of Osun State and Nigeria.

UNIOSUN operates a collegiate system. There are eight colleges in six campuses located in the six geo-political zones of the state. These are:

(i) College of Agriculture, Ejigbo Campus
(ii) College of Education, Ipetu-Ijesa Campus
(iii) College of Health Sciences, Main Campus, Osogbo
(iv) College of Humanities and Culture, Ikire Campus
(v) College of Law, Ifetedo Campus
(vi) College of Management and Social Sciences, Okuku Campus
(vii) College of Science, Engineering and Technology, Main Campus, Osogbo
(viii) Postgraduate College, Main Campus, Osogbo

THE VISION

The vision of Osun State University is to be a centre of excellence through the provision of highly qualitative teaching and learning experiences which will engender the production of entrepreneurial graduates capable of impacting positively on their environment while being globally competitive.

THE MISSION

The mission of UNIOSUN is to create a unique institution committed to the pursuit of academic innovation, skills-based training and a tradition of excellence in Teaching, Research and Community service.

The UNIOSUN Ethics Review Committee is responsible for producing guidelines for the conduct of research and for ensuring that all University Colleges/Faculties have in place appropriate procedures for the consideration and conduct of research. The University Ethics Review Committee will consider, give guidance on research referred to it from Colleges/Faculties and hear appeals on decisions made by Colleges/Faculties. In exceptional cases, the University Ethics Review Committee shall itself make decisions on research.

The University Ethics Review Committee is concerned primarily with the general principles of

natural justice, reasonableness and fairness of the decision made by the College/Faculty Ethics Review Committee (C/FERC). It also acts to ensure compliance with legal and other requirements covering researches across the entire University.

UNIOSUN believes that excellence in research, teaching and learning, professional conduct and services cannot be achieved without sound ethical standards. This policy aims to strengthen the awareness of ethical principles and issues in the conduct of research, thereby specifying the obligations of researchers, sponsors and the beneficiaries of research. The core values of ethics at UNIOSUN are based on the principles enshrined in the Nigerian constitution as well as the National Health Research Ethics Code (NHREC). This policy covers ethical issues as it affects staff, students and visitors to UNIOSUN in research, teaching and learning as well as in professional conduct and services.

1.2 JUSTIFICATION FOR THE UNIOSUN POLICY ON RESEARCH ETHICS

Despite the large number of Codes of Ethics, unethical conducts persist in research executed all over the world and particularly in the developing world. Several obstacles facing research in developing countries include the following:

(i) The shortage of human, institutional and financial resources.
(ii) The relatively low priority assigned to research.
(iii) The impact of cultures, religion and norms that undermine ethical requirements such as informed consent.
(iv) The increase in volume of research in Nigeria has necessitated the formulation of ethics policy in guiding research activities.

The Ethics Policy will:

(i) Promote the aims of research.
(ii) Encourage the values that are essential to collaborative work.
(iii) Ensure that researchers are accountable.
(iv) Build public support for research.
(v) Promote social and moral values.

1.3 GOAL AND OBJECTIVES

GOAL

The overall goal of this policy is to establish an acceptable standard for research integrity, teaching and learning as well as professional conduct and services at UNIOSUN.

OBJECTIVES

The objectives include:

(i) Providing guidelines for the conduct of research undertaken by staff, students and visitors.
(ii) Establishing a framework for the University Ethics Review Committees.

(iii) Developing an acceptable standard for teaching and learning.
(iv) Maintaining and regulating different ethical practices and professional conduct.

1.4 OSUN STATE UNIVERSITY RESEARCH ETHICS COMMITTEE

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge. It comprises:

(i) Therapeutic procedures – interventions administered with the intent of providing direct benefit to the research participant.
(ii) Non-therapeutic procedures – interventions that are not administered with therapeutic intent and are only intended to answer the scientific question of the study (National Code of Health Research, 2007).

In order to adequately implement the UNIOSUN Policy on Research Ethics, four new Research Ethics Committees (UNIOSUNRECs) have been created in addition to the existing UNIOSUN Health Research and Ethics Committee (UNIOSUNHREC). The newly created committees are:

(i) Social Sciences and Humanities Research Ethics Committee (SSHREC);
(ii) Animal Care and Use Research Ethics Committee (ACUREC);
(iii) Plant Use and Conservation Research Ethics Committee (PUCREC); and
(iv) Science and Technology Research Ethics Committee (STREC).

In addition, the policy includes the Ethics of Teaching and Learning (ETL) and Ethics of Professional Conduct (EPC).

CHAPTER TWO

2.0 HISTORY OF ETHICS AT UNIOSUN

Efforts towards the institutionalization of ethical standards in UNIOSUN began at the College of Health Sciences HREC in 2011 with the drafting of a proposal for the establishment of the Human Ethics Committee at the UNIOSUN College of Health Sciences. The College took an appropriate step by initiating registration with the national regulatory body, National Health Research Ethics Committee; NHREC. Further to this, the university sponsored a delegate to the inaugural meeting of the Forum of the Chairmen of Health Research Ethics Committees in Nigeria in Abuja on 25th November 2011 to obtain all necessary information that will enable the registration of the UNIOSUN HREC with the national body.

The efforts were followed with the inauguration of the committee saddled with the responsibilities of creating and sustaining a UNIOSUN-wide awareness of the existence and importance of adhering to ethical standards in the course of conducting research (clinical and non-clinical) in 2012.

The College later instituted an HREC committee, trained its members to perform the functions of the HREC, receiving and reviewing proposals submitted to the committee and deciding appropriately in line with global and national ethical guidelines. The College HREC committee is fully active and functional.

Meanwhile, by a Memo Ref. No. REG/ADM/SM/17/Vol. 10/142 dated 28th September, 2020, the Vice-Chancellor set up a Global Ethics Committee to develop ethics protocols guiding research with human and animal subjects for the University. The Committee was later expanded to include representatives of Colleges in order to produce an acceptable document guiding all ethical issues in research for all discipline including Humanities. The ethical protocol will serve as a guide for all staff engaging in one research or the other as well as all PhD students of this University.

CHAPTER THREE

3.0 MAJOR POLICY ISSUES AND OPERATIONS

Some major policy and operational issues common to the five Ethics committees, Teaching and Learning, as well as Professional conduct now being established at UNIOSUN, will be addressed at this point to avoid repetition by each research ethics committee.

These are conflict of interest, research misconduct, monitoring and evaluation, material transfers, intellectual property rights, copyrights and patents.

3.1 CONFLICT OF INTEREST (COI)

(i) Conflict of Interest can be defined as: "A conflict between the private interests and official responsibilities of a person in a position of trust". It could also be defined as the interference of one private interest with another. CoI is found in situations in which financial and other characteristics may compromise or appear to compromise a researcher's judgment or integrity in conducting or reporting findings of a research.

(ii) Conflict of interest arises from a variety of impact of decisions made irrespective of the validity of the decision, competence of the decider and the degree of seriousness of the likely outcomes. It can originate from an individual, third party, groups institutions and donor priorities versus local needs of community. In the process of conducting research, choice of design can be biased to suit predetermined end and methodologies. During data processing and reporting, integrity of editing, coding should be done to avoid prejudices.

(iii) Most conflicts of interest arise at the time of proposal review at the competitive and often international level. It can also occur at a formal level when reviewers sign a *declaration that there are no conflicts of interest (mostly financial)* for the reviewer (shares in multinational companies, benefits from outcomes of study).

(iv) The review process focuses on the following areas of conflict: links between reviewer and Principal Investigator, Institution and other entities. In data gathering, CoI can arise at field level when interviewers recruit respondents in a way to suit their short- or long-term interests (e.g. to save time or effort). Coding/recording of data and selection of software for analysis to prevent the favouring of a particular point of view. The desire for promotion, poor income, inducement of a trip, preferential choice of publication, international clout of institutional gain may result in CoI. Anticipation of CoI, training, and effecting adequate supervision are keys to preventing Col.

3.2 RESEARCH MISCONDUCT

Research misconduct refers to practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It also refers to shortcomings in the professional conduct of researchers (European Science Foundation 2010). Examples include fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. **Another common form of misconduct is the practice whereby an investigator withholds or delays the publication of research results for financial reasons.** This usually occurs when an investigator is

pressurized by the donor agency to delay the publication of results which may be perceived to hurt the financial fortunes of a donor agency.

Other examples of misconduct related to publications include:

(i) Complimentary authorship: A situation in which a person who has not made any contribution to a paper is cited as an author.
(ii) Submission of paper with sections lifted from other papers without their acknowledgments.
(iii) Re-submission of previously published data with minor alterations and no acknowledgements.
(iv) Submission of papers by lecturer from students' dissertation without students' permission.
(v) Fabrication – making up data or results and recording or reporting them as true.
(vi) Falsification – manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record (i.e. the record of data or results that embody the facts emerging from the research, and includes, but is not limited to, research proposal, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books).
(vii) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism in this sense includes self-plagiarism.
(viii) Research misconduct does not include honest error or differences of opinion.

Detection of any misconduct should be reported to the appropriate authority (as stated in Monitoring of Research). A response to an allegation of research misconduct will usually consist of several phases, including:

An inquiry - the assessment of whether the allegation has substance and if an investigation is warranted;

An investigation – the formal development of a factual record, and the examination of that record leading to the dismissal of the case or a recommendation for a finding of research misconduct or other appropriate remedies.

(ix) Adjudication, during which recommendations are reviewed and appropriate corrective actions determined.

3.3 MONITORING AND EVALUATION (M&E)

The following are required for monitoring and evaluating research projects:

(i) Membership of the Monitoring Team (MT) should comprise of some members of the EC (Ethics Committee) and co-opted members. Community representatives are required to be part of the M&E.
(ii) Empowerment of the MT to scrutinize any part of the project with fair openness.
(iii) Adequate funding should be provided for the activities of the MT by the University

through the different communities.

(iv) The working activities of the various M&E should be directed according to the flexibility of their schedule.

(v) Timing of the M&E should be as directed by the committee and be periodic with or without notice to the investigators.

(vi) Investigators should submit Progress reports, at least annually, to the EC which will be available for the MT.

(vii) It is expected that investigators should not hinder or place mechanism in place to hinder the ethical work of the M&E members.

(viii) It is expected that all the Research Participants should be accessible for interview by the MT.

(ix) Part of the MT responsibilities is to observe Clinical examination; Laboratory methods; Safety measures, and all information gathering instruments including questionnaires.

3.4 MATERIALS TRANSFER AGREEMENT

Transfer of samples and biological materials such as animals, herbs and plants out of Nigeria shall require a Materials Transfer Agreement (MTA) detailing the type of materials, anticipated use, location of storage outside Nigeria, duration of such storage, limitations on use, transfer and termination of use of such materials subject to any law, regulations and enactment in Nigeria. The purpose of MTA is to protect the interests of local researchers and Nigeria's human and natural resources in all its biodiversity as well as how they can be legitimately used. It ensures that the interests of all relevant parties, human and community participants in research and the Nigerian nation are protected from exploitation and egregious harm.

3.5 INTELLECTUAL PROPERTY (IP)

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

3.6 COPYRIGHT

Copyright is a legal concept giving the creator of an original work the exclusive rights to it and to who may use it and for what purposes. This is usually for a limited time only and ensures that the copyright holder is credited for his or her work.

3.7 PATENTS

A patent is a form of intellectual property (which also includes copyrights, brand rights and design rights) that gives its owner the legal right to exclude others from making, using, or selling an invention for a limited period of years in exchange for publishing and enabling public disclosure of the invention. Patents are issued for inventions, not discoveries. The invention must comprise a technical solution to a technical problem. Vague ideas cannot be patented. In contrast, products, processes, devices and applications may all be patented. The invention must also be new. Any publication of the invention prior to a patent application will be an obstacle to patent protection.

CHAPTER FOUR

4.0 UNIOSUN ETHICS RESEARCH REVIEW BOARD

The University is committed to the highest ethical standards in the conduct of its research activities. To entrench this practice, the University has decided to consolidate its ethical review activities and bring them under the supervision of the Ethical Research Review Board (ERRB) for its diverse activities.

The University shall establish and operate an Ethics Research Review Board (ERRB) under the Vice-Chancellor's office.

Functions of the ERRB

The principal functions of the ERRB shall be to:

(a) Coordinate and regulate all matters pertaining to research ethics and integrity at the University.
(b) Oversee the activities of its ethical Review Committees.
(c) Advise Senate on policies and matters relating to research ethics and integrity.
(d) Prepare and submit annual report to Senate through the Vice-Chancellor.
(e) To make the final decision (approval/rejection/other recommendation) on submissions and appropriately communicate same.

Structure of ERRB

The ERRB consists of the following five Research Ethics Committees:

(a) Health Research Ethics Committees (HREC).
(b) Social Sciences and Humanities Research Ethics Committee (SSHREC).
(c) Animal Care and Use Research Ethics Committee (ACUREC).
(d) Plant Use and Conservation Research Ethics Committee (PUCREC).
(e) Science and Technology Research Ethics Committee (STREC)

Members shall serve for three years.

Composition of ERRB

The membership of the ERRB shall be as follows:

(a) Chair – Deputy Vice-Chancellor (Academic, Research, Innovations & Partnerships)
(b) Chairs of the five Research Ethics Committee
(c) Two laypersons from the public
(d) Head of the Legal Unit
(e) Director, Office of Research and Innovation Management (ORIM)

(f) Principal Assistant Registrar (DVC ARIP's Office), (Secretary)
(g) At least 30% of the membership shall be females (where possible).

GENERAL GUIDELINES FOR PROPOSAL SUBMISSION

A cover page specifying:

(i) Title, Full names, Qualifications, Sponsors, Collaborating Institutions of Investigators, Corresponding Investigator who must be the project coordinator or Local PI of the protocol and bears responsibility for the research.

Background to the Study

(ii) A description of the previous related research (state-of-the-art) and current knowledge must be provided

Rationale for the study

The underlying principles for the study must be stated are to be provided.

Objectives of the study

Outline the objectives of the study.

Methodology:

(a) Study design stating clearly the nature of the study (descriptive, drug trial, experimental)
(b) Sample size determination
(c) Sampling/interview detailing inclusion/exclusion criteria & frequency
(d) Statement on invasive sampling (blood, tissue, etc.); inclusion/exclusion criteria and frequency of sampling
(e) Data collection procedure
(f) Physical examination procedure if inclusive
(g) Follow up details if required
(h) Laboratory procedures to be used
(i) Intervention statement to be included
(j) Data analysis package to be used

Instrument for data collection e.g. questionnaire to be administered must be included in the protocol

Ethical Considerations to be addressed in the protocol as a separate section (see below):

Informed Consent Form

Where applicable, a translation of the questionnaire and informed consent in the Local language of participants must be provided to facilitate clear understanding.

(a) Confidentiality of Data
(b) Translation of Protocol to local language and in the simplest level

(c) Compensation and/or Direct Benefits to Participants
(d) Non-Maleficence to participants
(e) Issues of Equity and Justice in Participants Selection
(f) Right to Decline/withdrawal from study without Loss of Benefits

VOLUNTARY INFORMED CONSENT PROCESS

Informed consent is a process NOT a form. Informed consent of the participant is one of the fundamental requirements for the conduct of ethical research with human participants. Such consent must be voluntary (obtained without manipulation or under pressure) and based on sufficient information as to the risks and benefits associated with participants in the project. Use of a written consent form which is the preferred method of obtaining participants' consent to carry out procedures may be substituted with waiver consent for emergency situations.

An informed Consent form must clearly state the essence of the study in a few statements. It should also mention each of the above ethical issues before finally requesting signature and dates from participants. **The informed Consent section should be personalized by the person giving the consent.**

The consent document must be clearly written and/or verbally explained so as to be understandable to participants (in the local language, wherever applicable). The language must be non-technical. Unavoidable scientific, technical or medical terms must be plainly defined and explained. It is the PI's responsibility to ensure quality of consent procedure.

Components of informed consent are:

(a) Information: Details provided to the participants must be comprehensive.
(b) Comprehension: Investigator must ensure that the informed consent process is clearly understood by the participants/guardian before accepting to participate in the study.
(c) Voluntariness: All study participants must volunteer
(d) Competence: All study participants must have competence (except those with diminished capacity, to make informed decision to enrol or decline involvement in a study). Capacity for participation may be evaluated in terms of age, mental or physical ability among others.

Content of Informed Consent Form:

(a) Name and Address of Principal Investigator
(b) Person to contact for answer to questions, or in event of research related injury or emergency should be clearly stated with full address and telephone numbers.
(c) Purpose of Research must be clearly stated.
(d) Procedures must be explained in simple words describing details of what the participants would be expected to undergo. The numbers of times that the sample will be taken or questionnaires administered must be stated.
(e) 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 also be advised as to the availability of the product after discontinuation of the study, indicating possible cost implication or whether drug

would be available to the patients free of cost.

(f) Foreseeable risks or discomforts to the participants must be explainable in full. Such risks include physical injury, possible psychological, social, emotional, economic harm, discomfort, or inconvenience. If risk is unknown, it should be so stated.

(g) Length of time that the participant is expected to participate. If participant is expected to participate over a long period of time, it should be clearly indicated. Any new information that develop 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.

(h) Treatment for adverse events: Explain that therapeutic measure would be available to the participants in case of adverse events or injury as a result of his or her participation in the study. Should a disease condition (or a comparable social condition) be diagnosed in the course of a study, it is the responsibility of the PI to refer the affected participant for appropriate care. All research-related adverse reactions are the financial responsibilities of the researchers.

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

CONFIDENTIALITY

UNIOSUN recognizes the ethical principle of confidentiality to mean keeping information given by or about an individual in the course of conducting a research or a professional relationship secure and secret from others. To this extent, it shall ensure that:

(a) any research data, either in paper form or electronic, including medical records and biological samples shall be kept in such a way that no unauthorized persons have access to them;

(b) no description traceable to research participants shall be done without the necessary precaution;

(c) a comparable standard or mechanism should be in place to ensure the confidentiality and security of personal information concerning research participants;

(d) information of research participants should be anonymised to a large extent;

(e) how the data/samples will be obtained, and the purposes for which they will be used should be adequately discussed in any submitted research protocol before approval;

(f) countries or sponsors to which the data/samples will be sent should be adequately discussed in any submitted research protocol for the review process and approval.

UNIOSUN recognizes that certain conditions might be possible when the principle of confidentiality can be ethically breached. Such conditions 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 research 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.

Voluntary Participation

Respect for persons is a fundamental ethical principle.

(i) Osun State University Ethics Policy therefore believes that no research should be conducted against a person's wishes.

(ii) His or her consent to participate in research must thus be obtained voluntarily.

(iii) No potential participant in any research should be made to partake in any study by any form of coercion.

Participation/Rights to withdraw

The Osun State University recognizes the research principle that research participants have the right to withdraw from any initially given consent without any penalty or withholding any benefits. To this extent,

(i) At the beginning of any study, investigators should make clear in their protocol a plan to explain to participants their right to withdraw from the research at any time, irrespective of whether or not some compensation has been offered.

(ii) Research participants have the right to request that their data, including recordings, be destroyed. There are however exceptions to certain observational or organizationally designed studies. Nevertheless, the investigator must attempt to ensure that participants (including children) know of their right to consent or withdraw. This should be acknowledged.

Signature/ThumbPrint

The final stage in the process of Informed Consent is to append the signature or thumbprint. 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 thumbprint as a witness. Investigators should be aware of the cultural attitude towards certain participant attributes (see appendix II)

Consent Process for Special Populations

The Health Research Ethics Committee (HREC) shall require that particular care be taken in plans to enrol participants who are classified as special and vulnerable populations such as children (under 18); pregnant women; human foetuses; sex workers; physically and hospital patients; mentally challenged persons; students; infant (under the age of one year); the elderly (ages 60 and over); illiterate persons and institutionalized persons such as prisoners. When dealing with any of these populations; investigators are required to use a written or verbal consent/assent form. The protocol submission form must, however; clearly indicate the appropriate category of special population to be included as research participants.

CONSENT AND ASSENT FROM CHILDREN

Individuals under the age of 18 years cannot legally consent to be involved in research protocols. The permission 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 the 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, the 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 protocol, which must be explained to him or her in a language the child can understand. This personal assent must be documented on the written consent form and, as appropriate, in the child's medical record.

Minimal risk is defined as, 'the probability and magnitude of harm or discomfort anticipated which are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

PREGNANCY CLAUSE

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 participant's 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.

REVIEW PROCEDURE

Committee Procedures

(i) The Committee shall meet at least once a month for proposal reviews and approvals.

(ii) 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 element of review should include 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 and Approvals

Types of Reviews

Ethics Committee should specify the procedure for each of these reviews. Three types of reviews are conducted by the HREC. These are Exempt, Expedited, and Full Review. (45 CFR 46 Code).

(a) Exempt Review: Exempt is provided to research proposals in which there is virtually no risk to the participants **(e.g. routine physical examination such as checking body temperature or blood pressure)**.

(b) Expedited Review: This type of review involves research with minimal risk or request for minor changes in already approved proposals. CHAIR/Designee can review.

(c) Full Review: This category of review is recommended for research in which there is more than minimal risk to participants (such as invasive procedures);due attention

must be paid to the process of selection of participants, informed consent procedures; examples of more than minimal risk include research involving invasive procedures such as blood sampling, tissue biopsy etc.

Types of Approvals

As part of its review of a protocol or amendment, the committee will assign a status to each protocol. That status will be one of the following:

(i) Approved – If full approval is granted, the investigator may begin the research proposed in the protocol.

(ii) Pending Conditional – A "Pending–Conditional" status may be stipulated, requiring modifications in the protocol and/ or consent form before initiation. No research may be started until all conditions have been met and a formal approved has been obtained from the Committee.

(iii) Pending Deferral - A deferred protocol must be substantially revised and resubmitted to the Committee. No research may be started until all conditions have been met and formal approval has been obtained from the Committee.

(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 a severe or unnecessary risk to the participants.

Conditions for Approval

(a) Approval is given for a specified period of not more than one year in the first instance. 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.

(b) Approval is given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being affected.

(c) Approval is given on the condition that a copy of the final report of the research project is lodged with the HREC for its information and record.

(d) Approval is given on condition that researchers accept to notify the Review Committee if and when a project is curtailed, terminated or completed by sponsors or other regulating authorities of the project.

(e) 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.

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

Challenges of Research

Research must function with honesty and integrity within the ethical acceptable framework at all times. Academic dishonesty including any of those listed below is regarded as serious offences. Conflict of interest can occur in research when the professional judgement is unduly influenced by other interests such as financial gains or personal status. This is sometimes

unavoidable but must be carefully managed by disclosure and transparency for the result of the research and the well-being of the participants. Researchers must pay particular attention to issues of travel and conference sponsorship, recruitment fees, co-authorship of article, funding for facilities. Some of these issues have been addressed earlier under major policy issues and operations.

These include:

(i) Conflict of interest
(ii) Competence of Investigator
(iii) Scientific Integrity and Misconduct
(iv) Plagiarism
(v) Fabrication
(vi) Intellectual Property Rights
(vii) Disagreement between two ethics committees.

Process for revision of suspension

(i) The ethics committee may reverse its decision to suspend research if the issue(s) that necessitated the action is (are) resolved to committee's satisfaction.
(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 to carry out 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 (180) days.

Process for termination of research

Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation 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), sponsor(s), and the UNIOSUN (ERRB), researcher(s), department(s) shall be entitled to appeal to the decision of the committee to terminate the research to the ERRB within FOURTEEN (14) days of receipt of notification.

Process for appeal of the ethics committee's decision to suspend/terminate research

Upon receipt of an appeal of the decision of the ethics committee to the determinate research, the UNIOSUN ERRB may at his discretion, take up such an appeal.

Where the appeal is sustained:

(i) The UNIOSUN ERRB may with reasons, direct the ethics committee to approve the research and provide continuity oversight.
(ii) The UNIOSUN ERRB may mandate modification(s), which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuity oversight.
(iii) The UNIOSUN ERRB may sustain the decision of the ethics committee and dismiss the appeal

Research practice is **prohibited** if it is immoral or contrary to reasonable expectations and therefore, found unjustifiable if: (1) the action can be justified for one person, but the same action cannot be justified for every person, (2) if we can make an exception for one person but cannot justifiably make the same exception for everyone in the same situation; and (3) if the exception cannot be made known to the public.

A. FREEDOM OF RESEARCH, ETHICS, AND SOCIETY

1. Core value of research and research ethics

Researchers shall adhere to research ethics standards/policy which includes requirements regarding honesty, impartiality, and willingness to accept their fallibility.

2. The importance of independent research

Research institutions and research policy bodies are to facilitate free and independent research. The institutions must ensure that research that complies with scholarly quality requirements is not suppressed because a topic is controversial. The intrinsic needs of research for originality, transparency and the verification of prevailing opinions can come into conflict with some parties' desire to prevent topics from being explored. Research must be safeguarded against control from the inside or the outside that interferes with well-founded problems for discussion that are at loggerheads with financial, political, social, cultural, or religious interests and traditions.

3. The social, cultural and linguistic rules of research

Research policy institutions must give priority to research efforts so that they, directly or indirectly, in the short or the long term, can benefit society and instil cultural values.

4. The communication and enforcement of research ethics standards

It is incumbent upon institutions and individual researchers to develop and maintain good research practice. Institutions are to ensure compliance with (and avoid breaches) research ethics standards.

B. RESPECT FOR INDIVIDUALS

5. The obligation to respect human dignity.

Researchers shall work on the basis of basic respect for human dignity.

While research can help promote the value of human life, it can also threaten it. Researchers must show respect for human dignity in their choice of topic, in relation to their research subjects, and in reporting research results. This implies that research processes must be held in conformity with certain standards:

(a) ensuring freedom and self-determination;

(b) safeguarding against harm and unreasonable suffering;

(c) protecting privacy and close relationships.

6. The obligation to respect integrity, freedom and right to participate

Researchers shall respect their subjects' integrity, freedom and right to participate. Individuals need to be able to influence what happens to them in important areas of their lives. Due caution is required, especially when:

(a) self-respect or other values of importance to the individual are at stake;
(b) the research subjects have little chance to avoid participating in the research process, e.g. when the research is being done as field work in an institution;
(c) an individual actively helps furnish information, e.g. by agreeing to be observed or interviewed;
(d) an individual is identifiable, e.g. when individuals and groups can be recognised in research reports;
(e) the individual has limited or no ability to look after his or her needs and interests.

7. The obligation to prevent harm and suffering

Researchers have a responsibility to prevent research subjects from being submitted to harm or other sufferings. Researchers bear a responsibility for ensuring that their research subjects are not exposed to suffering. However, the risk of causing minor suffering must be weighed against researcher's quest for the truth.

8. The obligation to inform research subjects

Research subjects are to be given all the information they require to gain a reasonable understanding of the field of research in question, of the consequences of participating in the research project, and of the purpose of the research. Subjects shall also be informed about who is funding the research. Due care must be exercised when information cannot be given before the research is initiated. For example, if the real purpose of an experiment cannot be disclosed; such exemptions from the disclosure requirement must be justified by the value of the research and the lack of alternatives.

9. The obligation to obtain free and informed consent

As a general rule, research projects that include individuals can be initiated only after securing participants' free and informed consent. The informants have the right to withdraw from participation at any time, without this entailing any negative consequences for them. Free consent means that the consent has been obtained without outside pressure or constraints on individual freedom of action. The Researcher gives adequate information to the subject about their participants in the research project. The information must be given in a format that can be easily understood by the informant.

10. Research licences and the obligation to report

Research and students' projects that is involved in the processing of personal data must be reported to RECOL Ethics committee.

11. Regard for third parties

Researchers should consider and anticipate effects on third parties that are not directly included in the research. Interviews, archival studies and observations often result in the scientist gaining access to information about far more individuals than those who are the focus of the study in question, or that the research may have an impact on the privacy and close relationships of individuals not included in the research, but who are drawn in as parties closely related to the informants. Qualitative investigations often take place in small, transparent communities. The protection of third parties is especially important in such studies. Special consideration should be given to potential negative consequences when children are indirectly involved in the research.

12. Children's right to protection

When children and young people participate in research, they are entitled to special protection that should be commensurate with their age and needs. Research on children and their lives and living standards is valuable and important. Children and young people are key contributors to some studies. Their needs and interests can be protected in ways different in connection with research on adult participants. Parental consent is usually required when children under the age of 15 (or as specified by Child Right Act) will be taking part in research.

Some of these rights include:

(a) rights not to be violated;

(b) choice of words (Avoidance of foul languages that can corrupt the mind of young child;

(c) avoidance of things that can have (any form of) negative effect on the health and well being of a child;

(d) the life of the child must not be endangered;

(e) protection of the identity of child to protect his/her integrity must be guarantee (such as interview of a raped or any form of violated child);

(f) coercion and any other use of force should be avoided.

13. The obligation to respect individuals' privacy and close relationships

Researchers shall show due respect for an individual's privacy. Informants are entitled to be able to check whether confidential information about them is accessible to others. Respect for privacy aims at protecting individuals against unwanted interference and exposure. This applies not only to emotional issues, but also to questions that involve sickness and health, political and religious opinions, and sexual orientation. Researchers should be especially compassionate when they ask questions that involve intimate issues and they should avoid placing informants under pressure. What is perceived as sensitive information can vary from one individual or group to the next.

14. The obligation to respect confidentiality

Research subjects are entitled to a guarantee that all information they provide about their private lives will be treated confidentially. Researchers must prevent the use and dissemination of information that could harm individual research subjects. Research material must usually be anonymised, and strict requirements must apply for how lists of names or other information that would make it possible to identify individuals are stored and destroyed. The requirement is based on the need for freedom combined with the protection of privacy. The existing legislation governs the use of certain types of information and sets limits of what kind of confidentiality a researcher can promise informants. Informants are to be informed if others can access the material. Individuals in the public eye may find freedom jeopardised by the increased media attention devoted to them. However, insofar as they have voluntarily sought public attention, or have accepted positions that entail publicity, their freedom cannot be said to be threatened to the same extent as that of the other people. Beyond this, consideration for privacy and for other involved parties, e.g. people's families require that the obligation of confidentiality must apply. The methodological requirements for verifiability mean that confidentiality cannot always be ensured in historical studies or studies of individuals. Where consent has not been obtained, researchers must exercise special care. In many cases, passive participation in research through studies of existing registers will represent a negligible threat to the freedom and privacy of individuals. However, such re-use of personal data usually requires consent if the study of

registers is to be supplemented by information obtained through active contact with the informants, or if the research generates sensitive new information on uniquely identifiable individuals.

15. The obligation to restrict re-use

Identifiable personal data collected for one particular research purpose cannot automatically be used for another research. Such data must not be used for commercial or administrative purposes. This requirement is based on respect for individuals' freedom and privacy. Re-use of personally identifiable data usually requires the consent of the research subjects. This does not apply to data that have been anonymised.

Anonymised data implies that names, personal identification numbers and other uniquely identifiable characteristics are removed so that the data can no longer be traced to an individual. This obligation to obtain consent does not, however, apply to links between anonymised registers.

16. Requirements for the storage of information that can identify individuals

Data related to identifiable individuals shall be stored responsibly. Such data shall not be stored any longer than what is needed to attain the objective for which it was processed. The storage of information about identifiable individuals usually requires that information be provided to and consent obtained from those concerned. Researchers shall consider the need for storing data that allows the identification of individuals. Where it is necessary to store such data, personally identifiable information should be stored separately and not electronically. The other electronically stored research material can contain a reference number to associate it with the data stored manually. Personally identifiable information (e.g. lists of names, field notes, interview material) shall be stored responsibly for a limited period of time, and then be deleted once it has served its original purpose.

17. Respect for posthumous reputations

Caution shall be exercised when deceased people are the subject of research. The fact that the deceased can no longer raise objections does not reduce the requirement for meticulous documentation. Out of respect for the deceased and their surviving relatives, researchers must choose their words with care. Graves and human remains must be treated with the utmost respect where research is concerned.

18. Respect for the values and motives of others

Researchers must show respect for the values and views of research subjects, even if they differ from those generally accepted by society at large. Researchers should not ascribe irrational or unworthy motives to anyone without providing convincing arguments for doing so. Research is often concerned with the behaviour and values of minorities, e.g. religious groups, ethnic minorities, youth groups or political subcultures. Researchers are under an obligation to take subjects' self-image seriously, and to avoid descriptions that diminish their legitimate rights.

19. **Researchers' responsibility for clear role definition**

Researchers are responsible for explaining to their research subjects the limitations, expectations and requirements that pertain to their roles as researchers. Participative

observation in field work can also lead researchers to become friendly and establish close relationships with (some) informants. Parallel roles may serve valuable purposes in research, but the use of information obtained by virtue of such roles for research purposes may require consent. Where relevant, researchers are required to make it clear that participation in the research does not affect entitlement to ordinary public services.

C. REGARD FOR GROUPS AND INSTITUTIONS

20. Regard for private interests

Researchers shall respect the legitimate reasons that private businesses, special interest organisations, etc. may have for not wanting information about themselves, their members or their plans to be published. It can be of great public interest to obtain information about how private enterprises and special interest organisations function in society.

Individuals and organisations are under no legal obligation to provide information except where specific statutory provisions apply to special types of information. If they refuse access, their wishes are to be respected. Notwithstanding, organisations should make their archives available for research.

Those who choose to undertake research on organisations that are basically opposed to the research must exercise the utmost care in their documentation and methods. Situations can arise in which researchers have reason to suspect abuse in connection with an activity.

All things considered, it can be ethically responsible to continue the research process if the abuse cannot be exposed or documented by other means. A researcher is under the same obligation as any other citizen to prevent serious infractions of the law.

21. Regard for the public administration

Public agencies should make themselves available for research into their activities. The general public's legitimate interest in the functioning of social institutions is one reason for giving researchers the greatest possible insight into public administration and government agencies. Public archives should be made available for research. Access can be restricted for reasons of personal protection, over-riding national interests or national security. Classified material should be declassified as soon as it is safe to do so.

22. Respect for vulnerable groups

Researchers bear a special responsibility for protecting the interests of vulnerable groups throughout the research process. Vulnerable and disadvantaged individuals and groups will not always be equipped to defend their interests in respect of researchers. Accordingly, researchers cannot take it for granted that ordinary procedures for eliciting information and consent will ensure individuals' self-determination or protect them from unreasonable suffering.

Furthermore, vulnerable groups may not want to be subject to research for fear of being viewed by the general public in an unfavourable light. Protecting a vulnerable group can sometimes be counterproductive. Such efforts may serve to protect society at large from gaining insight into processes that lead to discrimination and rejection.

Researchers who collect information about the characteristics and behaviour of individuals and groups should avoid using classifications or designations that give rise to unreasonable generalisation, resulting in practice in the stigmatisation of particular social groups.

The vulnerable groups include but not limited to the following:

(a) The minor: Parental consent is usually required when a minor (child) is involved in research.

(b) Imbeciles: The consent of the trustee or that of the parents is required when dealing with an imbecile of any degree.

(c) The sick: The consent of next of kin or spouse or that of the parent is required.

(d) Married Pregnant woman: The consent of the husband is required.

(e) Married: Consent of the spouse is required.

(f) Corpse/Dead person: The consent of the next of kin or spouse or that of the parent is required.

(g) Person living with disability: Privacy must be guaranteed.

(h) Special specie, such as albino, dwarf, lesbian, homosexual, hermaphrodites. Identity must be protected.

23. The requirement for independence

Researchers must not allow themselves to become dependent on informants. Research into social problems can reveal criticisable or illegal situations, e.g. plans to commit violent acts or failure to care for children, exposing researchers to conflicting, loyalties, particularly with a view to the obligation of confidentiality. Researchers must avoid complicity in unlawful behaviour, even if it were to benefit their research. Like everyone else and regardless of the obligation of confidentiality, researchers are legally bound to prevent serious future infractions of the law, for example, by reporting them to the police. Research on criminal communities can engender conflict between promises of confidentiality made to informants and the obligation to report ongoing or planned serious criminal acts. Such conflicts can be prevented by explaining the limits on the promise of confidentiality to the informants.

24. The preservation of cultural monuments

Researchers shall show due regard for preservation needs associated with all types of cultural monuments. The preservation of sites, monuments, artefacts, texts, archives, remains and information about times past is based on the interests of present and future generations in learning about their history and culture. In dealing with human remains from archaeological excavations, researchers should be especially aware of ethical problems associated with research on this type of material. Human remains from pre-reformation times are automatically protected under the Cultural Heritage Act, while more recent remains do not enjoy the same protection. All remains should, however, be covered by the same protection since they constitute important source material for future generations.

25. Research on other cultures and times

Research on cultures other than the researcher's own poses special requirements for dialogue with representatives and members of the culture under investigation. The requirement regarding the consent of individuals that live in the society being studied must be combined with knowledge about and respect for local traditions and the powers that be. Insofar as

possible, researchers should cooperate with the local inhabitants, members of the culture in question, and their representatives and local authorities. Wishes for local participation or control can engender conflicts relative to the research's requirement for quality and independence. This places stringent demands on the planning and implementation of such projects.

26. **Limits on cultural recognition**.

Researchers must weigh consideration for the recognition of cultural differences against consideration for other fundamental values and human rights. Naturally, respect for and loyalty to the cultures in which the research is being conducted do not mean that one must accept conditions such as discrimination or culturally motivated abuse. When undertaking a normative analysis of such conditions, a distinction must be made between a description of norms and practices in the culture being studied and researchers' normative discussions of these conditions in the light of defined value standards.

Researchers must exercise due caution and consider how it would be advisable to act when encountering phenomena such as culturally motivated assaults on life and health or infringements of other human rights.

D. THE RESEARCH COMMUNITY

27. Scientific integrity

Researchers and research institutions shall comply with and promote standards for scientific integrity. Dishonesty involves a contravention of the quest for truth in the name of science. Distinctions can be made between more or less severe breaches, from negligence and sordidness to academic misconduct. Examples of severe, intentional or grossly negligent breaches of standards include the fabrication and falsification of data and plagiarism. The requirement regarding scientific integrity applies in full to all types of research. Institutions are required to have routines that prevent dishonesty and promote honesty.

28. Plagiarism

Plagiarism of others' text, material, ideas and research results is unacceptable and constitutes a serious breach of ethical standards. In terms of research ethics, plagiarism involves stealing content from the works of other writers and researchers and publishing it as one's own. Researchers who use others' ideas or quotations from publications or research material, shall cite their sources. The grossest type of plagiarism is pure duplication. Plagiarism can nonetheless take other, more refined shapes, and apply to limited findings, ideas, hypotheses, concepts, theories, interpretations, designs, etc. Referring to another work earlier in one's text and then subsequently making extensive use of it without further reference is also plagiarism.

29. Good reference practice

All writers and researchers, regardless of whether they are amateur or professional, students or established researchers, shall strive to exercise good reference practice. The standards for citing quotations and referring to sources and literature differ from one subject to the next. Everyone is obligated to give the most accurate references possible to the literature they use. References should usually be to particular pages, paragraphs and chapters. This simplifies the verification of statements and arguments, including the use of sources. The subject areas and units that perform research are responsible for establishing and communicating rules for good

reference practice, as well as for facilitating understanding of such standards, ensuring compliance and reacting to infringements. Individual writers and researchers must practise their craft with intellectual integrity and deal with primary and secondary sources with honesty.

Supervisors bear a special responsibility for following up students' knowledge of and attitudes towards research ethics. Graduates should have developed sufficient professional self-criticism to ensure good reference practice in their future work.

30. Verification and subsequent use of research material

Research material should be made available to other researchers for verification and subsequent use. To discuss the 'shelf life' of researchers' analyses, other researchers must gain insight into the data and other relevant material, providing this does not involve an invasion of privacy or a breach of confidentiality (see also Sections 10 and 14).

Those responsible for collecting material generally have the first claim on its use (see also Section 33). Data collected based on public funding shall be made available to the public after a brief period.

31. Professional assessments

Professional assessments should reflect impartiality, objectivity, and transparency. All disciplines are characterised by competing schools of thought, and possibly even by disagreement on fundamental questions of scientific theory. Those responsible for the assessment of others' work must therefore be willing to seriously consider arguments and ways of thinking that are asserted by approaches other than their own. Researchers frequently participate in evaluations for academic posts. They consider master's theses, doctoral theses, project applications, articles in journals and the like. In such contexts, the judge must assess his or her own legal competence and work professionally and objectively.

32. Obligations in respect of colleagues

Researchers shall comply with research ethics standards, e.g. as regards transparency, impartiality and the willingness to be (self-) critical, and thereby to help promote good research. Research institutions shall strive to establish an atmosphere that is conducive to good research. Efforts should be made to maintain a culture based on constructive discourse and the productive management of professional disagreements. The well-balanced recruitment of researchers should be encouraged. Criticism must not be silenced because of the obligations of loyalty or obedience. Objectivity standards should be maintained, such as, for example, the requirement to avoid tendentious renderings of the work of researchers whose opinions differ from one's own. Research communities must sustain high methodological standards and encourage objective debate on the applications for and limitations of various methods and analytical techniques. Only those who have contributed to the documentation, analysis and writing of a scientific work shall be credited as co-authors or acknowledged for their contributions (see also Section 37).

33. **Student-supervisor relationship**

Supervisors are required to act in students' best interest, and not to take advantage of their dependence. This applies to professional findings as well as private lives. Supervisors must be cognisant of the asymmetry that exists in a supervisory situation. Supervisors' authority must

not be turned to their advantage or used to offend students. Supervisors must not take advantage of students' dependence.

In the event a supervisor would like to use material from a student's yet incomplete work in his or her research, the two must sign an agreement to that end. If the student has collected the material personally, it should only be used after the student is finished with the material, normally after taking the examination. The institution ought to draw up a standard contract for this. A supervisor must follow good reference practice in using the student's material and work. Supervisors should be careful how students' work is used by others before it is completed, and how the supervisor's participation is acknowledged.

Correspondingly, students ought to follow good reference practice when dealing with their supervisors.

34. The responsibility of supervisors and project managers

Supervisors and project managers must take responsibility for the research ethics problems their students or project members encounter. The responsibility of supervisors and project managers applies relative to participants that are affected by the project, e.g. research subjects. They must also take responsibility for problems that can arise for the person or persons who carry out the project if the research be considered a special strain on them. Supervisors and project managers also share responsibility for reporting the results of the projects. This responsibility also includes the clarification of challenges related to research ethics. (See also E and F.)

E. CONTRACT RESEARCH

35. The balance between contract research and researcher-driven research

This involves a general research policy responsibility to maintain a balance between different types of research, such as between different subject areas or between basic and applied research. Research institutions and individual researchers share responsibility for maintaining that balance as well as for informing and criticising, if so required, the players best suited for influencing the allocation of resources.

Research communities interact with the rest of society. Society funds research because it expects something in return. Political authorities give research institutions like universities and university colleges a high degree of autonomy to ensure that they can carry out free and independent research. Knowledge is a collective benefit. Were research to become overly privatised, society would suffer. This is because it is an important part of society's aggregate knowledge development. For that reason, there must be a balance between contract research and researcher-driven research (see also Section A).

36. The management of contract research

Public and private employers (principals) have a legitimate right to stipulate the parameters for contract research, if those parameters are not at variance with the requirements that apply to the research. However, that does not excuse researchers and research institutions from their share of the responsibility for the agreements they sign with principals.

Research institutions or researchers do not merely communicate their results; they also uphold the entire research community's credibility as a source of impartial knowledge. Research institutions and individual researchers have the right and obligation to point out any problems with the results, e.g. relative to planned decisions.

37. Research institutions and the individual researcher

Researchers who are part of larger research projects share joint responsibility for those projects. Individual researchers' contributions to research projects should be stated clearly. When research, and not merely contract research, is organised into large hierarchical projects, the relationship between individual researchers and project management is analogous to the relationship between the researcher/research institution and the principal. Where individual researchers at institutions and major projects experience a conflict between loyalty to their institution and ethically responsible methods, the point of departure must be that individuals share responsibility for what they are part of (see also Section 32). Copyright and the right to publish must be regulated by unambiguous agreements.

38. The independence of researchers and research institutions

Researchers and research institutions should maintain independence relative to their principal(s). Research institutions or researchers must avoid dependence on a principal that could undermine their impartiality. One inescapable source of dependence occurs when a principal funds research. This is especially true if an individual principal accounts for a significant share of the aggregate income of an institution or individual researcher. Accordingly, it is important to avoid a degree of congruence between self-interests and the principal's interests that is large enough to threaten one's ability to behave impartially (threat of self-interest).

The role of independent researcher e.g. at a university or university college, can in certain situations conflict with other roles researchers may have, e.g. the role of adviser or consultant (see the introduction about disciplines as clusters of activities). To the extent a researcher accepts an assignment that can undermine an institution's credibility, at the very least it is necessary to report the situation. In some situations, the conflict between roles will be so strong that the roles should not be combined.

39. Information about the funding of research

It is incumbent upon principals and researchers alike to inform the public about who is funding the research. It should be clear who is funding the research. Transparency in respect of funding could make it easier for researchers to safeguard themselves from unfair pressure from the funding party and thus ensure the researchers freedom and impartiality. Moreover, it is reasonable for principals to feel entitled to see that research they have funded is published.

40. The use of research results

Principals and researchers have a responsibility for preventing research results from being presented in a misleading manner. It is unethical to place limits on research to elicit particularly desirable results, or to produce research results in an intentionally skewed manner.

The principal must not be allowed to withhold research results so that the findings that are publicised give a distorted picture of one or more factors. Researchers must be able to protect

themselves against unfair pressure from the principal to draw conclusions and should under certain circumstances take advantage of their right to withdraw from assignments.

Principals must accept that researchers have the right to discuss their terms of reference as part of research reporting. The requirements for source material and valid reasoning are especially important when research can have consequences on the reputation or integrity of individuals or groups, or when it can affect political decisions. In such cases, it is especially important that researchers discuss alternative interpretations of their findings or point out scientific uncertainty. (See also Sections 1, 2, 3 and 45)

41. The right to publish

Knowledge is a collective benefit. Accordingly, as a rule, all research results should be published. It is also important that results can be verified. Publication is important for researchers' merit lists. If the principal would like to use research results to reach a broader audience, researchers can publish complete descriptions and results of the research project. This can be important both for preventing research results from being presented selectively or in a skewed manner, and for giving others an opportunity to verify the results.

Any limitations on the right to publish shall be stipulated by contract upon commencement of the project. (See also Sections 20, 21 and 45.)

F. SCIENCE COMMUNICATION

42. Science communication as a specialised task

Specialised research groups shall ensure that scientific knowledge is communicated to a broader audience outside the research community. Science communication involves communicating insights, ways of working and attitudes (the ethos of science) from specialised fields of research to individuals outside the field ('popularisation'), including contributions to social debates based on scientific reasoning.

This can refer to the communication of established insights into a subject along with results from recent research. Science communication is aimed at outsiders, whether they be specialists in other subject areas or individuals with no scientific background.

43. Requirements incumbent upon individuals and institutions

It is incumbent upon research institutions to pave the way for multi-faceted, comprehensive science communication characterised by high quality and relevance.

44. Interdisciplinary discussion and a democratic public.

One important aspect of science communication in modern society should consist of reciprocal popularisation (translation) between specialists from different fields of research.

Many of the major challenges facing society related, for example, to ecology, globalisation or human rights, call for the integration of different types of scientific knowledge. Although the public's level of education is continuously on the rise, that does not diminish the need for science communication.

In the light of the great complexity of reality, i.e. the limitations and scientific uncertainty related to individual disciplines, the standard for scientific humility should be at the core of science communication. Interdisciplinary and inter-institutional discussions should serve as a sort of extended peer review.

45. Participation in social debate and responsibility for how research is interpreted

Researchers ought to contribute to the public debate based on sound scientific reasoning. Such participation means that researchers use their scientific competency as grounds for contributions to the formation of public opinion. This can refer to information in an area that is up for debate, that one takes a well-grounded position on controversial topics, or that one tries to put new topics on the public agenda. Researchers do not usually have control over how the results of their research are used by others, but they do bear shared responsibility for how the results are interpreted, and thus how they can be applied in political, cultural, social and economic contexts. Accordingly, researchers should get involved in discussions about reasonable interpretations and the responsible use of research results. Other groups are also responsible for reasonable responsible behaviour in this context, e.g. information departments, the mass media, parties, special interest organisations, enterprises and administrative agencies.

Participation in social debate calls for high standards for impartiality, justification and clarity. There can be fuzzy transitions between participating in social debate as an expert and as an ordinary member of society. When professionals participate as ordinary members society, they should not use their titles or refer to specific scientific expertise.

46. The communication of results and verifiability

The requirement regarding verifiability applies equally to science communication and scientific publishing. Audiences for popular scientific presentations usually have neither the time nor the expertise to verify assertions made by research experts. This corroborates that the verifiability requirement must be just as important here as for scientific publications.

Foot/endnotes and literature indexes can weigh heavily on a text, but they can also help the interested reader to navigate through a large body of literature. It is also important to remember that specialists in other disciplines are part of the relevant audience, and that a large percentage of the general public has education beyond high school level.

47. The obligation to convey research results

Researchers bear a special obligation to convey research results to the participants in a comprehensible and responsible manner. Informants give something of themselves to researchers and are entitled to get something back. Informants should have an opportunity to correct any misunderstandings if possible. In certain cases, it is not automatically possible to convey the results in a form that is comprehensible for everyone, for example, if the results contain a lot of advanced statistics. In such case, researchers should adapt the results so that key findings and insights are conveyed in a manner that can be understood by the recipients.

4.1 HEALTH RESEARCH ETHICS COMMITTEE (HREC)

PREAMBLE

Definition of ethics within the context of human subject discipline

Human history is filled with numerous reports of abuse of research participants. The impetus to gain new knowledge frequently led to the testing of new chemicals, drugs and treatment modalities on humans. It is now widely accepted that any type of study involving humans must be carefully designed and monitored to protect the physical and psychological wellbeing of the participants. In addition to obtaining informed consent from each participant, scientists are required to monitor study participants closely and have strict procedures for reporting any adverse experiences during the study. Also, additional safeguards must be put in place to protect vulnerable populations, such as children, prisoners, and people with limited education or mental capacity.

Research ethics deal with the application of moral rules and professional codes of conduct to the conception, collection, collation, analysis, reporting and dissemination of research results. It also refers to acceptable code of conduct relating to subjects' right to privacy, confidentiality, and informed consent. These requirements were developed in recognition of the abuses of research subjects that had occurred in the past not only in Nigeria but also in both developed and developing countries. One of the ways of ensuring that research projects are conducted in an ethical way is review of protocols of research by properly constituted Research Ethics Committees (REC). The primary role of an HREC is to review protocols of studies involving human participants to ensure that they conform with internationally and locally accepted ethical guidelines. In addition, the REC is expected to monitor studies once they had begun and take part in follow-up action and surveillance until the end of the research. Committees have the authority to approve, reject or stop studies and to advice on required modifications to research protocols. The REC also performs other functions, such as setting policies or offering researchers about the importance of ethics in research. All research conducted by staff, students and visitors to the University on human participants must be of the highest ethical standard. Research projects on human participants have to receive approval before the project is commenced to reduce potential risks and document benefits for the community in which the research will be carried out. The ultimate goal of ethics in research is to promote high ethical standards in research for health.

The National Health Research Ethics Committee (NHREC) is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants in Nigeria. The UNIOSUN Health Research Ethics Committee (HREC) commenced activities in 2011 in accordance with the regulations of the NHREC.

The Research Ethics Committee in reviewing research proposal contributes to safeguarding the quality, dignity, rights, safety and well-being of all research participants because *respect for dignity* of all persons is a research principle. The REC's goal is never to **approve** the conduct of any research that has the potential to violate the rights of both potential and actual research participants. The work of the REC emphasizes the principle of justice such that benefits and burdens of research are distributed fairly among all groups in the society irrespective of gender, economic status, and culture or ethical considerations. The Committee is very independent from political, institutional or professional influences. It is competent, efficient and well-focused on timely reviews of proposals before the commencement of the projects. The committee also monitors implementation of approved research. The REC is concerned about the safety of participants, communities as well as the needs of researchers and relevant regulatory agencies and laws of the land.

ETHICAL PRINCIPLES

The code of Ethics on which the guidelines of HREC are formulated include the Nuremberg Code, the Belmont Report, the Council for International Organisations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research involving Human subjects, the 45 CFR part 46, the World Medical Association Declaration of Helsinki, as contained in the WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) and the Nigerian National Health Research Ethics Code (2007) among others. These guidelines are based on four Ethics principles which are of equal importance. These are:

(a) Autonomy (respect for human dignity; ability to make decision for oneself).
(b) Beneficence (obligation to 'do good' to participants/community).
(c) Non-maleficence (obligation to avoid harm to participants/community).
(d) Justice (distribution of benefits and burdens fairly).

Respect for Persons

In accordance with the Belmont Report, potential research participants should be treated as autonomous agents who have the right to decide whether or not they will like to participate in a research. The principle also acknowledges the fact that rights of persons with diminished capacity such as old age, physical impairment, lack of education, incarceration, debilitating financial and other social circumstances and mental illness must be protected from harm and risks. They must also be reassured of their right to voluntarily decision whether or not to take part in the research and to withdraw from it without suffering reprisals. The principle of respect for persons is emphasized in the informed consent context. This involves providing adequate information, giving ample opportunity to consider all options, sufficient time to respond to participants' questions, ensuring understanding of the information and obtaining participant agreement to take part in the research without undue influence or coercion. Freely giving consent should precede every research project. Written informed consent is preferred over verbal. In situation where written consent is unavailable recorded verbal consent is acceptable. Confidentiality of data collected from participants must be respected, safe guarded and treated as strictly private in all circumstances of research.

Beneficence and Non-maleficence

Beneficence deals with the responsibility of researchers to maximize benefits and minimize harm and risks to participants. Risks in research must be made clear to participants. Investigators must carry out reasonable assessment of potential risks and potential benefits involved in a research before implementation. The principle of beneficence also requires that investigators be competent enough to conduct the research and to safeguard the welfare of persons who participate in it to secure their physical, mental and social wellbeing.

Justice

Justice requires that equitable distribution among all segments of the society of both the burden and benefits. It is unjust and unethical to expose participants to risk and withhold its benefit from them. The Belmont Report states that ‘an injustice occurs when some benefits to which a person is entitled is denied without good reason', Research should be responsive to the needs of the people who participate in it and any product developed from such research must be made available to the participants. The principle of justice also requires fairness in the distribution of

both the benefit and risk of research. The burden and benefits of participation in research should be equitably distributed across the community. Research participants should be selected because of race, ease of access, or their compromised positions. The principle of justice requires inclusion of diverse elements of the population.

CLINICAL TRIALS

Preamble

In medicine, a clinical trial is a type of research study. It is synonymous with: clinical studies, medical research, and is an essential aspect of research bioethics. Clinical trial is defined as the systematic study in humans (patients or healthy volunteers) in order to discover or verify the efficacy and safety of medications or medical devices, biologics, or other interventions on patients in strictly scientifically controlled settings. CTs are required by Drug Regulatory Agencies (DRAs) such as National Agency for Food and Drug Administration Control (NAFDAC) in Nigeria and Food and Drug Administration (FDA) in USA for approval of new therapies. In recent times, there has been a steady rise in the number of clinical trials taking place in African nations including Nigeria. In CTs, both sponsors and investigators must be aware of ethical implications of these trials and abide by set standards. Being involved in clinical trials enables physicians to learn, become exposed to medical therapies and provide additional options or alternative treatments for their patients. The components of the clinical trial are the sponsor, the principal investigator, the research subject, the clinical research coordinator and the Drug Regulatory Agency (DRA). The empirical testing of the safety and efficacy of drugs either in treatment or research purposes is one essential aspect of research bioethics. To this extent, protocol submission and responsibilities of both sponsors and investigators are of importance. All protocols should adhere to the conditions stated earlier in this document.

Trials may be designed to assess the safety and efficacy of an experimental therapy, to assess whether the new intervention is better than standard therapy, or to compare the efficacy of two standard or marketed interventions. The trial objectives and design are usually documented in a clinical trial protocol provided by appropriate DRA.

REQUIREMENTS FOR CLINICAL TRIALS (CTs)

1. Ethical – This involves the following:

(a) Writing and submission of a protocol

(b) Full and informed consent of human participants

(c) Close supervision by appropriate Drug Regulatory Agencies

(d) All interventional studies must be approved by an Ethics Committee (IRB, ERC) before permission is granted to run the trial

2. Good Manufacturing Practice (GMP) – The part of the pharmaceutical quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use and as required by the product specification. All medicinal products and devices must pass GMP requirements.

3. Good Clinical Practice (GCP) – A standard by which clinical trials are designed, implemented and reported so that there is public assurance that the data are credible, and that the rights, integrity and confidentiality of subjects are protected. This must be ensured by investigators in all trials.

Design of CTs

Randomized Controlled Trial (RCT) – is the study design that provides most compelling evidence of a causal relationship between the treatment and the effect. In clinical trials, the investigators manipulate the administration of a new intervention and measure the effect of that manipulation.

Types of RCTs

Double–blind, placebo-controlled – This means that each study subject is randomly assigned to receive one of the treatments, which might be the placebo. Neither the subjects nor scientists involved in the study know which study treatment is being administered to any given subject. This is to prevent biases in administration of the drugs and the subsequent outcome of the study.

Phases of CTs

Pharmaceutical clinical trials are commonly classified into four phases (I-IV), and the drug development process will normally proceed through all four stages over several years. If the drug successfully passes through the Phases I, II, and III, it will usually be approved for use in the general population. It is not possible to draw distinct lines between the phases and diverging opinions about details and methodology do exist. Before pharmaceutical companies start clinical trials on drugs, extensive pre-clinical studies in animal models are conducted to ensure safety and dosage regimen.

Phase 0 trial – is a novel concept in CTs involving testing small, non-therapeutic amounts of drug to obtain preliminary pharmacokinetic information, in animals, and it helps to assist pharmaceutical companies in taking decisions on pursuing further development of the agent. The preclinical results must be made available by sponsor (Pharmaceutical Company) before the DRA approves clinical trials in human.

Phase I

This is the first stage of testing in human subjects (about 20-80) often in healthy volunteers. It assesses the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a therapy. These trials are almost always conducted in an inpatient clinic, where the subject can be observed by full-time medical staff. The subject is usually observed until several half-lives of the drug have passed. Phase I trials also normally include dose-ranging studies so that doses for clinical use can be refined. The tested range of doses will usually be a fraction of the dose that causes harm in animal testing. In some circumstances patients are used, such as with oncology (cancer) and HIV drug trials.

Kinds of Phase I trials:

a. SAD – Single Ascending Dose studies are those in which small groups of patients are given a single dose of the drug while they are observed and tested for a period of time. This is continued until pre-calculated pharmacokinetic safety levels are reached, or intolerable side effects start showing up (at which point the drug is said to have reached the maximum tolerated dose (MTD).

b. MAD – Multiple Ascending Dose studies are conducted to better understand the pharmacokinetics and pharmacodynamics of multiple doses of the drug. The dose is subsequently escalated for further groups, up to a predetermined level.

c. FE – Food effect that involves a short trial designed to investigate any differences in absorption caused by eating pre-dose, and its effect on the pharmacokinetic profile.

Phase II

This is a therapeutic pilot study performed on larger groups (20-300 patients) once initial safety of therapy is confirmed in phase I trials. It assesses clinical efficacy (or short – term safety) of the therapy; as well as to continue Phase assessment in a larger group of volunteers and patients. The development process for a new drug commonly fails during Phase II trials due to the discovery of poor efficacy or toxic effects. Design includes comparative active-control and placebo-controlled trials.

Phase III

This is randomized controlled trials (RCTs) on a large number of (possibly varied – multi-centred) patient groups (300 -3000 patients or more depending on the condition) and are aimed at being the definitive assessment of the efficacy of the new therapy, in comparison with current 'Gold Standard' treatment. It determines short and long – term safety/efficacy balance of formulations of the active substance, as well as the overall and relative therapeutic value.

The profile and more frequent adverse drug reactions (ADRs) must be explored. Phase III trials are the most expensive, time-consuming and difficult trials to design and run; especially in therapies for chronic conditions. Once a dug has proven satisfactory over Phase III trials, the trial results are usually combined into a large document ("Regulatory Document") containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life submitted for review to various regulatory authorities in different countries.

Phase IV

This is post-launch safety surveillance or post marketing surveillance (PMS) and ongoing technical support of a drug. Phase IV studies may be mandated by regulatory authorities or may be undertaken by the sponsoring company for competitive or other reasons. Post-launch safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and timescale than was possible during the initial clinical trials. Such adverse effects detected by Phase IV trials may result in the withdrawal or restriction of a drug.

Guidelines, Procedures and Protocol for Clinical Trial of drugs in Nigeria – NAFDAC requirement

All novel drugs must undergo clinical studies in Nigeria before being granted marketing authorization by NAFDAC.

Guidelines are pre-requisites to ensure the ethical and scientific integrity of studies and research involving human subjects, and for generating valid observations and sound documentation of findings.

Objectives of guidelines are to:

(a) Serve the interests of the parties actively involved in the research process.

(b) Protect the rights and safety of subjects, including patients.

(c) Ensure that the investigations are directed to the advancement of Public Health objectives in Nigeria.

They apply specifically to studies undertaken in the cause of commercial drug development both prior to and subsequent to product registration.

Other important terminologies include:

Adverse Event (AE) – Any undesirable experience occurring to a subject, during clinical trials whether or not considered related to investigational product(s). Pre-trial data and information must be supplied to DRA and ERC.

Adverse Drug Reaction (ADR) – A reaction which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. In the case of clinical trials, injuries by over-dosing, abuse/dependence and interaction with other medicinal products should be considered as ADR.

Investigators – These are persons responsible for practical CT. They must be qualified person legally allowed to practise medicine/surgery or a research scientist in the area of biology, pharmacology or pharmaceutical science trained and experienced in research. He/she must have high ethical standards, integrity and be accountable to sponsor and DRA.

Case Report Forms (CRF) – A record of the data and other information on each subject in a trial as defined by the protocol. The data may be recorded on any medium, including magnetic and optical carrier, provided there is assurance of accurate input and presentation, and allows verification.

Documentation – All records in any form (including documents, magnetic and optical records) describing methods and conduct of the trial factors affecting the trial and the action taken. These include photocopies of submission and approval from the regulatory authorities and the Ethics Committee, Investigator(s) Curriculum Vitae, Consent Forms, Monitor Reports, Audit Certificates, Relevant Letters, Reference Rangers, Raw Data Completed CRF and the Final Report.

Accountability – Investigational product accountability is a necessary requirement for investigators and sponsors engaged in clinical trials especially with cancer agents, which sometimes fall under controlled drug substances. Accountability concepts such as storage, rational drug use, compliance, reconciliation and disposition.

Inspection – It is the responsibility of the Regulatory Authority to conduct announced or unannounced inspection visits at clinical trial sites. Such inspections shall consist, among other monitoring parameters a comparison of procedural practices of the clinical investigator with those set in the protocol.

Final report – This is a complete and comprehensive description of the trial after its completion, including a description of experimental (including statistical) methods and materials; a presentation and evaluation of the results and statistical analysis including critical statistical clinical appraisal.

Summary of Investigators' roles

(a) The investigator will be required to ensure that the protocol is accompanied with a certificate or clearance from the body that regulates drug usage and storage in Nigeria, in this case, NAFDAC and Federal Ministry of Health.

(b) The investigator as a matter of importance should be responsible for the appropriate medical care and safety (standard of care at the trial site) at both during the clinical trial and after for as long as possible depending on the nature of the disease.

(c) The investigator should ensure unbiased selection of the participants such that it is not based on other consideration apart from scientific criteria.

(d) The investigator, apart from general qualification to conduct such research must be thoroughly familiar with the properties, effects and safety of the drugs under investigations. This prerequisite knowledge must include pre-trial data as documented in the literature and awareness of all relevant current data.

(e) The investigator must ensure that clinical trials are done under conditions that guarantee adequate safety for all enrolled participants. To this extent clinical trial site used should be appropriate to the stage of development of the product under investigation and potential risks involved.

(f) Investigator(s) should be responsible for safe handling of drugs, apparatus, and instruments pertaining to clinical trial.

(g) All drugs and other investigational products must be duly accounted for and must be duly disposed of by the investigator(s).

(h) In the event of conflict of interest on the part of the investigator(s), it is mandatory that such interest be declared.

(i) Investigator(s) should ensure that participants' bio-data and trial profiles are kept in utmost confidentiality.

(j) When there are breaches in the approved protocol or where hazards out-weigh potential benefits, the research should be terminated and report sent immediately to the HREC.

RESPONSIBILITIES OF STAKEHOLDERS

a. The Institution shall:

(i) establish, nurture and maintain the committees.

(ii) facilitate funding and support for the committee secretariat and Staff.

(iii) share the burden of protection of human participants and that of the investigator.

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

b. The Ethics Review Committees shall:

(i) understand and apply the rules/guidelines;

(ii) review, modify and make appropriate recommendation(s) to ERRB appropriately;

(iii) conduct continuing review of approved projects;

(iv) observe the consent process and verify changes;

(v) suspend or revoke approval where applicable;

(vi) work with investigators to ensure that they develop ethically sound protocols;

(vii) provide training/education as soon as possible for both members and investigators;

(viii) provide effective communication of the decisions of the committee to investigators;

(ix) report all adverse events and serious non-compliance to the Osun State University Research Management Board.

c. The Researchers shall be:

(i) accountable for the consequences of their research projects.

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

(iii) professionally competent.

(iv) responsible for ensuring the use of sound methodology in their work as flaws in their methodology and design will result in a waste of human, monetary and other resources which is unethical.

(v) responsible for providing full information about the study to the ethics committee and human participants.

The information to be provided when submitting a clinical trial proposal for ethical review should include:

(i) Title/theme of research

(ii) Required experience of Human subject participants

(iii) Length of part participation

(iv) Risk/injuries/distress involved in the study

(v) Benefits (if any)

(vi) Compensation (if any)

(vii) Voluntariness for participation and withdrawal with no reappraisal.

(viii) Notification of an alternative treatment e.g. in medical interventions.

(ix) Confidentiality of identity/information/data

(x) Translation to local language of research protocol for the understanding of Human participants.

d. The Participants:

Are expected to request for information in order to have a clear understanding of the study and to ask question about:

(i) Required experience for participation

(ii) The research procedure

(iii) The purpose of the study

(iv) The length of participation

(v) Compensation (if any)

(vi) The risk and injuries that may be involved

(vii) Potential benefits of the study and

(viii) To clarify all doubts before accepting to participate in the study

e. **The Communities:**

The university strongly supports the ethical principle that communities must participate in research. To this end, it would be considered culturally appropriate for researchers to involve the communities before and at every stage of research implementation. Consultation is required with the communities in which their research works are being carried out.

Permission from a leader(s) of the community is required before any research is discussed with the community or individuals. The leader of the community is considered to have the authority to encourage enrolment of participants in research. In each of these circumstances, to seek consent from an individual without seeking assent from leader(s) of the community, or creating public acceptance of research, may be considered disrespectful and may harm relationships within that community and between a community and researchers. The purpose of the community participation should be clearly explained to the appropriate community leader before project inception. However, this community consent does NOT replace individual consent which is mandatory.

f. **Sponsors:**

Most researchers, depending on the scope (for example clinical trial) receive a substantial sponsorship from both local and international bodies. In order to ensure that acceptable ethical standards are followed in such sponsored studies, the UNIOSUN ethics policy states as follows:

(i) That it is mandatory that such protocol be subject to independent ethics review in both the host site where the research will be conducted (in this case Osun State University as well as the sponsor's country(ies).

(ii) If a sponsor provides funding, a mechanism must be in place to ensure that the funds are being used in an ethically acceptable manner.

(iii) However, the country in which the research is to be conducted must also be satisfied with the ethical acceptability of the research.

(iv) In the event of difficulties, where the research ethics committees in the host site are asked to review research before it is reviewed in the country of the sponsor. There should be an assurance that when such studies are no longer sponsored after the review process, a reimbursement of funds used should be made.

(v) Ethics committees are not and should not be under any obligation to place themselves under pressure to accept the sponsor's opinion regarding submitted protocol.

(vi) If the ethics review committee from a sponsoring country does not approve the research, the sponsor cannot fund it. If a research ethics committee from a host site does not approve the research, then the research cannot be conducted within that country despite approval from the sponsoring country.

GUIDELINES FOR THE COMPOSITION OF HEALTH RESEARCH ETHICS COMMITTEE

Membership guidelines:

Procedures for identifying and recruiting EC members are guided by the International and National Ethics Code of Conduct. The responsibilities expected of the members should be well outlined. The person responsible for making the appointment and the procedure for selection should take note of membership requirements. Conflict of interest should be avoided and transparency entrenched in this regard. Terms of appointment should include the duration, guidelines for renewal of appointment, disqualification procedure and replacement procedure. Conditions of appointment should also be drawn to include the willingness of members to publicise their names, professions and affiliations. It should also include reimbursement to members for their work. A confidentiality agreement on meeting deliberations should be signed by all EC members including the administrative staff. Quorum requirement for reviewing and decision making should be clearly stated. This should include the minimum number/proportion of membership to form a quorum (one-third of total number of members). Stipulated professional requirements (e.g. physician, lawyer, statistician, and lay-person) must be included with gender and religious balance; alternates and independent consultants appointed for their expertise in ethical, legal aspects, specific diseases and methodologies or may be representatives of communities, patients or special interest groups. The initial and continuing education of EC members are extremely important. Training should be linked with other ECs in the zone, the region and the country to lead the way for optimal research.

Composition of Health Research Ethics Committee (HREC)

The membership of HREC shall be as follows:

(i) Chair: To be appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor (ARIP)
(ii) Co-Chair: Chairman Medical Advisory Committee (CMAC) (Statutory)
(iii) Legal Officer
(iv) Two academic staff members from each of the Faculties of the College of Health Science, namely: Basic Medical Sciences, Basic Clinical Sciences, Clinical Sciences.
(v) One academic staff member from each of the following Faculties: Social Sciences and Law
(vi) One Statistician.
(vii) One member –Pharmacy Department of the Teaching Hospital
(viii) One member – Nursing Department
(ix) Two Community Representatives – Laypersons (1 Male and 1 Female)
(x) Secretary

The consent document must be clearly written and/or verbally explained so as to be understandable to participants (in the local language, wherever applicable). The language must be non-technical. Unavoidable scientific, technical or medical terms must be plainly defined and explained. It is the PI's responsibility to ensure quality of consent procedure.

Components of informed consent are:

(a) Information: Details provided to the participants must be comprehensive.

(b) Comprehension: Investigator must ensure that the informed consent process is clearly understood by the participants/guardian before accepting to participate in the study.

(c) Voluntariness: All study participants must volunteer

(d) Competence: All study participants must have competence (except those with diminished capacity, to make informed decision to enrol or decline involvement in a study). Capacity for participation may be evaluated in terms of age, mental or physical ability among others.

Content of Informed Consent Form:

(a) Name and Address of Principal Investigator

(b) Person to contact for answer to questions, or in event of research related injury or emergency should be clearly stated with full address and telephone numbers.

(c) Purpose of Research must be clearly stated.

(d) Procedures must be explained in simple words describing details of what the participants would be expected to undergo. The numbers of times that the sample will be taken or questionnaires administered must be stated.

(e) 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 also be advised as to the availability of the product after discontinuation of the study, indicating possible cost implication or whether drug would be available to the patients free of cost.

(f) Foreseeable risks or discomforts to the participants must be explainable in full. Such risks include physical injury, possible psychological, social, emotional, economic harm, discomfort, or inconvenience. If risk is unknown, it should be so stated.

(g) Length of time that the participant is expected to participate. If participant is expected to participate over a long period of time, it should be clearly indicated. Any new information that develop 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.

(h) Treatment for adverse events: Explain that therapeutic measure would be available to the participants in case of adverse events or injury as a result of his or her participation in the study. Should a disease condition (or a comparable social condition) be diagnosed in the course of a study, it is the responsibility of the PI to refer the affected participant for appropriate care. All research-related adverse reactions are the financial responsibilities of the researchers.

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

CONFIDENTIALITY

UNIOSUN recognizes the ethical principle of confidentiality to mean keeping information given by or about an individual in the course of conducting a research or a professional

relationship secure and secret from others. To this extent, it shall ensure that:

(a) Any research data, either in paper form or electronic, including medical records and biological samples shall be kept in such a way that no unauthorized persons have access to them.

(b) No description traceable to research participants shall be done without the necessary precaution.

(c) A comparable standard or mechanism should be in place to ensure the confidentiality and security of personal information concerning research participants.

(d) Information of research participants should be anonymised to a large extent.

(e) How the data/samples will be obtained, and the purposes for which they will be used should be adequately discussed in any submitted research protocol before approval.

(f) Countries or sponsors to which the data/samples will be sent should be adequately discussed in any submitted research protocol for the review process and approval.

UNIOSUN recognizes that certain conditions might be possible when the principle of confidentiality can be ethically breached. Such conditions include cases in which:

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

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

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

(d) The researcher or professional knows or suspects that an individual is harming himself/herself.

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

(f) The research or professional knows or suspects that a minor is being exploited or abused by others.

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

Voluntary Participation

Respect for persons is a fundamental ethical principle.

(a) Osun State University Ethics Policy therefore believes that no research should be conducted against a person's wishes.

(b) His or her consent to participate in research must thus be obtained voluntarily.

(c) No potential participant in any research should be made to partake in any study by any form of coercion.

Participation/Rights to withdraw

The Osun State University recognizes the research principle that research participants have the right to withdraw from any initially given consent without any penalty or withholding any benefits. To this extent,

(a) At the beginning of any study, investigators should make clear in their protocol a plan to explain to participants their right to withdraw from the research at any time, irrespective of whether or not some compensation has been offered.

(b) Research participants have the right to request that their data, including recordings, be destroyed. There are however exceptions to certain observational or organizationally designed studies. Nevertheless, the investigator must attempt to ensure that participants (including children) know of their right to consent or withdraw. This should be acknowledged

Signature/ThumbPrint

The final stage in the process of Informed Consent is to append the signature or thumbprint. 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 thumbprint as a witness. Investigators should be aware of the cultural attitude towards certain participant attributes (see appendix II)

Consent Process for Special Populations

The Health Research Ethics Committee (HREC) shall require that particular care be taken in plans to enrol participants who are classified as special and vulnerable populations such as children (under 18); pregnant women; human foetuses; sex workers; physically and hospital patients; mentally challenged persons; students; infant (under the age of one year); the elderly (ages 60 and over); illiterate persons and institutionalized persons such as prisoners. When dealing with any of these populations; investigators are required to use a written or verbal consent/assent form. The protocol submission form must, however; clearly indicate the appropriate category of special population to be included as research participants.

CONSENT AND ASSENT FROM CHILDREN

Individuals under the age of 18 years cannot legally consent to be involved in research protocols. The permission 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 the 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, the 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 protocol, which must be explained to him or her in a language the child can understand. This personal assent must be documented on the written consent form and, as appropriate, in the child's medical record.

Minimal risk is defined as, 'the probability and magnitude of harm or discomfort anticipated which are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

PREGNANCY CLAUSE

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 participant's 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.

REVIEW PROCEDURE

Committee Procedures

(i) The Committee shall meet at least once a month for proposal reviews and approvals.
(ii) 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 element of review should include 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 and Approvals

Types of Reviews

Ethics Committee should specify the procedure for each of these reviews. Three types of reviews are conducted by the HREC. These are Exempt, Expedited, and Full Review. (45 CFR 46 Code).

(a) Exempt Review: Exempt is provided to research proposals in which there is virtually no risk to the participants **(e.g. routine physical examination such as checking body temperature or blood pressure)**.
(b) Expedited Review: This type of review involves research with minimal risk or request for minor changes in already approved proposals. CHAIR/Designee can review.
(c) Full Review: This category of review is recommended for research in which there is more than minimal risk to participants (such as invasive procedures);due attention must be paid to the process of selection of participants, informed consent procedures; examples of more than minimal risk include research involving invasive procedures such as blood sampling, tissue biopsy etc.

Types of Approvals

As part of its review of a protocol or amendment, the committee will assign a status to each protocol. That status will be one of the following:

(a) Approved – If full approval is granted, the investigator may begin the research proposed in the protocol.
(b) Pending Conditional – A "Pending–Conditional" status may be stipulated, requiring modifications in the protocol and/ or consent form before initiation. No research may be started until all conditions have been met and a formal approved has been obtained from the Committee.

(c) Pending Deferral - A deferred protocol must be substantially revised and resubmitted to the Committee. No research may be started until all conditions have been met and formal approval has been obtained from the Committee.

(d) 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 a severe or unnecessary risk to the participants.

Conditions for Approval

(a) Approval is given for a specified period of not more than one year in the first instance. 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.

(b) Approval is given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being affected.

(c) Approval is given on the condition that a copy of the final report of the research project is lodged with the HREC for its information and record.

(d) Approval is given on condition that researchers accept to notify the Review Committee if and when a project is curtailed, terminated or completed by sponsors or other regulating authorities of the project.

(e) 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.

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

Challenges of Research

Research must function with honesty and integrity within the ethical acceptable framework at all times. Academic dishonesty including any of those listed below is regarded as serious offences. Conflict of interest can occur in research when the professional judgement is unduly influenced by other interests such as financial gains or personal status. This is sometimes unavoidable but must be carefully managed by disclosure and transparency for the result of the research and the well-being of the participants. Researchers must pay particular attention to issues of travel and conference sponsorship, recruitment fees, co-authorship of article, funding for facilities. Some of these issues have been addressed earlier under major policy issues and operations.

These include:

(i) Conflict of interest
(ii) Competence of Investigator
(iii) Scientific Integrity and Misconduct
(iv) Plagiarism
(v) Fabrication
(vi) Intellectual Property Rights
(vii) Disagreement between two ethics committees.

4.2 SOCIAL SCIENCES AND HUMANITIES RESEARCH ETHICS COMMITTEE (SSHREC)

Preamble

Research involving any discipline in social sciences and the humanities (which in this instance includes Education, Humanities & Culture, Law and Management & Social Sciences) shall be guided by the following four principles: respect for persons; justice; beneficence and non-maleficence**.**

Research offences in the Social Sciences and Humanities shall include but not limited to the following:

Fabrication –Fabrication involves making up data or results and recording or reporting them as factual results.

(ii) Falsification –Falsification entails manipulation research materials, equipment, or process, or changing or omitting data or results such that the research is not accurately represented in the research record.

(iii) Plagiarism – Plagiarism is the appropriation of another person's ideas, self, processes, results, words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts, including self-plagiarism.

It is expected that all researchers should ensure proper conduct of their studies as not to fall foul of these research offences otherwise would qualify for professional misconduct with its regulated penalty as contained in the University's Conditions of Service and the extant laws.

KEY AREAS COVERED BY THE COMMITTEE

The SSHREC shall function accordingly as follows:

(i) Communicate and enforce research ethics standards,

(ii) Convey the Guidelines for Research Ethics to the staff and students, and ensure training is provided on research ethics and the relevant acts of law that govern research. This will promote reflection on research ethics.

(iii) Take responsibility for researchers to follow the Guidelines for Research Ethics. They must have specific procedures to handle suspicions and accusations related to breaches of the Guidelines e.g., by creating committees to deal with scientific dishonesty, under their auspices.

(iv) Enforce laid down procedures in the event of breaches of research ethics standards.

(v) Review, modify and make appropriate recommendation(s) to ERRB appropriately.

TO WHOM DOES THIS CODE APPLY?

The SSHREC guidelines contain standards that apply to:

(i) Teaching and non-teaching staff of Osun State University intending to engage in behavioural research.

(ii) Undergraduate and postgraduate students registered as students in the Osun State University, interested in behavioural research.

(iii) Other researchers who are not members of the Osun State University community but intend executing any behavioural research within the University.

(iv) Research institutions, funders of research and other appropriating authorities in support of behavioural research affecting the Osun State University community.

COMPOSITION OF SSHREC

The membership of the SSHREC shall be as follows:

(i) Chair: A Professor from the humanities or behavioural sciences (appointed by the Vice-Chancellor of the recommendation DVC (ARIP)

(ii) Two experienced behavioural scientists from each of the Faculties of: Social Sciences, Education, Public Health and Arts (especially Philosophy and cultural studies), Faculty of Clinical Sciences (especially Psychiatry).

(iii) One Statistician

(iv) One lawyer

(v) Two community representatives (laypersons; 1 male 1 female)

(vi) Head of Research Ethics & Integrity Unit, (Secretary and Member)

EXEMPTION FROM REVIEW PROCESS

The following shall be exempted from the SSHREC review process: searches for existing literature, quality assurance activities or evaluation project design for self-improvement or program evaluation not meant to contribute to generalisable knowledge, interviews of individuals that focus on things not people. (e.g. questions on policies)

Process for exemption

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

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

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

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

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

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

Expedited Approval

Expedited review procedures can be considered when research activities present no more than minimal risk to human subjects. Inclusion on the expedited approval list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects e.g. collection of blood samples by finger prick.

(i) Prospective collection of biological specimens for research purposes by non-invasive means.

(ii) Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(iii) Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as or medical treatment or diagnosis)

(iv) Collection of data from voice, video, digital, or image recordings made for research purposes.

(v) Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

When Expedited review Categories do not apply

The expedited review procedure may not be used where identification of the subjects and /or their responses would reasonably place them at risk of criminality or civil liability or be damaging to the subjects or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Full Approval

Full approval shall be granted after the author/researcher has satisfied all ethical considerations as suggested by the reviewers of such protocol and this shall be granted at the consideration of a general meeting of SSHREC.

Process for Review of Multi-Institutional Research:

This is as contained under the section on sponsor.

Requirement for continual review of Protocol

Good ethical practices prescribe a continuous review process. All projects, particularly those large in scope and/or of prolonged duration shall enjoy continuous review process by SSHREC. Such projects through its principal investigator shall submit periodic report 6 monthly to the SSHREC for the purpose of review and approval for the continuation of such projects.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS (PI), CO INVESTIGATORS AND OTHERS

Principal investigators are individuals who have a formal appointment (Teaching or Non-teaching) at the Osun State University, Nigeria, or registered students of the University. The PI must be a full Professor or a PhD holder. The PI is responsible for the overall conduct if a research, including any modification to an earlier submitted proposal. The PI is the correspondent person with the SSHREC. Any investigator, other than the PI, is designated as a

co-investigator. Such investigator may carry out procedures performed on research participants, like conducting interviews, focus group discussions, administering questionnaire schedules, etc. However, the PI must be directly responsible for the activities of all research personnel.

The Investigator must submit a detailed protocol comprising the following information:

(a) A clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.

(b) A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.

(c) A statistical plan

(d) The criteria for terminating the study, and

(e) Details of the procedure for obtaining informed consent and safety of participants

(f) The presumed benefits to participants and any possible risks involved in participating

(g) Evidence that the investigator is qualified and competent to execute the study, or works under a competent supervisor, and that the investigator has access to adequate facilities for collecting primary or secondary data as required of the research.

(h) Describe how research outcomes will be evaluated and disseminated.

STANDARD OPERATING PROCEDURES (SOP)

The review committee shall be led by a Chairman,

(a) The Chairman of the SSHREC must have been formally trained in Research Ethics, preferably with a certificate/ diploma or degree.

(b) A minimum of two reviewers (three or more is preferred) shall review any proposal submitted.

(c) Consensus regarding the scientific acceptability of a submitted proposal (if there is no initial consensus, some group discussion regarding the proposal must take place)

(d) Students' research projects may have students included on the review committee, if desired. Evaluations of student research projects shall be done by a subcommittee based in each of the faculties that constituted SSHREC. The subcommittee shall have its members as constituted by the Dean of the faculty.

(e) The review may also be done within the context of a course, provided that all the criteria below are considered.

The SSHREC shall review and approve all research involving humans and subjects before it is initiated. This shall normally involve:

(a) A research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(b) Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(c) The following categories of people may submit protocol to SSHREC: faculty member, staff and students; as long as the research project satisfies a requirement imposed by the University as the condition for the award of a degree or completion of a course of study in the University or for expanding frontiers of academic knowledge.

(d) The procedures are performed with or involve the use of facilities or equipment belonging to the University patients, students, staff or facility;

(e) The protocol narrative must be detailed enough to enable the SSHREC objectively evaluate the scientific merit of the proposed research and potential risks and benefits to research participants.

(f) The protocol should be typed and paginated, not exceeding 10 pages, including references. Four copies of the protocol, an electronic version, and a one-page summary should be submitted to the SSHREC Office.

For the benefit of doubt, the following sections are essential:

A cover page specifying:

Research Title, Full name, Qualifications, Sponsors, Collaborating Institutions of Investigators corresponding Investigator; who is the PI of the protocol and bears responsibility for the research.

Background of the Study

(i) Brief literature on review on the subject matter

(ii) Statement of Research Problem

(iii) Objectives of the Study

(iv) Relevance of the Study

(v) Methodology

Study Design

(vi) Stating clearly the nature of the study –descriptive experimental, longitudinal, correlational, etc.

Participants:

(vii) Study population, sample size determination, sampling techniques

Instrument for Data Collection:

(viii) Describe the instrument, e.g. questionnaire, including standardization procedures. A sample of this should be included in the protocol.

(ix) Data collection procedure, including pretesting/pilot testing

(x) Data analysis package to be used

Ethical Considerations:

(xi) This should be clearly stated in the protocol as a separate section

(xii) Informed consent form: explain how it will be handled

Translation of research material:

If any, explain how it will be made valid and reliable.

Components of informed consent

Before the commencement of a research involving individuals or groups, the free and informed consent of the participants must be obtained. Thus, the researcher is responsible for:

(i) Introducing the theme or subject comprehensively with adequate information concerning the purposes; methods, demands, risk, duration and inconveniences of study.

(ii) Noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.

(iii) Obtaining appropriate consent from relevant community leaders and/ or recognized spokespersons.

(iv) Ensuring that in a situation where a participant lacks the competence to consent, a person with the legitimate authority to decide for that participant is provide with that information and may exercise that choice.

(v) Taking into special consideration consultation with state/Federal/local agencies with regard to the Import of the research and the sensitivity to the political and socio-cultural of the study areas.

(vi) Obtaining letter of introduction from appropriate authorities/Institutions.

Consent in Research and Power Relations

The interactions between researchers and informants are often characterized by power relations. Researchers should be aware of special challenges that could arise in peculiar circumstances, such as professional colleagues or teacher and students. In these cases, researchers should be prepared to offer assurance that refusal to participate in, or a decision to withdraw from the research, will not lead to any penalty or discrimination.

Consent Process for Special Populations

Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is sufficiently competent. Otherwise, the person's guardian or any other legitimate authority must give consent on his/her behalf.

Consent and Assent from Children

Informed consent to participate in research by a child or young person must be obtained whenever s/he has sufficient competence to make this decision, otherwise, parents/guardian or an organization required by law could make such decision on behalf of the child or young person. "A person below 18 years is not considered an adult; hence the researcher will need the consent of a parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years (that is, assent) without parental consent in specific circumstances.

Process for Amendment of Research

The committee shall require that applicants apply for permission to amend research protocols in any of the following circumstances:

(i) Where there are changes in any part of the research protocol
(ii) Where there are changes in named members of the research team
(iii) Where there are changes in research sites
(iv) Where there are changes in the sponsorship, institutional guidelines, institutional structure, the committee's requirements, national laws or exigencies that impact on the ethical conduct of research

The ethics committee shall require that researcher submits an application for original research approval where in its opinion, the proposed amendments are substantial, such as, but not limited to change in inclusion or exclusion criteria, sample selection, intervention, randomization and outcome measures. Under no circumstances shall the researcher deviate from approved protocol, except such as is necessary to eliminate immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of the ethics committee within TWENTY-FOUR (24) hours of such changes.

Process for suspension of research

The ethics committee shall have power to suspend any research that is not being conducted:

(i) In accordance with SSHREC's requirements;
(ii) In accordance with the existing legislation;
(iii) In accordance with existing institutional guidelines; or
(iv) Where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the ethics committee's decision and shall be reported within FOURTEEN (14) days to the researcher(s) institution, sponsor(s) and the UNIOSUN Ethics Research Review Board (ERRB).

Researcher(s), institution, or sponsor(s) shall be entitled to ask for reconsideration of the decision of the ethics committee to suspend research within FOURTEEN DAYS (14) days of receipt of notification.

4.3 ANIMAL CARE AND USE RESEARCHERS ETHICS COMMITTEE (ACUREC)

PREAMBLE

Animal experimentation is fundamental to the biomedical sciences, not only for the advancement of man's understanding of the nature of life and the mechanisms of specific vital processes, but also for the improvement of methods of prevention, diagnosis, and treatment of disease both in man and in animals as well as animal production.

The University shares the society's concern that the use of laboratory animals as research subjects in biomedical science must be justified by the assurance that the potential benefit to either humans, animals and/or the environment outweighs the potential harm to the animal subjects. Each research proposal must therefore be supported by a formal evaluation (an ethical

analysis) of harm to animals/benefit to humans, animals or the environment, which will determine if the overall likely benefit will outweigh the potential harm to the animals. Furthermore, justification for causing psychological or physical distress, illness or pain to animals should be based on any explicit or implicit assumption that animals experience these conditions in qualitatively different ways to humans.

Animal-based research should thus be appropriate and use no more animals than is necessary, as encapsulated as the four Rs of Replacement, Refinement, Reduction and Responsibility. Therefore, all scientists are urged to consider techniques that use minimal numbers of animals for research, institution of the lowest appropriate dose of drugs, medicaments, microbes, protozoa, viruses, feed components or other agents on animals. Alternative methods to animal experimentation such as computer, mathematical and in vitro modelling should also be considered. The 4th R (Responsibility) is a fallout of the fact that animal-based research has emergedinto a new era of performance-based outcomes, which reflects integrity, honesty, and scientific correctness in appropriate and reasonable use of laboratory animals; researchers must take responsibility for these.

The use of animals is also indispensable for testing the potency and safety of biological substances used in human and veterinary medicine as well as animal production and for determining the toxicity of the rapidly growing number of synthetic substances which may represent a hazard to health. This extensive exploitation by humans of animals implies philosophical and moral problems that are not peculiar to their use for scientific purposes, and there are no objective ethical criteria by which to judge claims and counterclaims in such matters. However, there is a consensus that deliberate cruelty is repugnant.

FUNCTIONS OF ACUREC

The Animal Care and Use Research Ethics Committee (ACUREC) is to provide oversight and assistance in ensuring compliances to all laws, regulation and policy governing the care and use of animals for research, teaching and testing.

KEY AREAS

(i) Evaluate and approve, subject to possible modification, or reject written proposals for animal studies submitted for ethical review.

(ii) Monitor, inspect and assess the acquisition, transport, production, housing, care, use, humane killing and disposal of animals, including breeding stocks.

(iii) Review research facilities program for humane care and use of animals once every two years

(iv) Develop acceptable standards for the establishment and maintenance of animal study areas at least every two years.

(v) Maintain a register of approved Projects and receive reports on their outcome.

(vi) Review concerns and complaints involving the care and use of animals at the institution either from the public or research facility personnel.

(vii) Make recommendations to the Ethical Research Review Board (ERRB) regarding any aspect of the institution's animal programme, facilities, or personnel training.

(viii) Withdraw approval for any approved Project and/or formally authorize the

humane killing of any animal which is being subject to unnecessary deprivation, fear, distress and pain.

(ix) If an activity is suspended, the appropriate authorities in conjunction with ACUREC, shall review the reasons for suspension, suggest appropriate corrective actions.

Review proposals submitted to her, modify and make appropriate recommendation to ERRB appropriately?

(i) Prepare and submit annual reports to the ERRB.

(ii) Training and retraining of all staff, students and visitors involved in animal use for research, teaching and testing.

These trainings include:

(i) Basic training for the first-time animal users.

(ii) Annual refreshers training for all animal users

(iii) Training on roles and responsibilities of ACUREC

(iv) Depending on the project, animal species, study models, ACUREC will recommend further appropriate trainings.

COMPOSITION OF ANIMAL CARE AND USE COMMITTEE (ACUREC)

The membership of ACUREC shall be as follows:

(i) Chair: Any Professor of Animal or any other Biomedical Science discipline of the rank of Professor appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor (ARIP)

(ii) One experienced scientist from each of the Faculties of: Agriculture (Animal Science and Wildlife and Fisheries), Social Science (Psychology), Science (Zoology), Pharmacy and Basic Medical Sciences.

(iii) One Statistician

(iv) One lawyer

(v) Two community Representatives (laypersons 1male 1Female)

(vi) Head of the Research & Linkages Unit

(vii) Secretary/member

STANDARD OPERATING PROCEDURE (SOP)

The Committee shall meet monthly over the following:

(i) Receipt of proposal

(ii) Evaluation of proposal

(iii) Approval/disapproval of proposal

(iv) Monitoring (periodical physical inspection and recommendation of appropriate sanction/correction where necessary).

(v) Ensuring biosafety and best research/teaching practices as related to: euthanasia in animals, Surgical procedures, Disposal of carcass (mandatory incineration), clothing, importation and exportation of animals, housing and feeding of animals, transport/transportation of animals, animal product

handling, monoclonal antibody production, cancer research, toxicity testing in mammals and fish, aging, pain research, infectious disease studies, vaccine trials etc.

Need for Protective Legislation and Regulation by the Government: Research Ethical Policy is of both moral and regulatory concerns. It requires both the legislative and regulatory protection by the government as provided by the NHREC Sub-Code for Research Involving Animals (FMOH, 2014).

4.4 PLANT USE AND CONSERVATION RESEARCH ETHICS COMMITTEE (PUCREC)

Preamble

From earliest time, humans continue to have impact on plant and animal species as well as the environment. Invariably, as human use of resources, energy, and space intensified over the past few centuries, the diversity of life has substantially reduced in most parts of the world. In order to sustain the earth and human kind, it is important that plants which provide food and medicine are well managed such that their continued availability is ensured.

Generally, it is important that plants, irrespective of whether they are useful to humans or not, do not go into extinction because of genetic modification or from bad agricultural practices. This may invariably destroy the ecosystem, which will have a far-reaching effect on the environment.

As is generally believed, ethics is about choices and continues to remain a moral issue. Sustaining the earth will definitely depend on sustainability of humans, other animals and the environment. Several questions arise:

(i) What do humans choose?
(ii) Is it only what is beneficial?
(iii) Will the earth eventually drift away?
(iv) What of estimated 21st century projection of 9 billion people?
(v) What will the present generation leave for the earth's future generations?

It is unethical to treat a plant or the environment with disrespect. The Osun State University agrees perfectly that there should be ethical guidelines on plant use and biodiversity conservation on her campuses in addition to maintaining other ethical principles of government guiding plant use. This shall be binding on all persons made up of students, staff and visitors to the University. The Committee on Plant will also maintain general oversight functions on plant use and conservation in the region.

GUIDELINES ON AGRICULTURAL PLANT USE AND NATIVE PLANT ACQUISITION

(I) The Osun State University recognizes that plants have intrinsic value apart from their usefulness to mankind and livestock as food, for aesthetics and raw materials for industries.

(ii) The destruction, removal, acquisition and trade of plants native to UNIOSUN require approval of the PUCREC of the University.

(iii) Crop varieties developed by researchers in the University can be exchanged with other persons or other institutions only by the researchers who developed the varieties. Such exchanges do not require the approval of the Ethics Committee but documentation of such exchanges/provision to others is required and an acknowledgement made if such varieties lead to the development of varieties.

(iv) All requests to collect wild plants from their natural environment in UNIOSUN must be submitted to and approval given by PUCREC before such collections can be undertaken

(v) For researchers and other interested parties who are not employees of the Osun State University, the intention for the use of the plants collected from the University must be declared on the request for collection document.

(vi) The University recognizes the role of diversity of plant species in the functioning and productivity of ecosystems as well as stability of the latter, hence encouraging the cultivation of more diverse varieties of plants on her campuses.

(vii) Collection of plants from UNIOSUN must not only follow a specified approved quantity of any plant species (or seeds of such species) that may be collected at any time, but areas where collections have been made recently should be avoided as much as possible by the same or other people.

(viii) Practices that will maintain and/ or promote diversity of plant species are encouraged.

(ix) The collection of endangered species is not allowed. Also, weak plants may not be collected for use, except for research.

(x) Rare or endangered species must be reported to the Ethics Committee for urgent steps targeted at conservation.

(xi) Notification of new diseases endangering plant species must be reported to the Ethics Committee.

(xii) Plant/Crop research and production practices must not endanger the diet and health of humans on the campus of the University and its environs and must not pose a threat to the environment.

NOTE: A vulnerable species is a species which has been categorized by the International Union for Conservation of Nature as likely to become endangered unless the circumstances that are threatening its survival and reproduction improve. Vulnerability is mainly caused by habitat loss or destruction of the species home.

GUIDELINES ON MEDICAL PLANT USE

Plants have always played a central role in indigenous cultures globally. Plant products are used as food, sources of medicine, and as raw materials for the making of clothing. Wood obtained from trees is used as fuel for cooking and to keep warm and for the construction of homes and tools. The indigenous knowledge on particular species of plants useful for these purposes is a key cultural adaptation to having a successful life in ecosystems. Therefore, an intrinsic reliance on plant products is just as important for people living in developed cities, as for those living in native tropical forests. Plants remain the celebrated source for the discovery

of drugs for various infections and diseases. Continued bio-prospecting in tropical rainforests and other natural ecosystems will discover new, previously unknown uses of plants as foods, medicines, and materials. The Osun State University recognizes that members of the community often use medicinal plants for research as well as management of diseases and infections. Below are some guidelines on their use:

(i) A communication on plants of the University and their medicinal as well as other uses should be consulted before plant collection.

(ii) Plants for research purposes should only be obtained from the UNIOSUN Biological Garden (the Medicinal Plant Garden) in order not to deface plants and thus the environment.

(iii) Plants must be properly authenticated from standard Herbaria and voucher specimens deposited.

(iv) After use for research, resulting plant residue (marc) should be properly incinerated.

(v) No new species of plants can be introduced into the campus of the University, without the approval of the Committee.

(vi) Plants shall not be transferred to other bio-diversities without the approval of the Committee in addition to approvals of other governmental agencies.

(vii) It is prohibitive to embark on bush fires and pesticide use without approval

(viii) It is unethical to fell a plant without consulting the Tree management Committee and PUCREC.

(ix) Intellectual properties rights must be properly respected in the event of drug development from the plants.

GUIDELINES ON GENETIC ENGINEERING AND TESTING OF GENETICALLY MODIFIED SPECIES

(i) The Osun State University supports and will promote the responsible use of technology to advance the welfare of humans and ensure the protection of the environment.

(ii) The use of any transgenic plant for research must first be documented with PUCREC.

(iii) Adequate care must be taken to prevent contamination of the environment with vectors carrying genes for antibiotic resistance or other reporter genes.

(iv) Disposal of wastes from laboratories where genetic transformation research is undertaken must conform to the standard global safety practices for such laboratories.

(v) Testing of transgenic/genetically modified plants must be done first in containment facilities before the field trials and a risk assessment undertaken.

(vi) Field trials require the approval of PUCREC.

GUIDELINES ON ENVIRONMENT CONSERVATION

The conservation of natural ecosystems is of great importance for many reasons, including the fact that it conserves ethno-botanical resources. Environmental ethics deals with aspects on the conservation of natural resources. Humans, other animals and living things are part of the society, so we must not ignore the fact that even plants and animals are a part of our lives. These are integral part of the environment and hence have a right to be considered as part of the human life. Consequently, it is clear that they should also be associated with our guiding principles as

well as our moral and ethical values. The University recognizes the fact that the environment needs to be conserved therefore some guidelines are listed below:

(a) Replacement of natural ecosystems with crop fields and need farms should be respected.
(b) Groundwater pollution should be avoided
(c) Soil erosion, aquifer depletion, soil degradation, should be avoided or kept at the barest minimum.
(d) Pesticide use must not endanger the environment.
(e) Other environmental stresses should be avoided.

COMPOSITION OF THE PUCREC

In the composition of membership of the Committee, gender balance shall be ensured. The plant Use and Conservation committee shall comprise:

(a) Chair – Any Professor of Agriculture (Plant Science/Forestry), Plant Biology or Pharmacognosy appointed by the Vice-Chancellor on the recommendation of DVC (ARIP).
(b) One experienced Scientist from each of the Faculties of Science (Plant Biology), Agriculture (Plant Science/Forestry), Technology (Environmental Science) Pharmacy/Pharmacology (Phytomedicine).
(c) One Statistician
(d) One Lawyer
(e) One Curator
(f) Two Community Representatives (Layman 1 male, 1 Female)
(g) Director, Office of Research and Innovation Management (ORIM)
(h) Secretary.

STANDARD OPERATING PROCEDURES (SOP)

The operational procedures of Plant Use and Biodiversity Conservation shall follow the procedures that have been presented in detail in the Health Research Ethics Committee section (Chapter 4.1) as outlined below:

(a) Submission of Protocols
(b) Reviews
(c) Responsibilities of Stakeholders
(d) Approvals
(e) Monitoring

Definitions within the Context of Plant Use and Biodiversity Conservation

Biodiversity: The variability among living organisms from all sources, including inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

Ecosystem: An ecosystem is a community of organisms (plant, animal and other living organisms together with their environment, functioning as a unit.

Ethnobotany: Ethnobotany is the study of the relationship between plants and people.

Conservation: A discipline concerned with the ways in which Earth's biological diversity is lost and the development of solutions to protect the natural functioning of ecosystems and the species found therein. Ethan botanical surveys of habitats provide valuable information on the number, kind, and health of species present. (Britannia Concise Encyclopaedia).

Environmental Ethics: This is a branch of environmental philosophy that studies the ethical relationship between human beings and the environment.

Genetic Technology: It is the process of manipulating genes in an organism, usually outside its normal reproductive process. It involves the isolation, manipulation and re-introduction of DNA into model organisms, usually to express a protein with an aim to introduce new characteristics to increase its usefulness, increasing the yield of a crop species, introducing a novel characteristic, or producing a new protein or enzyme.

Endangered Species: The conservation status of a species is an indicator of the likelihood of that endangered species not living i.e. any species that is in danger of going into extinction.

4.5 SCIENCE AND TECHNOLOGY RESEARCH ETHICS COMMITTEE (STREC)

PREAMBLE

Scientific and Technology ethics is geared towards developing sustainable solutions. Sustainability implies cultural, social and economic restructuring simultaneous with scientific and technology restructuring and goals. It involves not just developing appropriate science and technology but also requires a focus on the political, economic and social arrangements within which Science and Technology are developed and used.

Researchers in Science and Technology have three sets of obligations that motivate their adherence to professional standards. These are:

(i) an obligation to honour the trust their colleagues place in them. Science and Technology is a cumulative enterprise in which new research builds on previous results. If research results are inaccurate, other researchers will waste time and resources trying to replicate or extend those results. Irresponsible actions can impede an entire field of research or send it in a wrong direction, and progress in that field may be retarded. Embedded in trust is a responsibility of researchers to mentor the next generation who will build their work on the current research discoveries.

(ii) an obligation to themselves. Irresponsible conduct in research can make it impossible to achieve a goal, whether that goal is earning a degree, renewing a grant, getting promotion, or maintaining a reputation as a productive and honest researcher. Adhering to professional standards builds personal integrity in a research career.

(iii) an obligation to act in ways that serve the public. This is important because scientific and technological results and breakthroughs have greatly influenced

society. While some scientific results have directly affected the health and well–being of individuals, technological breakthroughs have changed the way things had been done. Even when the outcome of scientific and technological research does not have immediate applications, they sometimes provide the fundamental basis for future research studies.

By considering all these obligations - towards other researchers, towards oneself, and towards the public – researchers, in Science and Technology are obliged to be guided by rules and tenets that would assist them in making responsible choices. The Osun State University and Technology Research Ethics Committee (STREC) is to provide oversight and assistance in ensuring compliance with all laws, regulations and policies governing scientific and technological research in the University. Within the framework of sustainability, research ethics in science and technology have been developed considering the following fundamental issues, that:

(i) Scientific and Technological Research is a Social Process and not a discrete set of fragmented tasks.

(ii) Scientific and Technological research always takes place in a social context; it affects human relationships and involves political and ethical choices. Thus, scientific and technological ethics is not just about the values of individual scientists or engineers or technologists but must also focus on the context of their work and whether it constrains or enables a socially responsible scientific and technological practice. A focus on both micro and macro issues is needed to adequately address the ethical responsibilities of the profession. The focus on sustainability underlines the need to integrate macro issues such as broader social processes and the regulatory environment in which scientists, engineers and technologists operate.

(iii) Scientific and technological research, beyond taking place in a social context, must be seen as an integrated process that must seek to solve problems affecting society particularly in the immediate environment. With this approach, the focus must be to integrate research at the frontiers of knowledge with the engagement of the researcher in addressing real world social and environmental problems. This will require defining the problems the research seeks to solve, collecting and analysing data; and making recommendations as well as drawing conclusions in the light of the stated objectives.

TRAINING AND EDUCATION

Safety education must be provided “at the time of an employee's initial assignment to a work area where hazardous chemicals are present” and prior to assignments involving new exposure situations'. The University should ensure that the training program is consistent with the requirements of the regulations. All workers or staff members should be trained and the University should maintain an ongoing training and education program to ensure workers are aware of hazards present in their work area and hazards associated with individual work tasks and chemicals.

Elements that must be covered include:

(i) Measures workers can take to protect themselves from hazards including; any operational specific procedures; and personal protective equipment to be used.

(ii) Overview of the contents of the standards (of procedures) and where workers can get access to the standards.

(iii) Knowledge of permissible exposure limits to chemicals.

(iv) Location and availability of reference material on hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory.

(v) Methods and observations that may be used to detect the presence or release of a hazardous chemical.

(vi) Physical and health hazards of chemicals in the work area, including signs and symptoms associated with exposures to hazardous chemicals used in the laboratory.

Based on the above broad principles, research ethics in science and technology must include the following key issues:

i. **Professional Competence**

The researcher must be technically competent by training or experience or give full disclosure of pertinent limitations to undertake scientific and technological tasks.

ii. **Safety and reliability**: The researcher must accept responsibility and ensure that research decisions are consistent with safety, health and welfare of the public and to disclose promptly factors that might endanger the public or the environment.

iii. **Legal Obligations**

The researcher must be honest in stating claims or estimates based on available data. The researcher must avoid real or perceived conflicts of interest whenever possible; and to disclose them to affected parties when they do exist.

iv. **Social Responsibility**

Researchers must ensure that their research work is backed by social and environmental impact assessment of the impact of the research study. Also, the researcher must ensure that they understand the technology to be deployed, its appropriate application and potential consequences.

iv. **Respect for intellectual property**

Adequate reference must be made to other researchers where their materials, methods and data have been used in the development of new processes and procedures.

ETHICS OF CHEMICAL SAFETY

Almost every laboratory in the University uses chemicals in their activities. There is therefore the need for proper description of operation of the Chemical safety Program and for provision of guidance in establishing safe work practices for the use of chemicals.

Chemical Hygiene

Hazardous chemicals must be used in accordance with the Chemical Hygiene Plan, the laboratory specific Standard operating Procedures, or as recommended by certain reference material such as chemical storage guidelines, Material Safety Data Sheets (MSDSs). In general, all persons using chemicals must have access to information or knowledge about the hazards associated with the materials they handle including physical properties and biological effects of the chemical. At no time should employees be exposed above the permissible levels

established for the materials handled. Any laboratory operation using radioactive materials or radiation-producing equipment, must receive authorization from the appropriate Unit before starting work. Preventive measures must be instituted in each department or laboratory to eliminate fire hazards. Workers must be trained in fire safety techniques and flammable liquids must be properly managed in the laboratory. All hazardous materials must be properly disposed. Environmental regulations specifically prohibit the disposal of hazardous material via the sewer system, regular trash, or other unsafe routes. A comprehensive waste handling program should be properly managed by the Environmental Health and Safety Unit (EHS) to be set up by the University.

Radiation safety in Science and Technology

The radiation safety programme at the faculties of Science and Technology of the University combines the best efforts of its radiation safety Committee, its radiation safety staff and all of its employees, students and visitors to ensure the safe use of radioactive materials. The established policies and procedures issued by STREC is designed to ensure the accountability of radioactive materials.

There are four key components to radiation safety programme:

(a) The Radiation safety Committee
(b) The Environmental Health and Safety Office
(c) The Authorized User
(d) The Radiation Worker

The roles and responsibilities of each are described below:

i. The Radiation safety Committee:
   - oversees the radiation safety program
   - authorizes the use of radioactive materials
   - reviews incidents involving radioactive materials
   - sets policies for the use of sources of radiation
   - gives general supervision to the implementation of those policies

ii. **The Environmental Health and Safety Office**

The day-to-day operation of the radiation safety program should be managed within the Environmental Health & Safety office (EHS) yet to be set up by the University. Radiation Safety staff should be available to advise Authorised Users and radiation workers on radiation safety and regulatory compliance issues and to provide the following services:

   - training
   - personal monitoring and dosimetry services
   - bioassay
   - pregnancy counselling
   - laboratory radiation surveys
   - incident, spill and contamination management
   - radioactive waste management

iii. **The Authorised User**

Authorised Users are faculty members or senior staff members who would have been approved by the Radiation safety Committee (yet to be constituted) to use radioactive materials under specific conditions. An Authorised User is granted approval to possess and use specific isotopes **only** for the uses described in the authorisation application and is issued a possession limit for each of those isotopes.

Each Authorised User is responsible for:

(a) The health and safety of anyone using or affected by the use of radioactive materials under his or her direction or supervision.

(b) Personally attending initial and annual refresher training courses and ensuring that his/her employees, staff and visitors receive appropriate training.

(c) Ensuring that his/her employees, staff and visitors comply with relevant regulations, policies and procedures.

iv. **The Radiation Worker**

A radiation worker is anyone who uses radioactive materials or radiation – producing equipment and machines. The radiation worker's thorough training, compliance with regulations and procedures, careful work habits and respect for the health and safety of fellow workers are an integral part of the radiation safety programme and ethical practice.

A radiation worker's responsibilities include the following:

(a) Complete the initial radiation safety training program and, for open source users, attend annual refresher radiation safety training to be organized by the University.

(b) Be familiar with the isotopes in use; know the radiological, physical and chemical properties, presented by each one, and the types of hazards presented by each one, and the specific precautions and handling requirements for each isotope.

(c) Be familiar with all the relevant procedures of the radiation safety programme, including isotope purchasing and waste disposal procedures.

(d) Know how to properly use the appropriate radiation survey meter.

(e) Know how to use radiation monitoring badges and exchange them promptly at the end of the monthly or quarterly wear period.

(f) Maintain appropriate inventory, disposal and survey records.

(g) Secure radioactive materials by making sure that radioactive materials are locked away or are under immediate supervision within the laboratory.

(h) Inform co-workers and visitors to the work area about the presence of radioactive materials and of any precautions they should take.

(i) Know who to call in any incident involving sources of radiation and how to handle spills and personal contamination.

RADIATION SPILL AND INCIDENT PROCEDURES

An accident may happen to even the most careful worker(s), and any worker may be called upon to assist in the case of a spill, a contamination incident, or an emergency. Be prepared and

know how to respond before an incident, or an emergency. Be prepared and know how to respond before an incident happens.

GENERAL SAFETY RULES

The laboratory standard requires each department to develop written Standard Operating Procedures covering relevant health and safety information on hazardous processes, materials, and equipment use in laboratory. All persons in the laboratory must wear proper lab attire (lab coat). Persons using hazardous materials or performing potentially hazardous tasks must be provided with appropriate personal protective equipment such as safety glasses, aprons, lab coats and gloves. Any use of respiratory protective equipment must be certified and approved by Chemical safety Department if there is any in the Institution. Fume hoods must be checked and in proper working order prior to use. Each department should have safety showers and eyewash stations which must be kept readily accessible; corridors and exit paths must be kept clear and free of obstructions.

Periodic "in-house" inspections (monthly or quarterly) of laboratories should be conducted and documented by all departments in the University. Each department should develop and enforce comprehensive policies and procedures for compliance with general laboratory safety rules, provide information (particularly to new lab workers) on fundamental lab safety policies and procedures for their operation; ensure proper equipment, tools and furniture are provided to reduce the risk of injury.

The following laboratory items must be adequately labelled:

i. "Hazardous materials": defined as selected carcinogens, acute toxins and reproductive toxins.
ii. Explosive or highly flammable chemicals
iii Radioisotopes.
iv. High-voltage electrical equipment:

Personal Protective Equipment

Wearing appropriate personal protective equipment and practicing good personal hygiene as described below will minimize exposures to hazardous chemicals.

(i) Attire – All workers and visitors to any laboratory are required to wear appropriate lab attire such as a lab coat or apron.

(ii) Eye protection – it is required that all personnel including students, staff and visitors in laboratories wear safety glasses, goggles, or face shields at all times where eye hazards are present.

(iii) Face shields – Full face shields including face mask must be worn in addition to eye protection when conducting a procedure that may result in a violent reaction. Full face shields with bottom caps to protect the neck provide the best protection.

(iv) Gloves - Gloves are essential when working with hazardous substances. Proper gloves can prevent skin absorption, infection and chemical burns. Glove materials vary in their effectiveness at protecting against chemical hazards.

(v) Personal Hygiene – hands should be washed frequency throughout the day, after glove removal, before leaving the lab, after contact with any hazardous material, and before eating, drinking, smoking, or applying cosmetics.

(vi) Respiratory protection – Fume hood or other local exhaust ventilation must be used when working with materials that produce hazardous vapours or fumes.

Spills and Emergencies

The University should develop policies and procedures describing measures workers can use in the event of an emergency to protect people working in the lab, the environment, and the University facilities.

It is the responsibility of the department to provide and ensure that:

(a) all laboratory workers are to be trained to know the location(s) of and how to use emergency equipment such as safety shower/eyewash stations, fire alarm pull boxes, fire extinguishers, and emergency spill supplies.

(b) lab workers are informed about what to do in the event of a chemical spill.

(c) immediate steps are taken in situations that are life-threatening or when facility damage is imminent.

Waste Management Practices

Sound waste management practices are an essential part of the Code of Ethics of a science research and teaching facility. Laboratory waste consists of a range of by-products of either: chemical, biological, microbiological, medical or general nature. Since such waste is deemed to be potentially hazardous to those who come in contact with it, appropriate waste management procedures must be implemented for their safe disposal. The waste management procedures are to provide adequate information on waste disposal and waste minimization strategies in view of protecting the laboratory personnel and the University community from potentially hazardous waste and environmental pollutants/contaminants. These procedures assist staff and students in following an environmentally sound and standardized waste disposal practice for laboratory wastes with respect to:

(i) Handling,

(ii) Labelling requirements,

(iii) Specialised storage,

(iv) Record keeping,

(v) Biological monitoring of workplace and equipment,

(vi) Disposal of wastes.

HAZARDOUS WASTE DISPOSAL

In order to ensure proper disposal of chemical wastes and materials that become contaminated with chemicals, an Environmental Health Services Agency shall be established to enforce hazardous waste regulations for the community. The Agency, when established, will work closely with the University authority to develop their hazardous waste disposal programme. Waste material that is not obviously non-hazardous, like wastepaper, can be determined by such authority whether or not it meets the definition of a hazardous waste. The Agency will train employees and students in proper management and disposal practices. The community will also be educated about the approved routes for disposal of hazardous material. (No hazardous materials may be disposed of via the sewer system or regular trash.)

Environmental Programmes

The University will impose specific operational restrictions on science building fume hoods and wastewater discharges to ensure their effluents do not have a significant environmental impact. The Institution has direct responsibility for managing air emissions from their equipment as well as discharges to waste water systems. Chemical fume hoods should not be used as a disposal method for hazardous material such as a volatile solvent. Chemical not being actively used in a hood should be sealed to prevent evaporation. Hazardous wastes should never be discharged to the sewer.

BIOSAFETY ISSUES

Ethical issues raised on biotechnology concerns its applications in various fields that may impact on the environment and human health. Most of these concerns border on:

Biosafety

(a) Biosafety guidelines are related to issues raised at the conference of the parties to the Convention on Biological Diversity (CBD). This was adopted a supplementary agreement to the convention on January 29, 2000. The agreement is known as the Cartagena Protocol on Biosafety.

(b) Protocol is designed to protect biological diversity and human health from potential risks arising from genetically modified organisms (GMOs).

(c) It provides a clear legal framework for trans-boundary movement of the GMOs

(d) Unexpected interactions between modified organisms and the environment or other organisms produce risks to the environment and public health.

(e) The risks have to be addressed in order to use living modified organisms responsibly.

Modified organisms released into the environment could initiate processes of horizontal gene transfer and affect biotic balances

(a) They can evolve beyond their functionality and elicit unprecedented side effects on the environment and other organisms.

(b) The use of modified living organisms must therefore address biosafety issues when they have consequences for ecology and human health.

(c) Risk assessment procedures and methods must be established to safeguard human health and the health of the environment.

(d) Potential hazards associated with GMOs must be identified.

(e) Risk analysis profile of such hazard must be done.

(f) Development and application of biosafety regulatory framework is very necessary.

(g) Ethics review board approval is also important.

COMPOSITION OF THE SCIENCE AND TECHNOLOGY RESEARCH ETHICS COMMITTEE (STREC)

The membership of the STREC shall be as follows:

(1) Chair – A Scientist/Engineer of the rank of Professor appointed by the Vice-Chancellor on the recommendation of DVC (ARIP).

(2) One experienced Scientist from the Faculty of Basic & Applied Sciences

(3) One experienced Engineer from the Faculty of Engineering

(4) A Representative from each of the Faculties of Law, Social Sciences and the College of Medicine (Preclinical).

(5) Representatives of Professional Bodies and Agencies in Science and Technology such as the Nigeria Society of Engineers (NSE), NAFDAC, NASENI, SON etc.

(6) Two community representatives (laypersons: 1 male, 1 Female)

(7) Director, Office of Research and Innovation Management

(8) Member & Secretary

STANDARD OPERATING PROCEDURES (SOP)

The key areas of operations of the STREC are defined within the overall policy document of the University Ethics Research Review Board (EERB) and include the following major aspects:

a. Receive research proposals for scientific and technological research.

b. Define research themes in areas of science and technology within National science and technological policies and developmental frameworks such as the vision 2030

c. Develop acceptable standards and procedures for the establishment and maintenance of science and technological facilities for research, teaching and testing.

d. Inspect the research facilities and structures at least every three years.

e. Make recommendations to the ethical review board (ERRB) regarding any aspects of the institutions' science and technological programmes, facility or personnel training.

f. Review and approve required modifications to secure approval or withhold approval of proposed activities related to scientific and technological research.

g. Training and retraining of all staff, students and visitors involved in scientific and technological research to be able to:

- Understand the nature of professional responsibility
- Develop critical thinking skills and professional judgements.
- Understand practical difficulties involved in bringing about change.
- Develop professional ethical understanding throughout their working life.
- Be able to resolve problems arising from questionable practices.

h. Prepare and submit annual reports to the ERRB

Research ethics is not only a moral issue, but also a regulatory issue. It is proposed that the university includes ethics education in courses within the sciences and technology. This will ensure that researchers of the future have basic and fundamental knowledge for conducting appropriate research in science and technology.

CHAPTER FIVE

5.0 ETHICS OF TEACHING AND LEARNING (ETL)

PREAMBLE

Teaching and Learning is a core component required by Osun State University to fulfil her vision and mission. The primary teaching roles in the university are to educate undergraduate students; to educate and mentor graduate students and post-doctoral scholars and to serve as intellectual power house for the general and professional communities around. All students are entitled to adequate teaching and learning methods that will make them achieve their full potentials and become knowledgeable and proud graduates of UNIOSUN. All ethical issues relating to the section are under the purview of the UNIOSUN ERRB.

Osun State University among its vision to upgrade standard in education has the following goals:

(a) Teaching component: this has to do with the generation of knowledge, its dissemination and how such knowledge is preserved.

(b) Research component: this deals with the creation of knowledge through exploration and discovery, and represents in its broadest sense, the learning component of university life.

Principles of Quality Teaching & Learning

(a) To promote quality teaching and learning practice (QTLP) that will encourage quality assurance measures that ensure quality outcome at all levels in the university.

(b) To ensure high-quality teaching and learning experiences for all students and teachers in the university.

(c) To provide a framework for teaching and learning that will permit flexibility and creativity

(d) To create awareness of how teaching and learning should take place

(e) To create a basis for monitoring and evaluating teaching and learning process in the university

(f) To highlight rules, regulations and sanctions guiding teaching and learning

(g) To identify specific areas of responsibility at the institutional, teachers and students' levels.

The University should:

(a) introduce quality assurance measures into teaching and learning activities across all programmes run in the university (undergraduate – mainstream and distance learners and postgraduate) so as to produce high grade graduates that can compete with graduates anywhere in the world.

(b) promote regular review of curriculum in line with the NUC standards and internally acceptable standards.

(c) provide funds for upgrading teaching aids, laboratories and facilities for teaching, learning and research.

(d) sponsor teaching development programmes for academic staff with little or no teaching experience especially for newly recruited staff.

(e) provide an enabling/ conducive environment for teaching and learning by making provision for the basic facilities such as adequate power supply, good lighting, ventilation and conveniences.

(f) ensure that class sizes are such that will enable good interaction between teachers and students especially for highly subscribed courses. Teacher: Student ratio should be within NUC recommended limits.

(g) establish a framework or mechanism for validating teaching and learning activities.

(h) should empower teachers and students to engage in learning and teaching that meet accreditation needs and make good use of information and communication technology (ICT) facilities.

(i) should acquire software that can be used to detect plagiarism by both staff and students.

(j) be sensitive to the particular needs of students and staff with disabilities by providing enabling environment and facilities for teaching and learning.

(k) be concerned about welfare and provide opportunities for student-work programmes to encourage students with financial needs to complete their studies.

(l) ensure and uphold that there is reciprocal respect between lecturers and students.

(m) should create opportunities (such as opinion boxes) for students and members of the university community to report forms of abuse and misconduct, or where there are possible threats and stigma.

(n) implement sanctions on both students and teachers according to the university's guidelines for disciplining students and staff who are offenders with all matters of misconduct with respect to teaching and learning.

RESPONSIBILITIES OF TEACHERS

The teacher should:

(a) ensure that effective teaching is conducted with reference to the university's vision and mission.

(b) maintain scholarship of teaching by being a lecturer that is widely read, intellectually engaged, and has the ability to transmit, transform and extend knowledge. To this extent, it should be ethical that the teacher saddled with these noble responsibilities should show from time to time to have proven ability for sustainable intellectual and skill development.

(c) present himself or herself for periodic evaluation of such skills integrated as an ethical principle for teaching in the university.

(d) respect the students both in the classrooms and outside the classrooms. It is expected that students will respect their lecturers; but it is often assumed. Teachers should earn their respect in their intellectual dissemination of lectures/teaching and be civil in their demands from students. They must respect the state of their students' knowledge and goals; respect the circumstances of their lives — work, other courses, family responsibilities. They must respect the relative intellectual endowment of their students; their ideas, their aspirations, their beliefs must be respected. Lecturers must make it evident that they respect and value their students as individuals if we are to be successful in engaging their minds.

(e) ensure that learning materials are made available on time, as needed, and without frustration; schedules announced and kept; non-punitive and appropriate assessment must be ensured. Efficient and effective feedback should be encouraged and enforced. Results are graded and made available as at when due.

(f) create an enabling environment for interaction between lecturers and students. A Good climate for learning is a climate in which the student is at ease with the lecturer and with others in the class, and is confident that questions and ideas will be welcomed, respected, and answered. In such a climate, the student can feel like a contributor rather than a consumer, and also, engagement of the mind and intellectual growth can occur. Foul and obscene language should be discouraged from lecturers to students as they interact within and outside the classroom.

(g) understand that physical appearances of both lecturers and students shall be of utmost ethical elements in the university. To this extent, appropriate dressing that dignifies the respect for persons within a learning environment should be upheld by the teacher within the university. There shall be an enforceable dress code made available for students.

(h) should not be involved with or encourage any form of cheating or plagiarism amongst students. All erring students and teachers should be appropriately reported according to the university's guidelines on malpractices and misconduct.

(i) make use of a wide range of teaching strategies, including the use of various information and communication technologies (ICTs).

(j) encourage students to develop independent learning skills by providing appropriate tasks to develop analytical and critical thinking skills.

(k) ensure that students are not given projects that are over-tasking financially and /or otherwise. It is expected that projects should not be more than what is considered normal.

(l) not use students as guinea pigs in their bid to achieve their personal goals.

(m) make sure that all forms of harassment and abuse (sexual, physical, and emotional) towards students are avoided by him or her.

For general conduct of examination regulations and disciplines refer to the current students' handbook.

RESPONSIBILITIES OF STUDENTS

The students should:

(a) be willing to take major responsibility for their learning and should motivate self to participate in an active learning community that challenges and stimulates intellectual, scholarly, personal and interpersonal growth;

(b) strive for tolerance and integrity; acknowledge their personal responsibility for their value judgments and ethical behaviour towards others;

(c) show tolerance and appreciation for diversity and multiple viewpoints; have a sense of responsibility and respect for self and other members of the university community;

(d) work effectively and purposefully to achieve their goal of learning;

(e) come fully equipped and prepared to maximize the learning opportunity in the university;

(f) should dress appropriately or in accordance with any approved dress code in such a way

that promotes the respect for a person within the learning environment;

(g) should not engage in cheating of any sort including examination malpractices and plagiarism which involve copying other people's work (fellow students or other published work) without due reference to the original authors. Where it occurs, should be punishable by existing laws in the university;

(h) avoid the use of foul and obscene language against lecturers and other students;

(i) should avoid all forms of harassments and abuse (sexual, verbal, physical, and emotional) against lecturers and fellow students.

Plant, humans and other animals are important components of the biological environment. In addition to disruption to the lives of people who currently inhabit the earth, the depletion of natural resources poses great risk to the sustenance of diverse life forms and future generations of human. Conservation of natural resources is important for today as well as the future and is the duty of all.

The importance of teaching and learning in our university cannot be overemphasized. The responsibilities cut across the management, teachers and students. This document highlights such roles and responsibilities for different groups and if sustained, it is expected to be a guideline that will enhance the quality of graduates for the University.

CHAPTER SIX

6.0 RECOMMENDATIONS OF THE UNIOSUN ETHICS COMMITTEE

In line with global standards, the UNIOSUN Ethics Directorate (UNIOSUN ERRB) to be located under the Vice-Chancellor's office should be established. In addition, the following recommendations are made:

(a) The Ethics Policy shall be periodically reviewed within a minimum of three (3) years.

(b) The University Ethic Policy shall be available on the University website.

(c) The University ERRB and UNIOSUN HREC shall register with all national regulatory bodies such as National Health Research Ethics Committee and others

(d) Each Research Ethics Committee must develop a full Standard Operating Procedure (SOP) for its internal committee purposes.

(e) The Research Ethics Committees shall be adequately funded by the University. An initial take-off grant should be given to each committee. Thereafter, an annual subvention is recommended with additional effort from each committee to generate funds for training and maintenance.

(f) The University should put modalities in place for on-line access to training towards the policy guidelines implementation.

(g) Ethics committee shall report any unethical conduct of research to the appropriate University authority for necessary sanctions.

(h) College/Faculty ethics committees shall review only undergraduate projects marked for expedited reviews (except postgraduate research endeavours and faculty members). This will facilitate decentralization and reduction in the energy and time required for more complex proposals. However, such College/ Faculty decisions should be approved or ratified by the relevant Ethics Committee.

(i) The University shall construct a standard incinerator for proper carcass disposal.

(j) Plants growing on the campus should be properly labelled. Each plant should state: date planted, genus, species, variety, family, authority, native origin and habitat. This is irrespective of whether it is wild, cultivated or its use as an ornamental or as a medicinal agent.

(k) The University shall establish an Environmental Health and Chemical Safety (EHCS) Department to monitor, certify and approve usage of protective equipment and equipment used in laboratories, as well as chemical and biological wastes.

(l) The University shall set up a Radiation Use and Safety Unit (RUSU) to regulate and monitor compliance by laboratories.

(m) Functional contact telephone lines should be activated in the entire University.

(n) Emergency Response Guidelines books which list incident contact phone numbers and procedures should be posted in every laboratory for contact in emergencies.

(o) In order to make teaching and learning easier for highly subscribed courses, it is recommended that class sizes are regulated to the prescribed capacity.

(p) Postgraduate Students should submit a proposal of their projects detailing time lines and financial implications to a faculty-based ethics committee while final approval shall rest with the Postgraduate Board.

6.1. POLICY IMPLEMENTATION AND REVIEW

(1) **Funding of the Committees**

The full implementation of this policy has financial implications. Therefore, the University administration must provide adequate funds to establish and maintain these committees to ensure full implementation. Funds are required to maintain the five Ethics Review Committees and to run their activities to make them really functional such that they are able to fulfil their oversight responsibilities.

(2) **Infrastructure Development and Administration**

In order for all Ethics Committees to fully perform their functions, there is need to provide infrastructure and equipment office spaces (for each of the committees) such as computers, scanners, printers, and telephone among others.

(3) **Capacity building of personnel**

All Ethics Committees shall be staffed by trained personnel to ensure that they perform their functions including review, education of the researchers and monitoring of approved research projects. Members of the Committees also need initial and continuing education to ensure that they provide adequate and timely review of the protocols that will be submitted to the committees for consideration. it is recommended that the University conducts training programmes for members of the committees.

(4) **Sensitization of the university community to the ethics Policy**

The ethics policy has made several innovative recommendations which should improve the quality of teaching and learning in the University. The recommendations also address acceptable conduct among both staff and students of the University. There is therefore the need for all members of the university community to be aware of the existence of this policy and consequently comply with them. To this end, the policy document should be widely distributed using existing channels of communication. There is also need for the conduct of seminars and workshops for full sensitization of the policy.

(5) **Periodic Review of the Policy**

There is need for monitoring and evaluations to determine the impact of the policy on the University community as well as periodic review of the document.

(6) **Ensuring compliance with the guidelines of the Policy**

There is need for compliance with all the recommendations of this policy by all affected members of the University community. The University should use appropriate sanctions to ensure compliance using existing channels such as the Staff and Students Disciplinary Committees.

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MEMBERS OF THE GLOBAL ETHICS COMMITTEE

1. Professor Anthony Kola-Olusanya, Deputy Vice-Chancellor (ARIP) - Chairman
2. Professor Amos O. Popoola, Provost, College of Science, Engineering & Technology - Member
3. Professor M.O. Olayiwola, Ag. Director, Office of Research & Innovation Management - Member
4. Dr Taiwo Ojurongbe, Ag. Director, Quality Assurance - Member
5. Dr John Agbonifo, Acting Director (GASDI) - Member
6. Dr B.A. Ajayi, representative of College of Agriculture - Member
7. Dr S.B. Adeyemi, representative of College of Education - Member
8. Dr Mikail Folorunsho, representative, College of Humanities & Culture- Member
9. Dr M.A. Nasir, representative of College of Law - Member
10. Dr Olubukunola Omobuwa, representative of College of Health Sciences- Member
11. Dr Babalola Oginni, representative of College of Management & Social Sciences - Member
12. Dr W.F. Sule, representative of College of Science, Engineering & Technology - Member
13. Dr K.A. Bashiru, representative of Postgraduate College - Member
14. Mr Marcus Awobifa, Deputy Registrar/Director (Advancement) - Member/Secretary

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Appendix I

COLLEGE OF AGRICULTURE (COA) POLICY ON RESEARCH ETHICS

Background

Research Ethics in Agriculture is intended to guide the conduct of research at all levels (i.e. staff, graduate and undergraduate students) in the College of Agriculture. It addresses the conduct of research from two perspectives: Sciences (Agronomy, Animal Science, Fisheries, Forestry and Wildlife), and Social Sciences (Agricultural Economics and Agricultural Extension). All researchers are expected to apply for ethical clearance from the University Research Ethical Committee through the College of Agriculture Research Ethics Committee (CoAREC).

Membership of the Committee

The CoAREC shall have the following members:

(a) Chair: A Professor to be appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor, Academic, Research, Innovation and Partnerships (ARIP)
(b) College Representative on the University Ethics Committee
(c) Heads of Department or their representatives
(d) A Veterinarian or a Toxicologist
(e) College Librarian
(f) A Secretary

Members shall serve for two years.

Note: The Committee shall have the discretion to co-opt as deemed fit.

Eligibility criteria for collecting Ethical Approval Form

(i) Staff conducting research which may be Grant award research or self sponsored research
(ii) Postgraduate research students
(iii) Postgraduate professional students
(iv) Final year undergraduate student projects

Roles of Investigators

(i) The investigator will be responsible for appropriate handling, care and safety of the objects of the research (plants, animals, wildlife, aquatic animals, fish and the environment).
(ii) The investigator or supervisor must be qualified to conduct the research and be familiar with the plant, animal and other subjects.
(iii) Investigators must use appropriate methodologies and designs in research studies to avoid waste of human, monetary and other resources which is unethical.
(iv) Ensure that all drugs and other regulated treatment materials are duly accounted

for and disposed of in accordance with stipulated guidelines after the investigations.

(v) Ensure that conflicts of interest among investigators are declared in the report of the experiment.

(vi) Ensure that studies are terminated when the hazards of that particular study outweighs the potential benefits.

(vii) Must provide full information about the study to the Ethics committee. This should include title of the study, purpose of the study, duration, risks, benefits, compensations among others.

Ethics in Animal Experimentation

Animals used in research in the College of Agriculture include: Laboratory animals, Farm animals, wildlife and Aquatic animals. In all, the following points must be adequately taken care of in animal studies:

(i) due care of animals, humans and the environment

(ii) appropriateness of experimental design and chosen subjects/samples (appropriateness to the research question, lack of bias, precision and power);

(iii) compliance with Nigeria's legislation where the project is based (law, requirements, rules, standards)

(iv) permission/license should be obtained for studies involving any special or designated sites.

Five major questions for ethical considerations

(i) Does your study involve any special or designated sites (Protected areas)?

(ii) Does your study require a license or permission?

(iii) To your knowledge, does your study involve participants from any of the following groups?

- Children under the age of 18 years
- Adults over the age of 65 years

(iv) Does your study involve any of the following?

- The carrying out of invasive procedures such as:

a. The use of equipment that releases substances, pollutants or noise into the environment. Environment includes land (including any geological features), air, water, wild flora and wild fauna and the built environment.

b. The capturing, tagging and or implanting a device inside or on the body of animals (from the environment).

c. The removal from the environment of any animal, plant or other significant material

d. The manipulation of any habitat including any waters (includes territorial and coastal waters, estuaries, rivers and other surface watercourses, lakes and ponds and ground waters).

e. Introducing substances (including rocks, soil, dyes, salt, fertilizers, smoke, drugs/tranquillizers, enzymes, placebos, food substances and supplements).

f. Manipulating posture and the obtaining of samples such as blood, urine, saliva, DNA and tissue.

g. Visual and sound recording of participants.
h. The involvement of the participant/animal in any physical or mental activity that would or might induce psychological stress, anxiety or humiliation and or cause significant pain.

(v) Does your study involve the collection of information by any of the following methods?
a. Questionnaires or surveys eliciting written, oral or electronic responses
b. The observation or recording of human behaviour
c. Will the participant remain identifiable after routine anonymisation steps have been taken?
d. Will any questions relate to sensitive topics? Examples of 'sensitive topics' includes -
i. The participant's mental or physical health
ii. Illegal or political behaviour
iii. Their experience of violence, abuse or exploitation
iv. Their gender or ethnic status

NB: researcher must be able to justify through the proposal submitted that the research will consider due care of animals, humans and the environment, appropriateness of experimental design and samples, impact of undertaking research including benefit or harm, and compliance with legislation whether in Nigeria where the project is based or abroad.

RESEARCH ETHICS IN FISHERIES AND AQUATIC RESOURCES MANAGEMENT

Certain ethical standards are relevant during the conduct of research in fisheries and aquatic resources management which include the following:

Fish Sampling

1. Ensure the fishing gears are as recommended for the particular study.
2. Ensure that fish caught are stored as recommended.
3. Ensure that contact surfaces for fish handling are not contaminated.
4. Ensure the physical damage to the fish is minimized so the body features can be easily identified and measurable.
5. Ensure the experiments for which fishes are to be used for are for scientific gain.

Fish Welfare

1. Ensure the fish is feeling well and free from pain or fear.
2. When welfare refinements are used (e.g. analgesia), it should be at the required dosage.
3. Fish should be free from food deprivation.
4. Environmental challenges such as sudden changes in water quality should be reduced.
5. Fish should be free from behavioural – interactive restrictions.
6. Fish should be free from mental and physical suffering.

Fish Transportation

1. It is important to know the source of fish before transport.
2. Ensure stress and injury during transportation is reduced.
3. Ensure the water quality is maintained during transport so as to reduce stress and onset of disease.
4. If fish is caught from the wild, it should be noted because of the stress during transport.
5. Ensure oxygen is provided for emergency or buffer if the distance is long.
6. Ensure fish are not fed before transport so as to reduce ammonia build-up and reduce metabolic rates.
7. When fish gets to its destination, avoid a sudden change in water

Fin Clipping (Tagging)

1. It can cause pain to fish therefore the use of analgesic is recommended.
2. Amputation of caudal fin can affect fish behaviour.
3. Care must be taken because clipping can introduce secondary infection and change movement behaviour.

Ethics in Forest Resources Management

1. Honesty and prudence in carrying out the research activity
2. Objective understanding of the morality of the discipline
3. Openness and respect for intellectual property
4. Confidentiality in data handling and processing.
5. Responsible publication of data

Social and Economic Research in Forestry

In forest management, a range of social and economic services are available:

(a) Research project design and management

(b) Providing advice on the design and conduct of social and economic research/issues in forestry and the wider environment.

(c) Providing advice for the evaluation of forestry, environmental and health interventions including other social and economic programmes.

Forestry Research viewpoint and Methodology

We carry out research to develop a better understanding of the ways in which trees and woodlands can benefit society, and make useful decisions about their management and use.

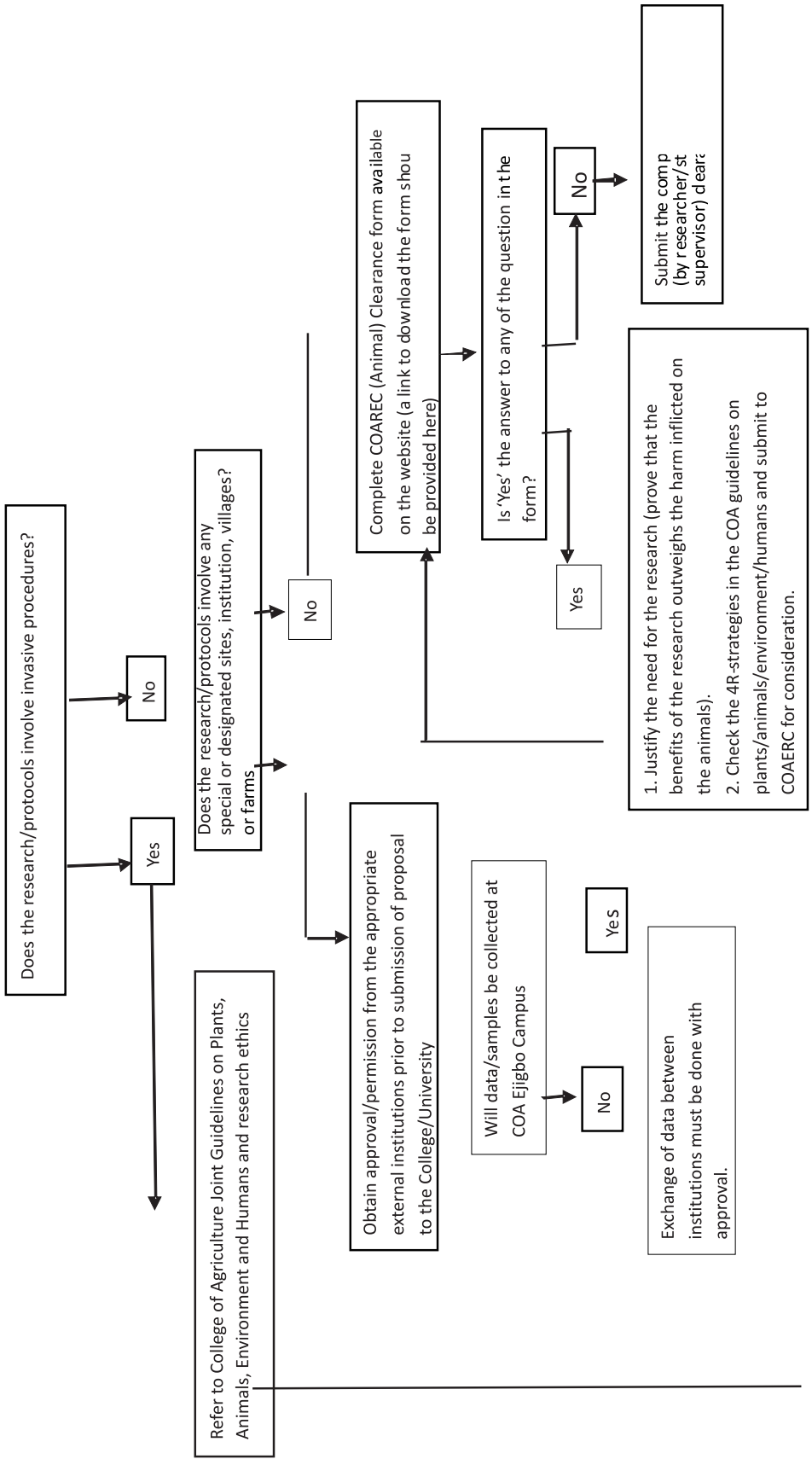
We follow research ethical standards and practices to ensure the principles of integrity and quality, enabling participation, informed consent, confidentiality and data protection, avoiding harm and impartiality.

Research Ethics in Plants

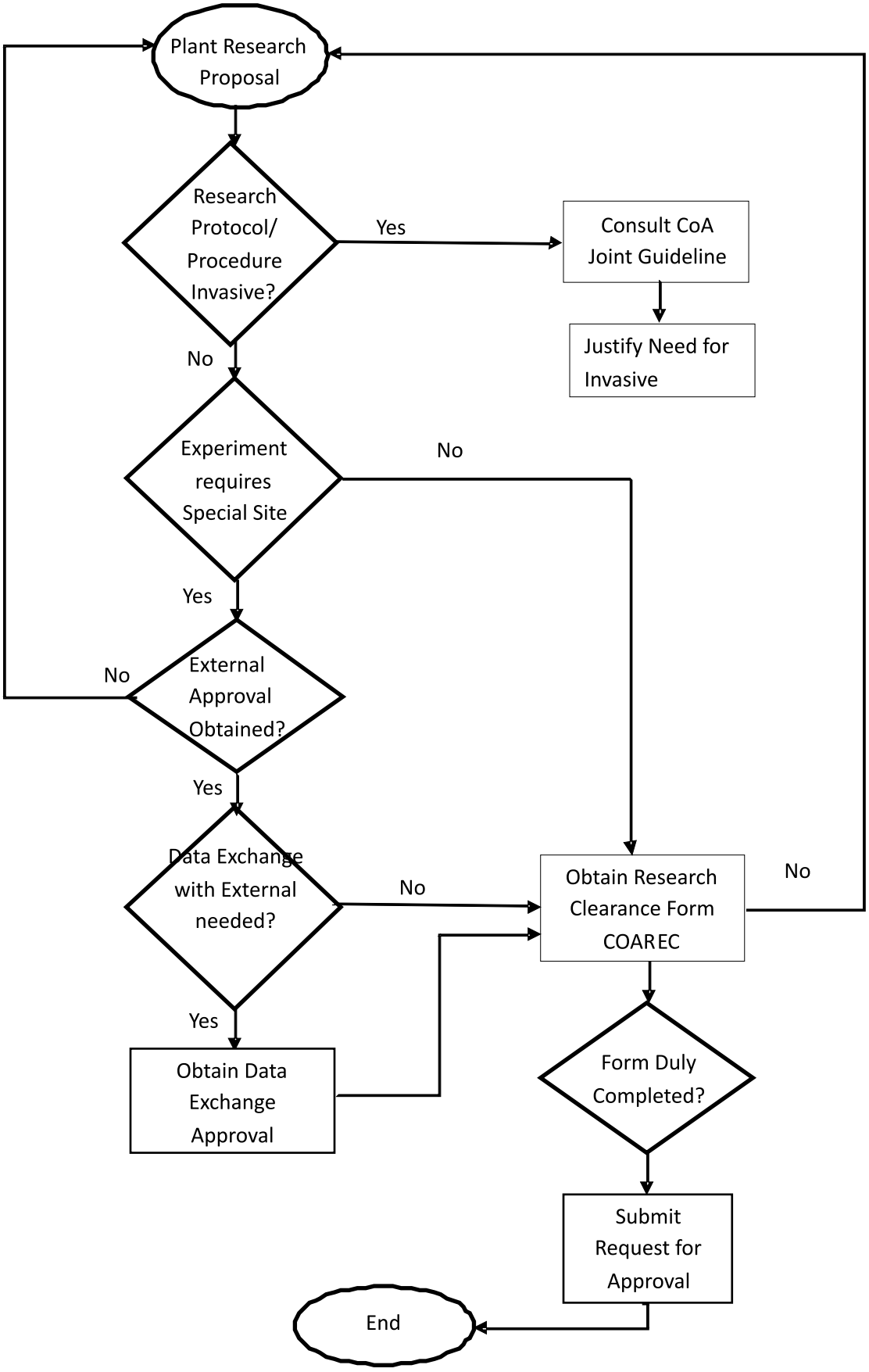
The researchers focus on producing safe food and feed with little or no or harmful impact on the environment. Thus, their activities involve humans, animals, soil, air and plants. The ethical issues involved can be classified into:

Ethical issues of (a) plants, (b) crop/feed production, and © human capacity building.

College of Agriculture Ethical Committee (Animal) Flowchat



College of Agriculture Ethical Committee (Plant) Flowchart



Guidelines for Research (General)

1. **Scientific honesty**: Do not commit scientific fraud (i.e., do not fabricate, fudge, hide, destroy, or misrepresent data).Any form of fabrication, falsification, and plagiarism is not acceptable.
2. **Carefulness**: Strive to avoid careless errors or sloppiness in all aspects of scientific investigation.
3. **Intellectual freedom**: Scientists should be allowed to pursue new ideas and criticize old ones. They should be free to conduct research they find interesting.
4. **Openness**: Share data, results, methods, theories, equipment, and so on. Allow people to see your work, be open to criticism.
5. **The principle of credit**: Do not plagiarize the work of other scientists, give credit where credit is due (but not where it is not due).
6. **The principle of public responsibility**: Report research in public media when:
7. The research has an important and direct bearing on human happiness and
8. The research has been sufficiently validated by scientific peers.
9. Researcher should obtain written indication of interest from those involved in the study.
10. The information collected by a researcher during his/her research work is the property of the University but kept in his custody and should not be misused.
11. The researcher should be mindful of the ethical issues in the following steps of conducting research:

A. <u>Initiating the research</u>

(i) Selecting a topic for research that will indicate the importance of the study and without any ethical issue.

(ii) Designing experiments that must basically follow the stipulated ethical guidelines. This must be incorporated into the study at this stage.

(iii) Collecting and reporting data by researchers should follow laid down principles that must be strictly adhered to. Confidentiality should be highly observed in the handling of privileged information.

(iv) Analyzing data with appropriate statistical tool, avoid data slicing and never falsify data or alter research results.

(v) Drawing and reporting inferences should be done with objectivity in order not to mislead the public with the researcher's work.

(vi) Establishing and maintaining credibility in one's research is very crucial. Avoid plagiarism by subjecting your work to appropriate plagiarism check software.

B. <u>Preparation of scientific documents</u>

(i) Preparing proposals–Proposals must be carefully prepared and convince granting bodies that the project is viable.

(ii) Proposal budgets – This is the cost plan of covering all stages of the research work, it must be prepared with all honesty and should be able to show that the project has been carefully thought through.

(iii) Indirect cost recovery- It includes: overhead, facilities and Administrative (F &A) costs. Provisions must be made for the recovery of institutional cost incurred by the

university to support externally funded research projects. Such funds are pooled and used for research sustainability in the university. The university guidelines on this must be strictly followed.

(iv) Peer review- All publications from one's research studies must pass through reputable peer reviewing outlets.

(v) Authorship and shared recognition – Only individuals that have contributed substantially to a particular study at one point of the other must be included in the authors' lists and other people that have contributed but not to the level of authorship may be recognized in the appreciation.

C. Conflict of Interest

The use of official position and influence for personal gain to redirect the course of research is not permitted.

D. **Intellectual Property Rights** (IPR) of a researcher will be maintained with high integrity.

GUIDELINES FOR PLANT RESEARCH

1. In the case of researching with farmers' participation, it is compulsory to protect the rights of people in the study area as well as their privacy and sensitivity.
2. Child labour is not allowed either in crop production or research.
3. The confidentiality of those involved in the observation must be respected, keeping their anonymity and privacy protected.
4. There is zero tolerance for violation of standard codes of scholarly conduct and ethical behaviour in professional scientific research.
5. During the conduct of an experiment, the researcher should avoid:
6. Technologies that damage the environment
7. Undue influence of private sponsors (fertilizer/pesticide/seed companies)of research.
8. Research on certain subjects, including products or services that might do harm to the environment or make food unsafe.
9. Research activities that can result into contamination of nearby land and water bodies with runoff chemical fertilizers, pesticides or genetically modified organisms.
10. Unprofessional/ineffective waste disposal/management practices.
11. Research on technologies that might cause dislocation among farmers

RESEARCH ETHICS IN AGRICULTURAL ECONOMICS AND EXTENSION

Research ethics offer procedures for conducting research responsibly. It also helps to educate and monitor social scientists to conform to high standard of ethics in conducting their research. The following is a summary of some general ethical principles in a social research:

1. Honesty:

Research data, procedures, methods and results should be reported honestly. The status of research publications should be declared. Data should not be fabricated, falsified and misinterpreted.

2. Objectivity:

Social scientists must avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research.

3. Integrity:

Social scientists must fulfil promises and research agreements. They are expected to conduct their research with sincerity and be consistent in their thought and action.

4. Carefulness:

In conducting research, social scientists must not commit careless errors and negligence. They must examine their own work and that of their peers carefully and critically. Detailed record of research activities must be kept.

5. Openness:

Social scientists are expected to share research data, results, ideas, tools and resources openly with their peers. They must be open to criticism and be receptive new ideas.

6. Respect for Intellectual Property:

Social scientists must respect patents, copyrights, and other forms of intellectual property. Permission must be sought and granted in order to use unpublished data, methods and results. Citations from others must be given due credit and research works of others must not be plagiarized.

7. Confidentiality:

All information obtained for research purposes must be treated with utmost confidentiality. Respondents' identity must not be known (anonymous). Under no circumstance should social scientists divulge information obtained from respondents publicly. All confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records must be protected.

8. Safety and consent:

All research information must be obtained from the respondent under safe and secured condition. They (respondents) must give their consent to information and should not be forced to participate in research. Information should be obtained directly and not by proxy.

9. Responsible Publication:

Research publications in social science should help to advance research and scholarship and not just for career progression only. Wasteful and duplicative research publications should be avoided

10. Responsible Mentoring:

When supervising students' research work, the supervisor is expected to assist to educate, mentor, and advise them properly. Their welfare must be taken into consideration and they should be given room to make their own decisions.

11. Respect for Colleagues:

When collaborating or working with other colleagues, respect and treat them fairly.

12. Social Responsibility:

Social research should help to promote social norms and prevent or mitigate social harms through research, public education, and advocacy.

13. Non-Discrimination:

There should be no form of discrimination in social research. Social scientists should avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors that are not related to their scientific competence and integrity.

14. Competence:

Social research should help to maintain and improve researcher's professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

15. Legality:

Social research should be conducted under the existing legal framework of the place where the research is being conducted. Social researchers should know and abide by relevant laws and regulations, as well as institutional and governmental policies as it relates to their research activities

16. Animal Care:

When animals are used in research experiments, they must be handled properly with care and respect. Experiments with animals that are not necessary or are poorly designed should be avoided.

17. Human Subjects Protection:

When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy.

18. Reproducibility/Replication/Repeatability:

The method of a research should be adaptable or adoptable to get the same result in order to validate and ensure the reliability, test the veracity of claim, promote teaching and error, promote transparency and integrity.

19. Falsification of data

It is unacceptable for any scientist to falsify data or intentionally misrepresent data. This can mislead the society as well as reducing the integrity of the person.

20. Analysis of data

Data analysis should be handled by an expert to avoid wrong results and interpretation which can mislead the society.

Appendix 1A

College of Agriculture Ethics Committee

Full Ethics Assessment Form

APPLICATION FOR ETHICAL APPROVAL FOR A PROPOSED RESEARCH PROJECT FROM COLLEGE OF AGRICULTURE ETHICS COMMITTEE

This application form is to be completed by STAFF, POSTGRADUATE (PG) and UNDERGRADUATE (UG) STUDENTS seeking ethical approval for an individual research project where it is obvious that ethical assessment is required.

This form must be completed electronically (no hand written application please!). All information required must be inputted without any attachment except those requested on this form. Duly signed and completed hard copy version of this form should be submitted to the Secretary of College of Agriculture Ethics Committee.

Note: Research must NOT begin until approval has been received from the appropriate College Ethics Committee.

Section 1: Applicant Details

Name	
Email	
Department	
Position	☐ Staff ☐ Undergraduate ☐ Postgraduate (Taught) ☐ Postgraduate (Research)

Section 2: Applicant Details

Project Title	
Project Funder (s)	
Proposed Start/End Date (dd/mm/yyyy)	Start date --/--/---- End date --/--/----
Category	☐ UG ☐ PG (taught) ☐ PG (research) ☐ Staff research
Preliminary Ethical Flag(s)	☐ Animals ☐ Plants ☐ Environment ☐ International (outside Nigeria) ☐ Humans (Non-Clinical)
Supervisor (Student projects only)	
Who is responsible for the overall management of the research? Name & Position	
Who designed the research? Name & position	

Who is conducting the research? Name & position	
Project type (nature of this project)	☐ Questionnaire / Survey ☐ Experiments ☐ Wildlife field survey ☐ Observational ☐ Other- define:

Section 3: Project objectives and proposed research methods

In a simple language provide a brief summary (1,000 words) of the objectives of this research, methods, benefits and risks to gain understanding of how the project will be conducted. For experimental design, present an outline in a step-by-step format describing the key tasks including how data will be collected and used.

Section 4: Animal

Please complete this section if the project was flagged 'Animal' in section 2.

Please answer the question below

S/N	The research will involve	Yes	No
1	Capturing of animal from their natural environment		
2	The transportation of animals either domestic/from the wild		
3	Housing requirements		
4	Feeding animals with supplements, placebo, enzymes etc.		
5	Taking of blood samples from the animal		
6	Taking of tissue/flesh from the animals		
7	The use of equipment/invasive methods		
8	Subjecting animals to stress		

If you have answered 'Yes' to any of the 8 questions, please provide further details in the box below (in not more than 500 words). Please, provide detailed protocol and provide the locations in which your research will take place, the anticipated risks (destruction of habitat, disturbance of any kind, emissions etc), potential damage and possible mitigation measures.

Section 5: Environment

Please complete this section if the project was flagged 'environment' in section 2.

Please answer the question below

S/No	The research will involve the following	Yes	No
1	The release of any substance into the environment		
2	The release into the environment of any animal, plant or other organism		
3	The release into the environment of any pollutant not covered by 1. or 2. above, such as noise, fertilizers, herbicides etc.		
4	The removal from the environment of any animal, plant or other organism		
5	The removal from the environment of any substance		
6	The manipulation of any habitat including any waters		

If you have answered 'Yes' to any of the 6 questions, please provide further details in the box below (in not more than 500 words). Please, provide detailed protocol and provide the locations in which your research will take place, the anticipated risks (destruction of habitat, disturbance of any kind, emissions etc), potential damage and possible mitigation measures. Kindly attach a copy of licence/permission letter for designated sites

Section 6: Human (Non-Clinical)

Please complete this section if the project was flagged 'Human participant in non-clinical setting' in Section 2.

Participant information

S/No	The research will involve the following	Yes	No
1	Children under the age of 18years		
2	Adults over the age of 65 years		
3	The questions to be asked might induce psychological stress, anxiety or humiliation, shame (sensitive topics e.g rape)		
4	The observation or visual recording of participants behaviour		
5	The sound recording of participants		
6	Will the participant remain identifiable after routine anonymisation steps have been taken?		

If you have answered 'Yes' to any of the 6 questions, please provide further details in the box below (not more than 400 words). Please, provide detailed protocol and attached the questionnaires to be administered to the end of this form

Section 7: Data management and Gantt chart

Briefly describe (100 words) how data will be used (including storage) and how participants' information confidentiality will be maintained. Please attach a copy of your Gantt chart/timeline (start date to end date) for your research/experiment.

Section 8: Risk Considerations and Management Procedures (Health and Safety Precautions)

Regarding the nature of the research, provide potential risk(s) to researchers and possible safety precautions to be taken. The risks include: .personal safety issues, such as lone or out of normal hours working, visiting participants in their homes; travel arrangements, and working in unfamiliar environments. Please complete (explain risk management procedures) and attach risk assessment form as a supporting document to this Ethical assessment form.

Section 9: Supporting documentation

Please, provide copies of any applicable documents in support of your answers. Ensure that each attached file has an appropriate file name when submitting the electronic copy e.g. COA_ANS/2010/0150_Questionnaire. Tick the document attached

Document	Attached
Participant consent form	
Questionnaire(s)	
Permission/licence	
Gnatt chart	
Project risk assessment	
Others (please list)	

Section 10: Declaration

I certify that the information contained in this application is accurate. I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligations and the rights of the participants. I confirm that the research will be conducted in line with all University, legal and local ethical standards.	
Name of principal investigator	
Signed	
Date	
Name of Major Supervisor	
Signed	
Date	

The appropriate Ethics Committee has considered the ethical aspects of this proposal. The Committee recommends that the programme/project be:

☐ **Approved** ☐ **Deferred (for reasons attached)** ☐ **Not approved**

Name of Committee Member	
Ethics Committee Concerned	
Signed	
Date	

RISK ASSESSMENT FORM

Risk Assessor's Name:	i.e. Students name	**Accountable Managers Name:**	i.e. Supervisor	**Planned Review Date**	

Task or Activity Description	**Location:**	
	Persons at Risk - Affected Groups: e.g. student, respondents	
	A –	B –
	C –	D -
	E –	F -

Provide highlights of potential hazards, existing controls you will put in place, risk level (high, medium and low) and additional control/required action and date (if applicable)

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
This risk level has been reduced as low as is reasonably practicable			

Assessor's Signature:		**Date:**	
Manager's Signature		**Date:**	

	1st Review	2nd Review	3rd Review	4th Review	5th Review
Assessors Name:					
Managers Name:					
Date of Review:					

NB: *Assessor (student), manager (supervisor)*

Appendix II

COLLEGE OF EDUCATION (COE) POLICY ON RESEARCH ETHICS

Background

The College of Education Research Ethics Committee was set up sequel to the directive of the Ethics Review Committee established by the Osun State University to develop, maintain and create awareness of ethical issues arising from the conduct of research using human subjects amongst College members.

The Committee is responsible for producing guidelines for the conduct of such research and for ensuring that all departments comply with the guidelines for the consideration and conduct of research. Specifically, the Committee is saddled with the responsibilities of preparing a draft policy document that will among other things, guide and promote research, core values of collaborative work, accountability, public support for research and moral values.

PRINCIPLES AND OBJECTIVES

Principles

The research ethics policy (REP) of the College of Education is developed from the internationally accepted guidelines for staff and student researchers to:

(a) implement ethical policies in research taking into consideration strategic focus on local, regional and national priorities;

(b) engage in private research projects or consultancies with external organizations in line with laid down ethical values;

(c) encourage the application of ethical principles and guidelines in the conduct of quality research

Objectives

The College Research Ethics Committee (CREC) will work to ensure that the general principles of natural justice, reasonableness and fairness of the decisions made which **shall be subject to yearly review by**:

(a) ensuring high-quality research with compliance to appropriate ethical standards for the benefit of the society;

(b) identifying and analyzing the strengths, weaknesses, opportunities and threats affecting ethical issues of research at the College and to effectively promote both general and specific research activities based on good ethical code of conduct and practice;

(c) deciding the processes for the establishment and operation of ethical procedures in research;

(d) ensuring appropriate training for every member of the College Research Ethical Committee with a view to refreshing and updating guidelines;

(e) enhancing research efforts in all fields and disciplines such that researchers can attain international repute;

(f) introducing modalities for rapid Departmental reviews and accelerate considerations of proposals in order to assist efforts of researchers for external funding and project completion;

(g) applying best practices for mutual learning and positive ethical culture in view of contemporary methodologies and experiences;
(h) considering matters referred to it by Departments in respect of their internal reports as long as such can be satisfactorily resolved at the College level
(i) ensuring that all staff, students and researchers are aware of the ethical issues and potentials surrounding their field of interest
(j) considering annual reports from Departments on issues of research and making recommendations
(k) facilitating and monitoring the dissemination of research findings through publications in peer-reviewed journals, books and other scholarly recognized outlets;
(l) developing and provision of **policies** for all Departments in the College as it concerns the conduct of research;
(m)providing feedback to Osun State University Ethics Committee

RESPONSIBILITIES OF THE COLLEGE RESEARCH ETHICS COMMITTEE

CREC shall be responsible for the development and implementation of research ethics code in the College. The committee's substantive and procedural functions will be in accordance with the Osun State University Research Ethics Policy. Its activities among others will include the following:

(a) The College shall appoint an active researcher and academic, who shall be a professor as its convener and chair.
(b) The College research ethical code shall be consistent with the University Research Ethics Policy.
(c) The CREC shall meet monthly to address pertinent issues.
(d) The specific dates of meeting of the College Research Ethics Committee must be incorporated into the College calendar for transparency of dates of meetings and to avoid clashes of meetings for members.
(e) The CREC shall accept research proposals from departments.
(f) The Agenda and minutes of the CREC shall be documented and records thereof kept.
(g) The CREC shall work harmoniously with the Osun State University Ethics Research Review Board (ERRB).
(h) CREC shall draw up a strategic functional and implementation plan for every academic year.
(i) CREC shall submit quarterly reports of its activities to the Provost of the College.
(j) Forward copies of the strategic functional plan to the Osun State University Ethics Research Review Board (ERRB).
(k) Review, modify and make appropriate recommendation(s) to ERRB appropriately.
(l) Submit quarterly reports of its activities to the Osun State University Ethics Research Review Board (ERRB).

COLLEGE RESEARCH ETHICAL VALUES (CREV)

These include narration of ethical values on the relationship between the College and the researcher, Research Participants, Research Community, Research Clients and the Environment.

(1) College and the Researcher

The researcher must ensure that any sole research or any other research conducted with associates, employees, or students conforms to ethical values and principles stated in this policy.

(2) Researcher and Research Participants

The researcher needs to inform participants in the research project about the objectives, principles and implications of the research so they can make wilful decisions as regards their consent on participation and disengagement from such project, if/where such arises. Where necessary, incentives and inducements should be stated clearly at the onset of the engagement for participants to determine their volunteer status and also to forestall wild arguments. The researcher should not regard the pursuit of knowledge as the supreme goal of the research project at the expense of the personal, social and cultural values of the participants.

It is important that the researcher should bear in mind the need to observe the privacy ethics of confidentiality and anonymity guiding research projects in order to ensure that no injury, distortions or harm filters into the psychological well-being of participants, including infants. While carefully ensuring that discussions on findings are done with caution, reports on his/her findings may be subject to public scrutiny.

(3) Researcher and the Research Community

The CREC should educate the researcher (or the research team) not to misuse his/her position as a researcher for personal gain. The researcher should ensure that design, methodology and execution of the research are done in a scientific and scholarly manner and also accept responsibility for all techniques, paradigms, conceptualization of the findings and reports on limitations of the findings which will be made available to public criticisms.

(4) Researcher and the Sponsor/Clients of Research

The researcher has the right to demand from the client of his research, clearly set out conditions and terms of the research or service, after which an explicit agreement or contract may be drawn between the two parties. The researcher should accept the right of the client to request information on the conduct of his research or service at any stage in the course of the research. However, he should not tolerate interference by clients that may jeopardize the scientific integrity of the research or prejudice the interest of the research participants. The researcher may not provide the client with information that may reveal the identity of individual participants in the research without permission from such participants. The researcher should not take a sole decision on the possibility of publication of his research findings in scientific journals without negotiating or consulting with his clients.

(5) Researcher and Society

The College is committed to research that will make significant contributions directly/indirectly to the welfare and quality of life of Nigerians in particular, and the world in general, not neglecting the improvement in the lives of both disadvantaged and deprived Nigerians.

(6) Researcher and the Environment

The researcher must maintain the highest standards of safety in procedure, equipment, and premises. The researcher should evaluate and declare the potential impact of his research on the environment, especially when it has to do with concrete sites like buildings and construction sites, mining and industrial settings, soils, water bodies (ponds and lakes, streams, rivers, subsurface waters), and the atmosphere. This declaration will assist in providing adequate monitoring and research control in the environments under research.

COLLEGE RESEARCH ETHICS

This covers non-biomedical research activities that involve human subjects including human body parts and human body fluids. The proposals must have ethical approval by the CREC. Applications for the approval must be channelled through the Department before consideration by the CREC. Where questionnaires are involved, they should be subjected to ethical clearance as well.

Under the guidance of the Provost, the CREC must:

(i) Ensure the implementation of policy and procedures dealing with ethical issues in respect of education, social sciences and human psychology.

(ii) When working with different cultures, CREC must ensure that researcher(s) have adequate knowledge and respect for tradition, private interests, special groups and local authorities.

Other specialized research ethics

This covers research activities that involve hazardous biological, chemical, and geological materials. It also refers to researches conducted in hazardous environments. Safety considerations are of prime importance especially when dealing with radiation materials. The proposals must have ethical approval by CREC. Ethical clearance is also required where hazardous biological, chemical, and geological materials are used for teaching and exhibition.

The CREC must:

(i) Ensure that staff and students engaged in research activities dealing with hazardous, toxic and ionizing radioactive materials have an understanding of ethical issues, guidelines and code of conduct in performing such research;

(ii) Ensure that hazardous, toxic and ionizing radioactive materials are avoided as much as possible in the execution of research activities, but only used where there is no suitable alternative; and

(iii) Ensure that staff and students engaged in research activities dealing with hazardous, toxic and ionizing radioactive materials have adequate knowledge of appropriate accident and emergency procedures.

RESEARCH POLICY IMPLEMENTATION

The CREC shall manage research ethics affairs at the College level with the Provost providing strategic leadership on research ethics.

College Research Ethics Committee will liaise with key internal or external stakeholders at the

policy and strategic units for research development in the College in order to transmit information and provide mentoring for the Departments.

COLLEGE RESEARCH ETHICS COMMITTEE (CREC) COMPOSITION

The CREC shall have the following members:

(i) Chair: A Professor to be appointed by the Vice-Chancellor on the recommendation of DVC (ARIP)

(ii) College Representative on the University Ethics Committee

(iii) One member of staff from each department in the College, who shall not be below the rank of Senior Lecturer.

(iv) Two lay people (male and female) from the immediate local environment

(v) Any other relevant person on *ad-hoc* basis, as deemed fit.

Members shall serve for two years.

BENCHMARKING RESEARCH ETHICS OUTPUTS

This will be in accordance with the requirements specified in the Osun State University Policy on Research Ethics.

Exemption from Review Process

The following shall be exempted from the COEREC review process: searches for existing literature, quality assurance activities or evaluation project design for self-improvement or program evaluation not meant to contribute to generalisable knowledge, interviews of individuals that focus on things not people such as questions on policies.

Process for Exemption

1. COEREC may grant exemptions from review in any of the conditions enumerated above.
2. Applicants seeking exemptions shall submit the proposed research or adequate information about it to the COEREC, sufficient, in COEREC judgment, to make a determination.
3. Exemptions may be granted by the COEREC Chairperson or his designee from among members of the COEREC, in consultation with the COEREC Administrative Officer – where one exists.
4. In granting exemptions, the reviewer(s) shall exercise all the authorities of the COEREC except that the reviewer(s) may not disapprove the research.
5. Where the reviewer is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to the COEREC.
6. The Chairman of COEREC shall bring all exempted protocols to the next meeting of COEREC for notice, discussion and ratification.

Expedited Approval

Expedited review procedures can be considered when research activities present no more than

minimal risk to human subjects. Inclusion on the expedited approval list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involves no more than minimal risk to human subjects e.g. collection of blood samples by finger prick.

(1) Prospective collection of biological specimens for research purposes by non-invasive means.

(2) Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(3) Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as or medical treatment or diagnosis)

(4) Collection of data from voice, video, digital, or image recordings made for research purposes.

(5) Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs o practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

When Expedited Review Categories do not apply

The expedited protocol review should not be used where the identification of subjects and/or their responses may appropriately place them at risk of criminality or civil liability or would injure or stigmatize subjects, provided fair and adequate precautions are put in place to ensure that the risk of privacy violation and confidentiality violation is not more than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Full Approval

Full approval shall be granted after the author/researcher has satisfied all ethical considerations as suggested by the reviewers of such protocol and this shall be granted at the consideration of a general meeting of COEREC.

Requirement for continual review of Protocol

Good ethical practices prescribe a continuous review process. All projects particularly those large in scope and/or of prolonged duration shall enjoy continuous review process by COEREC. Such projects through its principal investigator shall submit a periodic report of 6 months to the COEREC for the purpose of review and approval for the continuation of such projects.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS (PI), CO-INVESTIGATORS AND OTHERS

Principal investigators are individuals who have formal appointment (Teaching or Non-teaching) at the Osun State University, Nigeria, or registered students of the University. The PI must be a full Professor or PhD holder. The PI is responsible for the overall conduct of a research, including any modification to an earlier submitted proposal. The PI is the correspondent person with the COEREC. Any investigator, other than the PI, is designated as a

co-investigator. Such investigator may carry out procedures performed on research participants, like conducting interviews, focus group discussions, administering questionnaire schedules, etc. However, the PI must be directly responsible for the activities of all research personnel.

The Investigator must submit a detailed protocol comprising the following information:

(a) A clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.

(b) A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.

(c) A statistical plan

(d) The criteria for terminating the study

(e) Details of the procedure for obtaining informed consent and safety of participants

(f) The presumed benefits to participants and any possible risks involved in participating

(g) Evidence that the investigator is qualified and competent to execute the study, or works under a competent supervisor, and that the investigator has access to adequate facilities for collecting primary or secondary data as required of the research.

(h) Description of how research outcomes will be evaluated and disseminated.

STANDARD OPERATING PROCEDURE (SOP)

The review committee shall be led by a Chairman:

(a) The Chairman of the COEREC must have been formally trained in Research Ethics, preferably with a certificate/diploma or degree.

(b) A minimum of two reviewers shall review any proposal submitted.

(c) Consensus regarding the scientific acceptability of a submitted proposal (if there is no initial consensus, some group discussion regarding the proposal must take place)

(d) The review may also be done within the context of a course, provided that all the criteria below are considered.

The COEREC shall review and recommend to Ethical Research Review Board (ERRB) for approval all research involving humans and subjects before it is initiated. This shall normally involve:

(a) A research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalisable knowledge.

(b) Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(c) The following categories of people may submit protocol to COEREC: faculty member, staff and students; as long as the research project satisfies a requirement imposed by the University as the condition for the award of a degree or completion of a course of study in the University or for expanding frontiers of academic knowledge.

(d) The procedures are performed with or involve the use of facilities or equipment belonging to the University patients, students, staff or facility;

(e) The protocol narrative must be detailed enough to enable the COEREC objectively evaluate the scientific merit of the proposed research and potential risks and benefits to research participants.

(f) The protocol should be typed and paginated, not exceeding 10 pages, including references. Four copies of the protocol, an electronic version, and a one-page summary should be submitted to the COEREC Office.

Components of informed consent

The free and informed consent of the participants must be obtained before the commencement of a research involving individuals or groups. Thus, the researcher is responsible for:

(a) Introducing the theme or subject comprehensively with adequate information concerning the purposes; methods, demands, risk, duration and inconveniences of study.

(b) Noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.

(c) Obtaining appropriate consent from relevant community leaders and/or recognized spokespersons.

(d) Ensuring that in a situation where a participant lacks the competence to consent, a person with the legitimate authority to decide for that participant is provided with that information and may exercise that choice.

(e) Taking into special consideration consultation with state/Federal/local agencies with regard to the Import of the research and the sensitivity to the political and socio-cultural of the study areas.

(f) Obtaining a letter of introduction from appropriate authorities/Institutions.

Consent in Research and Power Relations

The interactions between researchers and informants are often characterized by power relations. Researchers should be aware of special challenges that could arise in peculiar circumstances, such as professional colleagues or teacher and students. In these cases, researchers should be prepared to offer assurance that refusal to participate in, or a decision to withdraw from the research will not lead to any penalty or discrimination.

Consent Process for Special Populations

Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is sufficiently competent. Otherwise, the person's guardian or any other legitimate authority must give consent on his/her behalf.

Consent and Assent from Children

Informed consent to participate in research by a child or young person must be obtained whenever s/he has sufficient competence to make this decision, otherwise, parents/guardian or an organization required by law could make such decision on behalf of the child or young person. “A person below 18 years is not considered an adult; hence the researcher will need the consent of a parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years (i.e. assent) without parental consent in specific circumstances.

Process for Amendment of Research Proposal

The committee shall require that applicants apply for permission to amend research proposals in any of the following circumstances:

(a) Where there are changes in any part of the research protocol

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

(c) Where there are changes in research sites

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

The ethics committee shall require that researcher submits an application for original research approval where in its opinion, the proposed amendments are substantial, such as, but not limited to change in inclusion or exclusion criteria, sample selection, intervention, randomization and outcome measures. Under no circumstances shall the researcher deviate from the approved protocol, except such as is necessary to eliminate an immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of the ethics committee within TWENTY-FOUR (24) hours of such changes.

Process for suspension of research

The ethics committee shall have power to suspend any research that is not being conducted:

(a) in accordance with COEREC's requirements;

(b) in accordance with the existing legislation;

(c) in accordance with existing institutional guidelines; or

(d) where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the ethics committee's decision and shall be reported within FOURTEEN (14) days to the researcher(s) institution, sponsor(s) and the UNIOSUN Ethics Research Review Board (ERRB).

Researchers, organizations or sponsors shall be entitled to request a reconsideration of the decision of the Ethics Committee to suspend study within fourteen days of receipt of the notification.

Process for revision of suspension

(a) The ethics committee may reverse its decision to suspend research if the issue(s) that necessitated the action is (are) resolved to committee's satisfaction.

(b) 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 to carry out remedial measure(s).

(c) Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY (180) days.

Process for termination of research

Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation 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), sponsor(s), and the UNIOSUN (ERRB), researcher(s), department(s) shall be entitled to appeal the decision of the committee to terminate the research to the ERRB within FOURTEEN (14) days of receipt of notification.

Process for appeal of the ethics committee's decision to suspend/terminate research

Upon receipt of an appeal of the decision of the ethics committee to the determinate research, the UNIOSUN ERRB may at his discretion, take up such an appeal.

Where the appeal is sustained

(a) The UNIOSUN ERRB may with reasons, direct the ethics committee to approve the research and provide continuity oversight.

(b) The UNIOSUN ERRB may mandate modification(s), which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuity oversight.

(c) The UNIOSUN ERRB may sustain the decision of the ethics committee and dismiss the appeal.

Appendix IIA

RESEARCH ETHICS APPLICATION FORM

Applicants must complete Research Ethics Form. The appropriate recommendations, signatures and dates should be obtained before submission to the College Research Ethics Office.

GENERAL INFORMATION

1.1 Name of Principal Researcher:……..
Department:……
College:……..
Title and Qualifications…….
Tel:Office ……..Mobile……..…
Email:……Fax:……..

1.2 Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Office Tel:……..Cell…….....
Fax:……Email:…….
Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Office Tel:……..Cell……

Project Details

1.3 Full title and Abstract of the Project:
1.4 Research Problem
1.5 Research Objectives

Justification for the Study

1.6 Research Methodology
1.7 Expected Significance of Study
1.8 Other relevant Project Information
1.9 Proposed duration of Project (give start and end dates):
1.10 Place of Fieldwork:
1.11 Experimental Site:

General Ethical Concerns

1.12 Is this a degree-oriented research? If yes, give names and titles of supervisor(s), Departments and telephone numbers

……

1.13 If researcher does not possess a doctorate degree, give names and titles of mentor(s), Departments and telephone contacts

……

1.14 Where confidentiality is required in the research project, explain how it will be ensured and guaranteed?

1.15 Explain how the findings of the research project will be disseminated taking into consideration recognition of ethical concerns

1.16 It is required that consent is sought if human subjects are involved. Explain whether consent will be verbal or written. Attach a copy of the consent statement which will be applied to this study.

1.17 It is required that researchers declare any conflict of interest? Explain any conflict of interest (who, and how, and extent of conflict of interest). Failure to disclose any conflict of interest may result to disciplinary action.

1.18 Explain any physical, biological, chemical, safety, psychological or any related concerns/harm this research project can cause in its execution.

1.19 Is this a collaborative research with other institutions? If yes, give names, titles, qualifications, email addresses and telephone numbers of collaborators. Will additional ethical clearance be required from institutions of collaborators?

1.20 Will there be recorded media (audio, video or other – specify) involved in the execution of the research project? If yes, explain.

1.21 How will the research be funded? If human subjects are participants, have costs for transportation, feeding, and honoraria been factored into the budget? Explain.

EDUCATION RESEARCH ETHICS

1 What type of research is this?

2 Will information be collected from institutions such as universities, schools, employers, government and other agencies about individuals without their direct consent? If so, how will the information be sought and why will individual consent not be sought?

3 If recorded media (audio, video or other) will be used in the execution of the research project, specify where the materials will be retained after the study; for how long will they be retained; and how they will they eventually be disposed of?

4 Will children be engaged in the research? If so which age grouping? Will the children be those in the care of a local authority, orphanage, foster home, or living with their parents? Please explain.

5 Does the research focus on participants with special educational needs; physically or mentally ill? Vulnerable in other ways? Racial or ethnic minority? Please explain.

6 Will the research advance knowledge in Education?

Appendix III

COLLEGE OF HEALTH SCIENCES (CHS) POLICY ON RESEARCH ETHICS

1.0 Background

Article 97 of the Federal Government of Nigeria National Health Bill 2004 provides that "Every institution, health agency and health establishment at which health research is conducted, shall establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Committee." The main stipulated duties of such health research ethics committee shall include:

(i) Reviewing research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable disease; and

(ii) Grant approval for the conduct of research by the concerned individual(s), institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

1.1 Membership of the Committee

The UNIOSUN College of Health Sciences Health Research Ethics Committee shall include the following:

(i) Chairman to be appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor, Academic, Research, Innovation and Partnerships (ARIP)

(ii) College Representative on the University Ethics Committee

(iii) A Medical Doctor

(iv) A Legal Practitioner

(v) A Nurse

(vi) At least two lay persons (male and female)

(vii) A Community Health Worker

(viii) One representative of Medical Microbiology, Heamatology, Histology, Chemical Pathology and Pharmacology

(ix) A Secretary

Members shall serve for two years.

2.0 HREC Functions and Operations

UNIOSUN HREC shall:

(i) Operate in accordance with the provisions of the current version of the National Code of Health Research Ethics issued by the NHREC as well as the Standard Operating Procedure (SOP) issued by the NHREC.

(ii) Except when an expedited review procedure is used, research proposals shall be considered at regularly convened ordinary meetings of HREC at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas.

(iii) Where a member cannot physically attend a meeting, the member shall be accounted as being present if he/she can participate electronically, for example by teleconferencing for the majority of the duration of the meeting.

2.1 Frequency and structure of meetings of the UNIOSUN HREC

The ethics committee shall meet at least once a month in order to ensure that no research proposal is held up at the level of the committee. Each member must attend at least 75% of all meetings.

No more than half an hour at the start of each meeting be devoted to 'business issues': reading the minutes of the previous meeting, reports from subcommittees, new issues. The remaining time must be used to discuss and explore the different moral values within the institution. This is where free discussion on ethics is encouraged and decisions sought on this basis. Discussions on specific cases, their reports having been prepared and circulated in advance, are most likely to yield results. Such cases could be selected with a view to provoking discussions on informed consent, the means by which diagnosis is disclosed to the patient and relations, expenditure incurred by patients, the rationale and justification for expensive tests or therapies, relevance of research being undertaken within the institute etc Time should also be devoted at each meeting on reviewing relevant papers on medical ethics published in recent issues of journals, the focus being on how these can be used to improve standards in the institution.

2.2 Other functions of HREC

These could cover all aspects of patient care and research. Other activities of an ethics committee include:

(i) Production of guidelines on a broad range of topics such as disclosure of diagnosis, diagnosis of brain death, requesting permission to harvest organs for transplantation, obtaining informed consent are some examples;

(ii) Setting up and ensuring proper functioning of a forum for attending to complaints from patients and families. This forum must receive complaints in writing and provide assistance for illiterate patients to prepare such documents. Complaints, proceedings of hearings on them, decisions and actions taken must be kept on record;

(iii) Producing a document for the benefit of patients and their families, informing them of services provided by the institution, rights of patients and relatives, their responsibilities, means by which they may seek redress for any harm that may be done to them;

(iv) Conducting surveys on practices within the institution on a continuing basis: standards of patient care, unnecessary expenditure enforced on patients, truly obtaining informed consent when required. Patients and relatives could be polled on deficiencies/ malpractice witnessed by them and their suggestions for improvement.

(v) Obtaining feedback from faculty, other staff on the functioning of the ethics committee; perceived deficiencies and suggestions on how it might function more effectively. It may be necessary to permit anonymity of those making observations in order to safeguard them from victimisation and encourage free and frank observations.

(vi) Conducts seminars/ workshops/ mini- conferences on biomedical ethics, better research etc.

3.0 Important ethical considerations for research proposal review

All research proposals must conform to standard scientific and ethical guidelines. These must be scrutinised by a designated member of the committee to ensure that there is no glaring deficiency. (In case of such a deficiency, the proposal should promptly be returned to the researcher with a note on what is needed). All proposals received before a stipulated date must be discussed at the next meeting. The committee must pay special attention to the following:

(i) Will the study add substantially to existing knowledge?

(ii) Is the study scientifically, statistically and ethically valid?

(iii) Is it relevant?

(iv) Are the procedures involved or expected outcomes of this study likely to prove harmful? The committee has a moral responsibility to desist from any inquiry as soon as it becomes clear that it is likely to endanger mankind.

(v) If experiments on animals form an essential component, are humane practices built into the project?

(vi) If human subjects are involved, special attention must be paid to how truly informed consent is obtained, what measures have been provided in case of complications that may harm the subjects and how those defaulting from the study will be followed up if a drug or implant with medium or long term action is being used.

3.1 Process for regular research approval (culled from the National Code of Ethics)

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

(ii) In order for research to be approved, the decision shall ordinarily be arrived at by discussion and consensus or it shall receive the support of a simple majority of those members present at the meeting. HREC may, at its own discretion, invite representations from the applicant(s), sponsor(s), institution(s) or any other person(s) that it may consider relevant to provide information pertinent to the research during the review process.

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

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

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

(vi) Where HREC does not conclude its review in 3 months and has not referred the case to the NHREC, the applicant shall have the right to complain to NHREC with the possibility of reallocation of the proposal to another HREC and sanction of the concerned HREC

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

(viii) Where HREC has received representation from the applicant in response to an

existing decision, HREC may decide to uphold or modify its previous decision and shall communicate this decision to the applicant within 3 months of the representation.

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

3.2 HREC Records and Reports

HREC shall prepare and maintain adequate documentation of all its activities, including the following:

(a) All materials pertinent to research review such as:

(i) Copies of all research proposals reviewed.

(ii) All reviews that accompany the proposals.

(iii) Copies of approved consent documents, including forms, adverts etc.

(iv) All progress reports submitted by researcher(s), institution(s) and sponsor(s).

(v) All reports of injuries to participants and adverse events.

(vi) Attendance at meetings.

(vii) Date proposals submitted and date approval given.

(viii) Financial records.

(b) Minutes of HREC meetings which shall be in sufficient detail to show:

(i) Attendance at the meetings.

(ii) Actions taken by the HREC.

(iii) The vote on these actions including the number of members voting for, against, and abstaining.

(iv) The basis for requiring changes in or disapproving research.

(v) A written summary of the discussion of controversial issues and their resolution.

(c) Records of continuing oversight activities.

(a) Copies of all correspondence between the HREC and applicants, researchers, sponsors, and any other agent consulted by HREC in the discharge of its duties.

(b) Statements of complaints or information/data used to determine decision(s) on research.

4.0 Basic principles of research ethics

The primary responsibility for the conduct of ethical research lies with the researcher. It is a fundamental principle that staff and students engaged in research adopt a continuing personal commitment to act ethically, to encourage ethical behaviour in those with whom they collaborate, and to consult where appropriate concerning ethical issues. Researchers must take all reasonable steps to avoid actions with deleterious consequences for participants, themselves, or other researchers. The UNIOSUN HREC requires that all research conducted within her purview are in congruence with the following principles:

(i) Honesty in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.

(ii) Rigour, in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.

(iii) Transparency and open communication in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.

(iv) Care and respect for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

4.1 Challenges commonly associated with the conduct of Research

Research must be characterized by honesty and integrity within the ethical acceptable framework at all times. Academic dishonesty including any of the underlisted are considered as serious offences: Researchers must pay particular attention to issues of travel and conference sponsorship, recruitment fees, co-authorship of article, funding for facilities.

These include:

(i) Conflict of interest: can occur in research when the professional judgment is unduly influenced by other interest such as financial gains or personal status.

(ii) Competence of Investigator

(iii) Scientific Integrity and Misconduct

(iv) Plagiarism

(v) Fabrication

(vi) Intellectual Property Rights

(vii) Disagreement between two ethics committees.

The UNIOSUN HREC has developed forms for the purpose of submitting and reviewing research proposals submitted to her (please see appendices I and II).

5.0 World Health Organisation (WHO)'s recommendations on Research Ethics Committee resources

The entity establishing the REC supports it with adequate resources, including staffing, facilities, and financial resources to allow the REC to effectively carry out its responsibilities. As an integral part of a health research institution or health system, a REC receives:

(i) support staff, adequate in number and training to enable the REC to carry out its technical and administrative responsibilities;

(ii) adequate resources for the staff to fulfill its assigned functions, including office space and equipment and supplies (e.g. computers, stationery, telephones,

photocopying machines, shredding machine) to conduct administrative business, to store committee fi les, and to keep documents secure and confidential;

(iii) access to appropriate space for the committee to meet and adequate means for members to communicate as needed between meetings;

(iv) adequate financial resources to permit the committee to produce high-quality work;

(v) if considered necessary by the entity establishing the REC, resources necessary to compensate REC members, unless they are already being compensated for their time and effort on the REC through other means.

In the light of the above recommendations by the world's overall health body (WHO), the UNIOSUN HREC hereby implores the Management of UNIOSUN to kindly ensure that all the above recommendations are implemented and also that the registration of the HREC with the appropriate regulatory body (NHREC) be expedited so as to place the institution on the right pedestal for proper and effective execution of her research ethics responsibilities.

Appendix IIIA

OSUN STATE UNIVERSITY, OSOGBO
COLLEGE OF HEALTH SCIENCES

RESEARCHERS

Code Number: 0000/00/000/ A / H or B

1. NAME OF PRINCIPAL INVESTIGATOR (PI) AND DEGREES:

2. INSTITUTION:

3. ADDRESS OF ORGANIZATION FUNDING THE RESEARCH:

4. ADDRESS OF PRINCIPAL INVESTIGATOR(including Telephone Nos. or e-mail):

5. NAME & ROLE OF CO-INVESTIGATOR(S) (including Telephone Nos. or e-mail):

6. TITLE OF STUDY:

7. INTRODUCTION/BACKGROUND OF STUDY:

8. JUSTIFICATION OF THE STUDY

9. AIM AND OBJECTIVES OF THE STUDY
   (a) General Objectives

(b) Specific Objectives:

10. PROPOSED METHODOLOGY

a. Description of Study Area:

b. Study design:

c. Sample Size determination

d. Study Population

11. Research Instrument (e.g questionnaire, Focus Group Discussion, Spectrophotometry; please include report of Pre-Test test):

Inclusion Criteria:

Exclusion criteria

1. DATA MANAGEMENT PLAN:

2. LIMITATION OF STUDY:

3. BENEFITS OF THE STUDY TO SCIENCE:

4. BENEFITS OF STUDY TO THE COMMUNITY

16. **FOR OFFICIAL USE ONLY**

(a) Date of receipt: ……....

(b) Date Sent to Reviewers: …….

(c) Date received from Reviewer 1: ……..

(d) Date received from Reviewer 2: ……..

(e) Date received from Reviewer 3: ……..

(f) Final Decision of the Ethics Committee: …….....……..

If approved, date of final approval by Committee: …….....

Appendix IIIB

OSUN STATE UNIVERSITY OSOGBO/CHS

HREC

Reviewers Guide

PART A: ***Editorial Office Only***

SECTION I

Reviewer's Name:	
E-Mail:	
Manuscript Number:	
Title:	
Authors:	
Date Sent To Reviewer:	
Date Expected From Reviewer:	

PART B: ***Reviewer Only***

SECTION II: Comments per Section of Manuscript

GENERAL COMMENT	
Introduction:	
Methodology:	

SECTION II (Cont.)

Bibliography/References:	
Others:	
Decision:	

SECTION III - Please rate the following: ***(1 = Excellent) (2 = Good) (3 = Fair) (4 = poor)***

Originality:	
Contribution To The Field:	
Technical Quality:	
Clarity Of Presentation :	
Depth Of Research:	

SECTION IV - Recommendation: (*Kindly Mark With an X*)

Accept As Is:	
Requires Minor Corrections:	
Requires Moderate Revision:	
Requires Major Revision:	
Submit To Another HREC:	
Reject On Grounds Of (Please Be Specific):	

SECTION V: *Additional Comments*
Please add any additional comments (Including comments/suggestions regarding online supplementary materials, if any):

Appendix IIIC

OSUN STATE UNIVERSITY, HREC REVIEW FORM

Assessment Summary by College Ethical Review Committee

Assessor: Date:

Institution: **Telephone** **E-mail:**

For Studies involving human subjects:

1. Are the investigators qualified to carry out the procedure?	YES	☐	N☐	☐
2. Are the CVs' of the investigators submitted with the proposals?	YES	N☐	N☐	☐
3. Is it necessary to use human subjects?	YES	NO☐	N/A☐	☐
4. Is it a clinical study?	YES	NO☐	N/☐	☐
5. Does it involve epidemiological, social or behavioural research only?	YES	NO☐	N/☐	☐
6. Are toxicological and pharmacological data adequate?	YES	NO☐	N/☐	☐
7. Does the design include appropriate criteria for subject selection and for subject and study discontinuation?	YES	NO☐	N/A☐	☐
8. Are the facilities adequate for the work proposed?	YES	NO☐	N/A☐	☐
9. Is there a consent from which provides sufficient information to the subject as to the nature, risks and benefits (if any) of the study?	YES	NO☐	N/A☐	☐
10. Is it stated that consent will be voluntary and that the Subject has the right to withdraw at any time without Prejudice to his or her future medical treatment?	YES	☐	N/☐	☐
11. Is it stated that the information on the subject will be kept Confidential?	YES	NO☐	N/A☐	☐
12. Is the study design ethically acceptable?	YES	☐	N☐	☐

Appendix IVA

COLLEGE OF HUMANITIES AND CULTURE (CHC) POLICY ON RESEARCH ETHICS

1.0 Background

This policy establishes a framework for professional ethical issues in Humanities research. It will enhance academic excellence, honesty and research integrity among students and the faculty members.

The policy contains aim, research objectives, scope of research in humanities, important definitions, principles of research, collaborative research, research misconduct and penalties, professional standards, audit and assurance in humanities research.

Membership of the Committee

The UNIOSUN College of Humanities and Culture Research Ethics Committee shall comprise of:

(a) Chair: A Professor to be appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor (ARIP).
(b) College Representative on the University Ethics Committee.
(c) One member of staff from each department in the College, who shall not be below the rank of Senior Lecturer.
(d) Two lay people (male and female) from the immediate local environment.
(e) Any other relevant person on *ad-hoc* basis, as deemed fit.

Members shall serve for two years.

Frequency and structure of meetings of the UNIOSUN CHCREC

(a) The ethics committee shall meet at least once a month in order to ensure that no research proposal is held up at the level of the committee. Each member must attend at least 75% of all meetings.
(b) No more than half an hour at the start of each meeting be devoted to 'business issues': reading the minutes of the previous meeting, reports from subcommittees, new issues. The remaining time must be used to discuss and explore the different moral values within the institution. This is where free discussion on ethics is encouraged and decisions sought on this basis. Discussions on specific cases, their reports having been prepared and circulated in advance, are most likely to yield results. Such cases could be selected with a view to provoking discussions on informed consent, relevance of research being undertaken within the institute etc. Time should also be devoted at each meeting on reviewing relevant papers on ethics published in recent issues of journals, the focus being on how these can be used to improve standards in the institution.

1.1 AIM

In line with the vision and the mission of Osun State University to create a unique institution committed to the pursuit of academic innovation, skill-based training and a tradition of

excellence in teaching, research and community service, the College of Humanities and Culture's policy, procedures and guidelines for research ethics are set forth. The ethical policy of the College of Humanities and Culture (CHC) is set out to:

(a) raise ethical standard in relation to disciplines in humanities.
(b) develop an internationally accepted ethical guidelines and code of good practice for the different categories of researchers including staff and students in the College;
(c) commit the College to meeting international standards in research and research-focused teaching;
(d) enable the College and its researchers attain and maintain the highest ethical standards and to foster values of honesty, rigour, openness, care and respect;
(e) set out the general ethical principles, procedures and guidelines which the College requires its researchers to follow;
(f) encourage the application of ethical principles and guidelines in the conduct of quality research in an enabling environment;
(g) make the ethical policy apply equally to the College's staff and students conducting research at any level, and to any other person, regardless of their status, engaged in research under the auspices of CHC, on behalf of, or in association with CHC, and to cover all research conducted collaboratively with other higher institutions;
(h) implement research agenda and policies that take into consideration ethical issues with strategic focus on and alignment with local and national priorities.

1.2 OBJECTIVES OF GUIDELINES

The College of Humanities and Culture research ethics code is intended to:

(a) provide a set of generic ethical requirements to be observed when designing, conducting, recording and reporting research that involves human participants;
(b) provide an environment and support that are conducive to research and attract top faculty members and students;
(c) emphasize peer-reviewed research, publications, and related creative and professional contributions of all faculty members of the College;
(d) engage students in research experience that prepares them for a broad set of roles in society;
(e) ensure that all undergraduate and postgraduate students have opportunities to engage in research and innovation experiences;
(f) support engagement and inclusive collaboration with peer institutions and a diverse array of industry, professional, public sector, government, community, and civil society partners;
(g) foster equity, diversity, and inclusiveness, among researchers themselves and within research approaches and methodologies;
(h) respect human dignity, free and informed consent, vulnerable persons, privacy and confidentiality, justice and inclusiveness;
(i) balance harms and benefits, minimize harm and maximize benefit;
(j) communicate and celebrate the value of our research and innovation achievements in the College and the University.

Compliance with all these will provide assurance that the dignity, rights, safety and well-being of research participants in the College are of primary importance in any research study, that they are protected and that the results of their research are credible.

1.3 SCOPE OF RESEARCH IN HUMANITIES

Research in Humanities focuses on providing answers to fundamental questions and finding solutions to some of the most pressing challenges that face humanity. Research in Humanities discovers and understands humanity and sustains societies, promotes healthy communities, engages language, culture, art and values, advances governance, diversity and social justice to build a liveable society. Through emphasis on these key thematic areas, Humanities through disciplinary and interdisciplinary research create the novel approaches and breakthroughs that are needed to address issues of local, national, and global importance. This represents a sustained commitment to issues pertaining to the sustainability of human communities and the natural world. Research in Humanities contributes to international responses to global challenges, such as the United Nations Sustainable Development Goals (SDGs) in which the international research community is concentrating resources and talents.

2.0 Peculiarities in Humanities Research

(a) Research activities in humanities are basically people oriented; not animals and materials as in pure, physical and applied sciences.
(b) The results in humanities are subject-based hence they are largely depended on mood.
(c) They do not have immediate therapeutic functions.
(d) The impact of research in humanities is sometimes not always appreciated as compared to scientific researches.
(e) The hazards of research in humanities are often generally overlooked.

2.1 Significance of Research in Humanities

(a) Research in humanities enhances the understanding of ourselves and other peoples of the world in diverse areas.
(b) Research in humanities promotes the comprehension of different human actions and how such can positively or adversely affect the present and the future of our lives, the generations unborn and the world in general.
(c) Research in humanities enables the understanding of the various perspectives of different cultures to foster co-operation, reduce conflicts and induce development.

2.2 Reasons for Ethics in Research in Developing Nations

(a) There is the need to promote healthy and global participation in research activities.
(b) There is the need to protect individuals from harm, which can result from taking part in research studies.
(c) There is the need for justice to be attained while enjoying the research benefits.

COLLABORATIVE RESEARCH

Collaborative Research means researchers within and/or outside the discipline working together to achieve a common goal. In humanities, it will require two or more intra or inter faculty members, within or outside the institution who have the same or pursuing mutually interesting and beneficial research in their field.

3.1 Significance of Collaborative Research in Humanities

(a) To enhance ideas and increase creativity through peer-reviewed open literature research
(b) To improve the visibility of the author(s) and the research.
(c) To provide opportunities to expand researchers' views or horizon

3.2 Steps to Collaborative Research

(a) Collaborators must identify themselves
(b) Outline the objectives
(c) Collaborators must develop a plan for communication and follow up on tasks
(d) There should be a time line
(e) Ideas must be flexible
(f) Successes must be celebrated

3.3 How collaborative research can be achieved in the College of Humanities and Culture

Researchers in collaboration should:

(a) Access data
(b) Address mutual expectation for their accessed data before the beginning of the research
(c) Determine the authorship of the research.
(d) Apportion task to members of the team according to their areas of specialization and experience.
(e) Minutes of every meeting must be taken and sent to everyone involved in the research.

Exemption from Review Process

The following shall be exempted from the HCREC review process: searches for existing literature, quality assurance activities or evaluation project design for self-improvement or program evaluation not meant to contribute to generalisable knowledge, interviews of individuals that focus on things not people such as questions on policies.

Process for Exemption

(a) HCREC may grant exemptions from review in any of the conditions enumerated above.
(b) Applicants seeking exemptions shall submit the proposed research or adequate information about it to the HCREC, sufficient, in HCREC judgment, to make a determination.
(c) Exemptions may be granted by the HCREC Chairperson or his designee from among members of the HCREC, in consultation with the HCREC Administrative Officer – where one exists.
(d) In granting exemptions, the reviewer(s) shall exercise all the authorities of the HCREC except that the reviewer(s) may not disapprove the research.
(e) Where the reviewer is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to the HCREC.

(f) The Chairman of HCREC shall bring all exempted protocols to the next meeting of HCREC for notice, discussion and ratification.

Expedited Approval

Expedited review procedures can be considered when research activities present no more than minimal risk to human subjects. Inclusion on the expedited approval list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involves no more than minimal risk to human subjects e.g. collection of blood samples by finger prick.

(a) Prospective collection of biological specimens for research purposes by non-invasive means.

(b) Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(c) Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as or medical treatment or diagnosis)

(d) Collection of data from voice, video, digital, or image recordings made for research purposes.

(e) Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs o practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

When Expedited Review Categories do not apply

The expedited protocol review should not be used where the identification of subjects and/or their responses may appropriately place them at risk of criminality or civil liability or would injure or stigmatize subjects, provided fair and adequate precautions are put in place to ensure that the risk of privacy violation and confidentiality violation is not more than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Full Approval

Full approval shall be granted after the author/researcher has satisfied all ethical considerations as suggested by the reviewers of such protocol and this shall be granted at the consideration of a general meeting of HCREC.

Requirement for continual review of Protocol

Good ethical practices prescribe a continuous review process. All projects particularly those large in scope and/or of prolonged duration shall enjoy continuous review process by HCREC. Such projects through its principal investigator shall submit a periodic report of 6 months to the HCREC for the purpose of review and approval for the continuation of such projects.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS (PI), CO-INVESTIGATORS AND OTHERS

Principal investigators are individuals who have formal appointment (Teaching or Non-teaching) at the Osun State University, Nigeria, or registered students of the University. The PI must be a full Professor or PhD holder. The PI is responsible for the overall conduct of a research, including any modification to an earlier submitted proposal. The PI is the correspondent person with the HCREC. Any investigator, other than the PI, is designated as a co-investigator. Such investigator may carry out procedures performed on research participants, like conducting interviews, focus group discussions, administering questionnaire schedules, etc. However, the PI must be directly responsible for the activities of all research personnel.

The Investigator must submit a detailed protocol comprising the following information:

(a) A clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.
(b) A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.
(c) A statistical plan
(d) The criteria for terminating the study
(e) Details of the procedure for obtaining informed consent and safety of participants
(f) The presumed benefits to participants and any possible risks involved in participating
(g) Evidence that the investigator is qualified and competent to execute the study, or works under a competent supervisor, and that the investigator has access to adequate facilities for collecting primary or secondary data as required of the research.
(h) Description of how research outcomes will be evaluated and disseminated.

STANDARD OPERATING PROCEDURE (SOP)

The review committee shall be led by a Chairman:

(a) The Chairman of the HCREC must have been formally trained in Research Ethics, preferably with a certificate/diploma or degree.
(b) A minimum of two reviewers shall review any proposal submitted.
(c) Consensus regarding the scientific acceptability of a submitted proposal (if there is no initial consensus, some group discussion regarding the proposal must take place)
(d) The review may also be done within the context of a course, provided that all the criteria below are considered.

The HCREC shall review and recommend to Ethical Research Review Board (ERRB) for approval all research involving humans and subjects before it is initiated. This shall normally involve:

(a) A research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalisable knowledge.
(b) Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs

may include research activities.

(c) The following categories of people may submit protocol to HCREC: faculty member, staff and students; as long as the research project satisfies a requirement imposed by the University as the condition for the award of a degree or completion of a course of study in the University or for expanding frontiers of academic knowledge.

(d) The procedures are performed with or involve the use of facilities or equipment belonging to the University patients, students, staff or facility;

(e) The protocol narrative must be detailed enough to enable the HCREC objectively evaluate the scientific merit of the proposed research and potential risks and benefits to research participants.

(f) The protocol should be typed and paginated, not exceeding 10 pages, including references. Four copies of the protocol, an electronic version, and a one-page summary should be submitted to the HCREC Office.

Components of informed consent

The free and informed consent of the participants must be obtained before the commencement of a research involving individuals or groups. Thus, the researcher is responsible for:

(a) Introducing the theme or subject comprehensively with adequate information concerning the purposes; methods, demands, risk, duration and inconveniences of study.

(b) Noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.

(c) Obtaining appropriate consent from relevant community leaders and/or recognized spokespersons.

(d) Ensuring that in a situation where a participant lacks the competence to consent, a person with the legitimate authority to decide for that participant is provided with that information and may exercise that choice.

(e) Taking into special consideration consultation with state/Federal/local agencies with regard to the Import of the research and the sensitivity to the political and socio-cultural of the study areas.

(f) Obtaining a letter of introduction from appropriate authorities/Institutions.

Consent in Research and Power Relations

The interactions between researchers and informants are often characterized by power relations. Researchers should be aware of special challenges that could arise in peculiar circumstances, such as professional colleagues or teacher and students. In these cases, researchers should be prepared to offer assurance that refusal to participate in, or a decision to withdraw from the research will not lead to any penalty or discrimination.

Consent Process for Special Populations

Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is sufficiently competent. Otherwise, the person's guardian or any other legitimate authority must give consent on his/her behalf.

Consent and Assent from Children

Informed consent to participate in research by a child or young person must be obtained whenever s/he has sufficient competence to make this decision, otherwise, parents/guardian or an organization required by law could make such decision on behalf of the child or young person. "A person below 18 years is not considered an adult; hence the researcher will need the consent of a parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years (i.e. assent) without parental consent in specific circumstances.

Process for Amendment of Research Proposal

The committee shall require that applicants apply for permission to amend research proposals in any of the following circumstances:

(a) Where there are changes in any part of the research protocol
(b) Where there are changes in named members of the research team
(c) Where there are changes in research sites
(d) Where there are changes in the sponsorship, institutional guidelines, institutional structure, the committee's requirements, national laws or exigencies that impact on the ethical conduct of research

The ethics committee shall require that researcher submits an application for original research approval where in its opinion, the proposed amendments are substantial, such as, but not limited to change in inclusion or exclusion criteria, sample selection, intervention, randomization and outcome measures. Under no circumstances shall the researcher deviate from the approved protocol, except such as is necessary to eliminate an immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of the ethics committee within TWENTY-FOUR (24) hours of such changes.

Process for suspension of research

The ethics committee shall have power to suspend any research that is not being conducted:

(a) In accordance with HCREC's requirements;
(b) In accordance with the existing legislation;
(c) In accordance with existing institutional guidelines; or
(d) Where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the ethics committee's decision and shall be reported within FOURTEEN (14) days to the researcher(s) institution, sponsor(s) and the UNIOSUN Ethics Research Review Board (ERRB).

Researchers, organizations or sponsors shall be entitled to request a reconsideration of the decision of the Ethics Committee to suspend study within fourteen days of receipt of the notification.

Process for revision of suspension

(a) The ethics committee may reverse its decision to suspend research if the issue(s) that necessitated the action is (are) resolved to committee's satisfaction.
(b) 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 to carry out remedial measure(s).

(c) Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY (180) days.

Process for termination of research

Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation 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), sponsor(s), and the UNIOSUN (ERRB), researcher(s), department(s) shall be entitled to appeal the decision of the committee to terminate the research to the ERRB within FOURTEEN (14) days of receipt of notification.

Process for appeal of the ethics committee's decision to suspend/terminate research

Upon receipt of an appeal of the decision of the ethics committee to the determinate research, the UNIOSUN ERRB may at his discretion, take up such an appeal.

Where the appeal is sustained

(a) The UNIOSUN ERRB may with reasons, direct the ethics committee to approve the research and provide continuity oversight.

(b) The UNIOSUN ERRB may mandate modification(s), which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuity oversight.

(c) The UNIOSUN ERRB may sustain the decision of the ethics committee and dismiss the appeal

Appendix IVB

RESEARCH ETHICS APPLICATION FORM

Applicants must complete Research Ethics Form. The appropriate recommendations, signatures and dates should be obtained before submission to the College Research Ethics Office.

GENERAL INFORMATION

1.1 Name of Principal Researcher:……..
Department:……
College:……..
Title and Qualifications…….
Tel: Office ……..Mobile…….…
Email:……Fax:……..

1.2 Name(s) of Co- Researcher(s):……..
Department:……
College:…….…….
Title and Qualifications……..
Office Tel:……..Cell…….....…
Fax:……Email:…….
Name(s) of Co- Researcher(s):……..
Department:……
College:…….…….
Title and Qualifications……..
Office Tel:……..Cell…….....
Fax:……Email:……...……

Project Details

1.3 Full title and Abstract of the Project:
1.4 Research Problem
1.5 Research Objectives

Justification for the Study

1.6 Research Methodology
1.7 Expected Significance of Study
1.8 Other relevant Project Information
1.9 Proposed duration of Project (give start and end dates):
1.10 Place of Fieldwork:
1.11 Experimental Site:

General Ethical Concerns

1.12 Is this a degree-oriented research? If yes, give names and titles of supervisor(s), Departments and telephone numbers

.....

1.13 If researcher does not possess a doctorate degree, give names and titles of mentor(s), Departments and telephone contacts

.....

1.14 Where confidentiality is required in the research project, explain how it will be ensured and guaranteed?

1.15 Explain how the findings of the research project will be disseminated taking into consideration recognition of ethical concerns

1.16 It is required that consent is sought if human subjects are involved. Explain whether consent will be verbal or written. Attach a copy of the consent statement which will be applied to this study.

1.17 It is required that researchers declare any conflict of interest? Explain any conflict of interest (who, and how, and extent of conflict of interest). Failure to disclose any conflict of interest may result to disciplinary action.

1.18 Explain any physical, biological, chemical, safety, psychological or any related concerns/harm this research project can cause in its execution.

1.19 Is this a collaborative research with other institutions? If yes, give names, titles, qualifications, email addresses and telephone numbers of collaborators. Will additional ethical clearance be required from institutions of collaborators?

1.20 Will there be recorded media (audio, video or other – specify) involved in the execution of the research project? If yes, explain.

1.21 How will the research be funded? If human subjects are participants, have costs for transportation, feeding, and honoraria been factored into the budget? Explain.

HUMANITIES RESEARCH ETHICS

1 What type of research is this?

2 Will information be collected from institutions such as universities, schools, employers, government and other agencies about individuals without their direct consent? If so, how will the information be sought and why will individual consent not be sought?

3 If recorded media (audio, video or other) will be used in the execution of the research project, specify where the materials will be retained after the study; for how long will they be retained; and how they will they eventually be disposed of?

4 Will children be engaged in the research? If so which age grouping? Will the children be those in the care of a local authority, orphanage, foster home, or living with their parents? Please explain.

5 Does the research focus on participants with special educational needs; physically or mentally ill? Vulnerable in other ways? Racial or ethnic minority? Please explain.

6 Will the research advance knowledge in Humanities?

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(v) Policy on Ethical Conduct in Research. University of Toronto, March 28, 1991. http://www.governingcouncil.utoronto.ca/

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Appendix VA

COLLEGE OF LAW (COL) POLICY ON RESEARCH ETHICS

Background

The College of Law adopted the following as research ethics policy of the College of Law, Ifetedo Campus of the University. This document conforms with the Osun State University Policy on Research Ethics and it is intended to cater for the peculiar needs of the College. However, the contents of this College of Law Policy on Research Ethics shall be consistent with the provision of Osun State University Policy on Research Ethics and any aspect that is not consistent shall be null and void to the extent of its inconsistency.

Composition of Ethics Committee

The RECOL shall have the following members:

(a) Chair: A Professor to be appointed by the Vice-Chancellor on the recommendation of DVC (ARIP).
(b) College Representative on the University Ethics Committee
(c) One member of staff that is not less than Senior Lecturer from each department in the College
(d) Two lay people (male and female) from the immediate/local environment
(e) Any other relevant person on *ad-hoc* basis.

Members shall serve for two years.

A. FREEDOM OF RESEARCH, ETHICS, AND SOCIETY
(See page 22 of the University Policy on Research Ethics)

B. RESPECT FOR INDIVIDUALS
(See page 23 of the University Policy on Research Ethics)

C. REGARD FOR GROUPS AND INSTITUTIONS
(See page 26 of the University Policy on Research Ethics)

D. THE RESEARCH COMMUNITY
(See page 28 of the University Policy on Research Ethics)

E. CONTRACT RESEARCH
(See page 30 of the University Policy on Research Ethics)

F. SCIENCE COMMUNICATION
(See page 32 of the University Policy on Research Ethics)

Exemption from Review Process

The following shall be exempted from the COLREC review process: searches for existing literature, quality assurance activities or evaluation project design for self-improvement or program evaluation not meant to contribute to generalisable knowledge, interviews of individuals that focus on things not people such as questions on policies.

Process for Exemption

(a) COLREC may grant exemptions from review in any of the conditions enumerated above.

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

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

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

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

(f) The Chairman of COLREC shall bring all exempted protocols to the next meeting of COLREC for notice, discussion and ratification.

Expedited Approval

Expedited review procedures can be considered when research activities present no more than minimal risk to human subjects. Inclusion on the expedited approval list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involves no more than minimal risk to human subjects e.g. collection of blood samples by finger prick.

(a) Prospective collection of biological specimens for research purposes by non-invasive means.

(b) Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(c) Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as or medical treatment or diagnosis)

(d) Collection of data from voice, video, digital, or image recordings made for research purposes.

(e) Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs o practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

When Expedited Review Categories do not apply

The expedited protocol review should not be used where the identification of subjects and/or their responses may appropriately place them at risk of criminality or civil liability or would injure or stigmatize subjects, provided fair and adequate precautions are put in place to ensure that the risk of privacy violation and confidentiality violation is not more than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Full Approval

Full approval shall be granted after the author/researcher has satisfied all ethical considerations as suggested by the reviewers of such protocol and this shall be granted at the consideration of a general meeting of COLREC.

Requirement for continual review of Protocol

Good ethical practices prescribe a continuous review process. All projects particularly those large in scope and/or of prolonged duration shall enjoy continuous review process by COLREC. Such projects through its principal investigator shall submit a periodic report of 6 months to the COLREC for the purpose of review and approval for the continuation of such projects.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS (PI), CO-INVESTIGATORS AND OTHERS

Principal investigators are individuals who have formal appointment (Teaching or Non-teaching) at the Osun State University, Nigeria, or registered students of the University. The PI must be a full Professor or PhD holder. The PI is responsible for the overall conduct of a research, including any modification to an earlier submitted proposal. The PI is the correspondent person with the COLREC. Any investigator, other than the PI, is designated as a co-investigator. Such investigator may carry out procedures performed on research participants, like conducting interviews, focus group discussions, administering questionnaire schedules, etc. However, the PI must be directly responsible for the activities of all research personnel.

The Investigator must submit a detailed protocol comprising the following information:

(a) A clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.
(b) A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.
(c) A statistical plan
(d) The criteria for terminating the study
(e) Details of the procedure for obtaining informed consent and safety of participants
(f) The presumed benefits to participants and any possible risks involved in participating
(g) Evidence that the investigator is qualified and competent to execute the study, or works under a competent supervisor, and that the investigator has access to adequate facilities for collecting primary or secondary data as required of the research.
(h) Description of how research outcomes will be evaluated and disseminated.

STANDARD OPERATING PROCEDURE (SOP)

The review committee shall be led by a Chairman:

(a) The Chairman of the COLREC must have been formally trained in Research Ethics, preferably with a certificate/diploma or degree.

(b) A minimum of two reviewers shall review any proposal submitted.

(c) Consensus regarding the scientific acceptability of a submitted proposal (if there is no initial consensus, some group discussion regarding the proposal must take place)

(d) The review may also be done within the context of a course, provided that all the criteria below are considered.

The COLREC shall review and recommend to Ethical Research Review Board (ERRB) for approval all research involving humans and subjects before it is initiated. This shall normally involve:

(a) a research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalisable knowledge;

(b) activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities;

(c) the following categories of people may submit protocol to COLREC: faculty member, staff and students; as long as the research project satisfies a requirement imposed by the University as the condition for the award of a degree or completion of a course of study in the University or for expanding frontiers of academic knowledge;

(d) the procedures are performed with or involve the use of facilities or equipment belonging to the University patients, students, staff or facility;

(e) the protocol narrative must be detailed enough to enable the COLREC objectively evaluate the scientific merit of the proposed research and potential risks and benefits to research participants;

(f) the protocol should be typed and paginated, not exceeding 10 pages, including references. Four copies of the protocol, an electronic version, and a one-page summary should be submitted to the COLREC Office.

Components of informed consent

The free and informed consent of the participants must be obtained before the commencement of a research involving individuals or groups. Thus, the researcher is responsible for:

(a) introducing the theme or subject comprehensively with adequate information concerning the purposes; methods, demands, risk, duration and inconveniences of study;

(b) noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation;

(c) obtaining appropriate consent from relevant community leaders and/or recognized spokespersons;

(d) ensuring that in a situation where a participant lacks the competence to consent, a person with the legitimate authority to decide for that participant is provided with that information and may exercise that choice;

(e) taking into special consideration consultation with state/Federal/local agencies with

regard to the Import of the research and the sensitivity to the political and socio-cultural of the study areas;

(f) obtaining a letter of introduction from appropriate authorities/Institutions.

Consent in Research and Power Relations

The interactions between researchers and informants are often characterized by power relations. Researchers should be aware of special challenges that could arise in peculiar circumstances, such as professional colleagues or teacher and students. In these cases, researchers should be prepared to offer assurance that refusal to participate in, or a decision to withdraw from the research will not lead to any penalty or discrimination.

Consent Process for Special Populations

Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is sufficiently competent. Otherwise, the person's guardian or any other legitimate authority must give consent on his/her behalf.

Consent and Assent from Children

Informed consent to participate in research by a child or young person must be obtained whenever s/he has sufficient competence to make this decision, otherwise, parents/guardian or an organization required by law could make such decision on behalf of the child or young person. "A person below 18 years is not considered an adult; hence the researcher will need the consent of a parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years (i.e. assent) without parental consent in specific circumstances.

Process for Amendment of Research Proposal

The committee shall require that applicants apply for permission to amend research proposals in any of the following circumstances:

(a) Where there are changes in any part of the research protocol

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

(c) Where there are changes in research sites

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

The ethics committee shall require that researcher submits an application for original research approval where in its opinion, the proposed amendments are substantial, such as, but not limited to change in inclusion or exclusion criteria, sample selection, intervention, randomization and outcome measures. Under no circumstances shall the researcher deviate from the approved protocol, except such as is necessary to eliminate an immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of the ethics committee within TWENTY-FOUR (24) hours of such changes.

Process for suspension of research

The ethics committee shall have power to suspend any research that is not being conducted:

(a) In accordance with COLREC's requirements;
(b) In accordance with the existing legislation;
(c) In accordance with existing institutional guidelines; or
(d) Where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the ethics committee's decision and shall be reported within FOURTEEN (14) days to the researcher(s) institution, sponsor(s) and the UNIOSUN Ethics Research Review Board (ERRB).

Researchers, organizations or sponsors shall be entitled to request a reconsideration of the decision of the Ethics Committee to suspend study within fourteen days of receipt of the notification.

Process for revision of suspension

(a) The ethics committee may reverse its decision to suspend research if the issue(s) that necessitated the action is (are) resolved to committee's satisfaction.
(b) 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 to carry out remedial measure(s).
(c) Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY (180) days.

Process for termination of research

Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation 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), sponsor(s), and the UNIOSUN (ERRB), researcher(s), department(s) shall be entitled to appeal the decision of the committee to terminate the research to the ERRB within FOURTEEN (14) days of receipt of notification.

Process for appeal of the ethics committee's decision to suspend/terminate research

Upon receipt of an appeal of the decision of the ethics committee to the determinate research, the UNIOSUN ERRB may at his discretion, take up such an appeal.

Where the appeal is sustained

(a) The UNIOSUN ERRB may with reasons, direct the ethics committee to approve the research and provide continuity oversight.
(b) The UNIOSUN ERRB may mandate modification(s), which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuity oversight.
(c) The UNIOSUN ERRB may sustain the decision of the ethics committee and dismiss the appeal.

RESEARCH ETHICS APPLICATION FORM

Applicants must complete Research Ethics Form. The appropriate recommendations, signatures and dates should be obtained before submission to the College Research Ethics Office.

GENERAL INFORMATION

1.1 Name of Principal Researcher:……..
Department:……
College:……..
Title and Qualifications…….
Tel: Office ……..Mobile…… .....
Email:……Fax:……..

1.2 Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Tel: Office:……..Mobile……...
Fax:……Email:…….
Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Office Tel:……..Cell……
Fax:……Email:…….

Project Details

1.3 Full title and Abstract of the Project:
1.4 Research Problem
1.5 Research Objectives

Justification for the Study

1.6 Research Methodology
1.7 Expected Significance of Study
1.8 Other relevant Project Information
1.9 Proposed duration of Project (give start and end dates):
1.10 Place of Fieldwork:
1.11 Experimental Site:

General Ethical Concerns

1.12 Is this a degree-oriented research? If yes, give names and titles of supervisor(s),

Departments and telephone numbers

……

1.13 If researcher does not possess a doctorate degree, give names and titles of mentor(s), Departments and telephone contacts

……

1.14 Where confidentiality is required in the research project, explain how it will be ensured and guaranteed?

1.15 Explain how the findings of the research project will be disseminated taking into consideration recognition of ethical concerns

1.16 It is required that consent is sought if human subjects are involved. Explain whether consent will be verbal or written. Attach a copy of the consent statement which will be applied to this study.

1.17 It is required that researchers declare any conflict of interest? Explain any conflict of interest (who, and how, and extent of conflict of interest). Failure to disclose any conflict of interest may result to disciplinary action.

1.18 Explain any physical, biological, chemical, safety, psychological or any related concerns/harm this research project can cause in its execution.

1.19 Is this a collaborative research with other institutions? If yes, give names, titles, qualifications, email addresses and telephone numbers of collaborators. Will additional ethical clearance be required from institutions of collaborators?

1.20 Will there be recorded media (audio, video or other – specify) involved in the execution of the research project? If yes, explain.

1.21 How will the research be funded? If human subjects are participants, have costs for transportation, feeding, and honoraria been factored into the budget? Explain.

LAW RESEARCH ETHICS

1 What type of research is this?

2 Will information be collected from institutions such as universities, schools, employers, government and other agencies about individuals without their direct consent? If so, how will the information be sought and why will individual consent not be sought?

3 If recorded media (audio, video or other) will be used in the execution of the research project, specify where the materials will be retained after the study; for how long will they be retained; and how they will they eventually be disposed of?

4 Will children be engaged in the research? If so which age grouping? Will the children be those in the care of a local authority, orphanage, foster home, or living with their parents? Please explain.

5 Does the research focus on participants with special educational needs; physically or mentally ill? Vulnerable in other ways? Racial or ethnic minority? Please explain.

6 Will the research advance knowledge in Law?

Appendix VIA

COLLEGE OF MANAGEMENT AND SOCIAL SCIENCES (CMSS) POLICY ON RESEARCH ETHICS

Preamble

The Research Ethics Guidelines primarily concern research, but also other research-related practices, such as teaching, research result dissemination, expert advice and management of institution. The word research often includes the work of graduate/doctoral research fellows and students at all levels, and the institutions are accountable for providing adequate training in research ethics. The guidelines apply to all public and private research, be it basic, applied or commissioned research.

The Management and Social Sciences Policy on Research Ethics (MSSPRE) guidelines have been drawn up to cover all the Management and Social Sciences disciplines as well as their wider areas of applications. In this context, Management and Social Sciences is being used as an umbrella term to cover the scope of the guidelines.

Key areas covered by the Management and Social Sciences Research Ethics Committee (MSSREC)

The MSSREC shall function as follows:

(a) Communicate and enforce research ethics standards,

(b) Convey the Guidelines for Research Ethics to the staff and students, and ensure training is provided on research ethics and the relevant acts of law that govern research. This will promote reflection on research ethics.

(c) Take responsibility for researchers to follow the Guidelines for Research Ethics. They must have specific procedures to handle suspicions and accusations related to breaches of the Guidelines e.g., by creating committees to deal with scientific dishonesty, under their own auspices.

(d) Enforce laid down procedures in the event of breaches of research ethics standards.

To whom does this Ethics Apply?

The MSSPRE guidelines contain standards that apply to:

(a) Teaching and non-teaching staff of Osun State University intending to engage in behavioural research.

(b) Undergraduate and postgraduate students registered as students in the Osun State University, interested in behavioural research.

(c) Other researchers who are not members of the Osun State University community but intend executing any behavioural research within the University.

(d) Research institutions, financiers of research and other appropriating authorities in support of behavioural research affecting the Osun State University community.

Composition of MSSREC

The membership of the MSSREC shall be as follows:

(a) Chair: A professor from the Management or Social Sciences appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor, Academic, Research, Innovation and Partnerships (ARIP).

(b) College Representative on the University Ethics Committee

(c) Two experienced behavioural scientists from the Faculties of Management and Social Sciences

(d) Two community representatives (lay persons; 1 male 1 female).

Members shall serve for two years.

Exemption from Review Process

The following shall be exempted from the MSSREC review process: searches for existing literature, quality assurance activities or evaluation project design for self-improvement or program evaluation not meant to contribute to generalisable knowledge, interviews of individuals that focus on things not people such as questions on policies.

Process for Exemption

(a) MSSREC may grant exemptions from review in any of the conditions enumerated above.

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

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

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

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

(f) The Chairman of MSSREC shall bring all exempted protocols to the next meeting of MSSREC for notice, discussion and ratification.

Expedited Approval

Expedited review procedures can be considered when research activities present no more than minimal risk to human subjects. Inclusion on the expedited approval list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involves no more than minimal risk to human subjects e.g. collection of blood samples by finger prick.

(a) Prospective collection of biological specimens for research purposes by non-invasive means.

(b) Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-

rays or microwaves.

(c) Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as or medical treatment or diagnosis)

(d) Collection of data from voice, video, digital, or image recordings made for research purposes.

(e) Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs o practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

When Expedited Review Categories do not apply

The expedited protocol review should not be used where the identification of subjects and/or their responses may appropriately place them at risk of criminality or civil liability or would injure or stigmatize subjects, provided fair and adequate precautions are put in place to ensure that the risk of privacy violation and confidentiality violation is not more than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Full Approval

Full approval shall be granted after the author/researcher has satisfied all ethical considerations as suggested by the reviewers of such protocol and this shall be granted at the consideration of a general meeting of MSSREC.

Requirement for continual review of Protocol

Good ethical practices prescribe a continuous review process. All projects particularly those large in scope and/or of prolonged duration shall enjoy continuous review process by MSSREC. Such projects through its principal investigator shall submit a periodic report of 6 months to the MSSREC for the purpose of review and approval for the continuation of such projects.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS (PI), CO-INVESTIGATORS AND OTHERS

Principal investigators are individuals who have formal appointment (Teaching or Non-teaching) at the Osun State University, Nigeria, or registered students of the University. The PI must be a full Professor or PhD holder. The PI is responsible for the overall conduct of a research, including any modification to an earlier submitted proposal. The PI is the correspondent person with the MSSREC. Any investigator, other than the PI, is designated as a co-investigator. Such investigator may carry out procedures performed on research participants, like conducting interviews, focus group discussions, administering questionnaire schedules, etc. However, the PI must be directly responsible for the activities of all research personnel.

The Investigator must submit a detailed protocol comprising the following information:

(a) A clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.

(b) A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.

(c) A statistical plan

(d) The criteria for terminating the study

(e) Details of the procedure for obtaining informed consent and safety of participants

(f) The presumed benefits to participants and any possible risks involved in participating

(g) Evidence that the investigator is qualified and competent to execute the study, or works under a competent supervisor, and that the investigator has access to adequate facilities for collecting primary or secondary data as required of the research.

(h) Description of how research outcomes will be evaluated and disseminated.

STANDARD OPERATING PROCEDURE (SOP)

The review committee shall be led by a Chairman:

(a) The Chairman of the MSSREC must have been formally trained in Research Ethics, preferably with a certificate/diploma or degree.

(b) A minimum of two reviewers shall review any proposal submitted.

(c) Consensus regarding the scientific acceptability of a submitted proposal (if there is no initial consensus, some group discussion regarding the proposal must take place)

(d) The review may also be done within the context of a course, provided that all the criteria below are considered.

The MSSREC shall review and recommend to Ethical Research Review Board (ERRB) for approval all research involving humans and subjects before it is initiated. This shall normally involve:

(a) A research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalisable knowledge.

(b) Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(c) The following categories of people may submit protocol to MSSREC: faculty member, staff and students; as long as the research project satisfies a requirement imposed by the University as the condition for the award of a degree or completion of a course of study in the University or for expanding frontiers of academic knowledge.

(d) The procedures are performed with or involve the use of facilities or equipment belonging to the University patients, students, staff or facility;

(e) The protocol narrative must be detailed enough to enable the MSSREC objectively evaluate the scientific merit of the proposed research and potential risks and benefits to research participants.

(f) The protocol should be typed and paginated, not exceeding 10 pages, including references. Four copies of the protocol, an electronic version, and a one-page summary should be submitted to the MSSREC Office.

Components of informed consent

The free and informed consent of the participants must be obtained before the commencement of a research involving individuals or groups. Thus, the researcher is responsible for:

(a) Introducing the theme or subject comprehensively with adequate information concerning the purposes; methods, demands, risk, duration and inconveniences of study.

(b) Noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.

(c) Obtaining appropriate consent from relevant community leaders and/or recognized spokespersons.

(d) Ensuring that in a situation where a participant lacks the competence to consent, a person with the legitimate authority to decide for that participant is provided with that information and may exercise that choice.

(e) Taking into special consideration consultation with state/Federal/local agencies with regard to the Import of the research and the sensitivity to the political and socio-cultural of the study areas.

(f) Obtaining a letter of introduction from appropriate authorities/Institutions.

Consent in Research and Power Relations

The interactions between researchers and informants are often characterized by power relations. Researchers should be aware of special challenges that could arise in peculiar circumstances, such as professional colleagues or teacher and students. In these cases, researchers should be prepared to offer assurance that refusal to participate in, or a decision to withdraw from the research will not lead to any penalty or discrimination.

Consent Process for Special Populations

Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is sufficiently competent. Otherwise, the person's guardian or any other legitimate authority must give consent on his/her behalf.

Consent and Assent from Children

Informed consent to participate in research by a child or young person must be obtained whenever s/he has sufficient competence to make this decision, otherwise, parents/guardian or an organization required by law could make such decision on behalf of the child or young person. “A person below 18 years is not considered an adult; hence the researcher will need the consent of a parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years (i.e. assent) without parental consent in specific circumstances.

Process for Amendment of Research Proposal

The committee shall require that applicants apply for permission to amend research proposals in any of the following circumstances:

(a) Where there are changes in any part of the research protocol
(b) Where there are changes in named members of the research team
(c) Where there are changes in research sites
(d) Where there are changes in the sponsorship, institutional guidelines, institutional structure, the committee's requirements, national laws or exigencies that impact on the ethical conduct of research

The ethics committee shall require that researcher submits an application for original research approval where in its opinion, the proposed amendments are substantial, such as, but not limited to change in inclusion or exclusion criteria, sample selection, intervention, randomization and outcome measures. Under no circumstances shall the researcher deviate from the approved protocol, except such as is necessary to eliminate an immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of the ethics committee within TWENTY-FOUR (24) hours of such changes.

Process for suspension of research

The ethics committee shall have power to suspend any research that is not being conducted:

(a) In accordance with MSSREC's requirements;
(b) In accordance with the existing legislation;
(c) In accordance with existing institutional guidelines; or
(d) Where research is associated with unexpected serious harm to participants.

Any suspension of research shall include a statement of the reason(s) for the ethics committee's decision and shall be reported within FOURTEEN (14) days to the researcher(s) institution, sponsor(s) and the UNIOSUN Ethics Research Review Board (ERRB).

Researchers, organizations or sponsors shall be entitled to request a reconsideration of the decision of the Ethics Committee to suspend study within fourteen days of receipt of the notification.

Process for revision of suspension

(a) The ethics committee may reverse its decision to suspend research if the issue(s) that necessitated the action is (are) resolved to committee's satisfaction.
(b) 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 to carry out remedial measure(s).
(c) Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY (180) days.

Process for termination of research

Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation 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), sponsor(s), and the UNIOSUN (ERRB), researcher(s), department(s) shall be entitled to appeal the decision of the committee to terminate the research to the ERRB within FOURTEEN (14) days of receipt of notification.

Process for appeal of the ethics committee's decision to suspend/terminate research

Upon receipt of an appeal of the decision of the ethics committee to the determinate research, the UNIOSUN ERRB may at his discretion, take up such an appeal.

Where the appeal is sustained

(a) The UNIOSUN ERRB may with reasons, direct the ethics committee to approve the research and provide continuity oversight.

(b) The UNIOSUN ERRB may mandate modification(s), which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuity oversight.

(c) The UNIOSUN ERRB may sustain the decision of the ethics committee and dismiss the appeal.

Appendix VIB

RESEARCH ETHICS APPLICATION FORM

Applicants must complete Research Ethics Form. The appropriate recommendations, signatures and dates should be obtained before submission to the College Research Ethics Office.

GENERAL INFORMATION

1.1 Name of Principal Researcher:……..
Department:……
College:……..
Title and Qualifications…….
Tel: Office ……..Mobile……..…
Email:……Fax:……..

1.2 Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Tel: Office ……..Mobile……
Fax:……Email:…….
Name(s) of Co- Researcher(s):……..
Department:……
College:…….
Title and Qualifications……..
Office Tel:……..Cell……....……
Fax:……Email:…….

Project Details

1.3 Full title and Abstract of the Project:
1.4 Research Problem
1.5 Research Objectives

Justification for the Study

1.6 Research Methodology
1.7 Expected Significance of Study
1.8 Other relevant Project Information
1.9 Proposed duration of Project (give start and end dates):
1.10 Place of Fieldwork:
1.11 Experimental Site:

General Ethical Concerns

1.12 Is this a degree-oriented research? If yes, give names and titles of supervisor(s), Departments and telephone numbers

.....

1.13 If researcher does not possess a doctorate degree, give names and titles of mentor(s), Departments and telephone contacts

.....

1.14 Where confidentiality is required in the research project, explain how it will be ensured and guaranteed?

1.15 Explain how the findings of the research project will be disseminated taking into consideration recognition of ethical concerns

1.16 It is required that consent is sought if human subjects are involved. Explain whether consent will be verbal or written. Attach a copy of the consent statement which will be applied to this study.

1.17 It is required that researchers declare any conflict of interest? Explain any conflict of interest (who, and how, and extent of conflict of interest). Failure to disclose any conflict of interest may result to disciplinary action.

1.18 Explain any physical, biological, chemical, safety, psychological or any related concerns/harm this research project can cause in its execution.

1.19 Is this a collaborative research with other institutions? If yes, give names, titles, qualifications, email addresses and telephone numbers of collaborators. Will additional ethical clearance be required from institutions of collaborators?

1.20 Will there be recorded media (audio, video or other – specify) involved in the execution of the research project? If yes, explain.

1.21 How will the research be funded? If human subjects are participants, have costs for transportation, feeding, and honoraria been factored into the budget? Explain.

MANAGEMENT AND SOCIAL SCIENCES RESEARCH ETHICS

1 What type of research is this?

2 Will information be collected from institutions such as universities, schools, employers, government and other agencies about individuals without their direct consent? If so, how will the information be sought and why will individual consent not be sought?

3 If recorded media (audio, video or other) will be used in the execution of the research project, specify where the materials will be retained after the study; for how long will they be retained; and how they will they eventually be disposed of?

4 Will children be engaged in the research? If so which age grouping? Will the children be those in the care of a local authority, orphanage, foster home, or living with their parents? Please explain.

5 Does the research focus on participants with special educational needs; physically or mentally ill? Vulnerable in other ways? Racial or ethnic minority? Please explain.

6 Will the research advance knowledge in Education?

Appendix VIIA

COLLEGE OF SCIENCE, ENGINEERING AND TECHNOLOGY (CSET) POLICY ON RESEARCH ETHICS

Background

A core component of all contemporary research ethics guidelines is that research protocols be subject to prior ethical review by a competent Research Ethics Committee. To have the latter in place, scientific principles and practices, ethical and regulatory requirements guiding research/scholarship activities in life sciences, engineering/technology and environmental science must be clearly understood.

Since our research endeavours in the College of Science, Engineering and Technology are as diverse as the differing Departments therein, this policy document encompasses ethical standards guiding responsible research in life sciences, engineering/technology and environmental sciences. The document is expected to guide and promote:

(a) Research
(b) Accountability in research
(c) Ethical/moral values
(d) Core values in collaborative research, among others

To realise the above core values, the document presents the following:

1.0 PRINCIPLES AND PRACTICES (STANDARD OPERATING PROCEDURE) GUIDING RESPONSIBLE DESIGN/CONDUCT OF RESEARCH TO MEET ETHICAL STANDARDS IN SET

Scientists in the College of Science, Engineering and Technology have ethical responsibilities to themselves, fellow colleagues, UNIOSUN community and the public. Therefore, they must responsibly design and, execute ethically acceptable scientific studies, and competently and honestly communicate same to the public. To be able to do these, core principles and standard operating procedures (SOPs) guiding different fields of research must be duly observed.

The first step towards conduct of ethically acceptable scientific studies in life sciences, engineering/technology and environmental science is to have requisite scientific training(s) in specific field with nationally/internationally-recognized certificates. While B.Sc. and/ or M.Sc. in specific field are acceptable to conduct scientific research, a research degree exemplified by a PhD is generally acceptable as mark of proficiency in design/conduct of research in the Sciences. As a matter of fact, it is recommended that research scientists have formal training in research ethics. However, with a PhD degree, a researcher is qualified to lead a research team, apply for research grants and execute scientific studies. He or she is also better positioned to mentor young/up-coming scientists on the right paths to responsible/professional scientific conduct. In addition, such researcher would be able to clearly choose suitable scientists within or outside his/her department for collaborative research.

Therefore, certified researcher/scholar would observe specific principles and SOP pertinent to his/her field thus:

(i) **Design and conduct of scientific study**– irrespective of fields in the College of Science, Engineering and Technology, a scientist must be able to make observation(s); develop/frame research questions; do in-depth and pertinent literature search concerning the specific observation(s); from these, he/she must be able to formulate testable research hypothesis/hypotheses; then design and conduct scientific study based on valid scientific laboratory or field methods (e.g. ensuring sterile environment, as well as, infection prevention and control in Microbiology/Virology); analyze the results therefrom and draw valid conclusion(s). The scientist must eventually publish the findings/conclusions of the research endeavour. The chance is very high that a scientist equipped with adequate relevant training and experience would conduct responsible research to the benefit of mankind.

(ii) **Potential benefits and risks involved in scientific study** – a qualified researcher in the College of Science, Engineering and Technology must be knowledgeable in conduct of research involving humans, animals or plants as participants or research subjects/units. Though science has been of tremendous benefits to man, animal and plants, scientific research activities are not risk-free. And depending on the field of study, risks in scientific research may be physical, social, financial, or psychological. So, a researcher must keenly take potential benefits and risks derivable from the study into consideration. He/she must be able to recruit scientifically-guided number of human participants or animals or plants. When it is possible, a study excluding major risks should be embarked upon; but when it is inevitable, ethically acceptable research would be one in which possible risks to man, animal or plant are minimized. At all times, researchers must ensure that potential benefits of scientific research outweigh the risks. Since harm to research participants/subjects may occur at individual, family or population level, researchers must make conscious efforts to preserve the total well-being of living and non-living components in research environment. This is especially important for researchers in engineering and environmental science who may not directly use living things as subjects in research.

(iii) **Selecting study population/site and recruiting study participants or subjects -** A research proposal would be ethically acceptable when researcher(s) are scientifically guided in selection of the most appropriate study population for research. For instance, adequate literature review would guide a researcher to select children in a given location/geographic region when conducting epidemiological study on a paediatric infectious disease. In the same vein, a soil scientist would select concerned soil areas to collect soil samples when the study concerns soil pollution. Researchers must obey the ethical standard which dictates that no class or human participants, as well as animals or plants bears more than its fair share of the burdens of participating in research. By the same yardstick, study population must not be deprived of direct or future benefits a study is designed to provide. Therefore, researchers must ensure equitable recruitment of human participants (animals or plants) when recruiting experimental/study subjects for research.

(iv) **Inducements and compensation for research participants** - A scientist would be deemed to have accorded ethical standard when he factored in compensation to research participants (humans or animals) for any costs/injury incurred in the course of participating in a research. The compensation could be in form of money for transport, child care, or time spent participating in a research; at times, it could be multivitamins to participants (humans or animals) when blood sample is taken for research, but this must be done by a health professional. The payment must not be too

much, when it is free medical care, it must not be too extensive, so as to avoid undue inducement of prospective human participants to consent to participate in a study counter to their better judgement or to compromise their understanding of the research process/protocol. Except when interviews or questionnaire forms are involved to include humans, research scientists in Geology, Plant Biology, Engineering or Environmental Science may not require the use of inducement/compensation.

(v) **Protection of research participant's privacy and confidentiality** - It would be disrespectful for a researcher to invade without proper consent, privacy of an individual in the course of conducting a research. This is also applicable to highly-priced animals like companion dogs or horses. So when applicable, researchers in the College of Science, Engineering and Technology would respect the privacy of every human participant in research; when it involves an animal, the consent of the owner must be adequately obtained before invading the animal's privacy. Invasion of privacy or breach of confidentiality of a prospective study participant may lead to feelings of embarrassment, loss of control, tangible harm like social stigma, rejection by peers or family or community, loss of opportunities such as housing or employment. Therefore, ethical/scientific principles dictate that due consents are obtained before using humans or animals (even plants such as endangered species) in research.

(vi) **Participant's informed consent process** – The principle of respect for persons (animals and plants inclusive) is the foundation of informed consent. A researcher wishing to use humans as participants in a given study must be able to objectively describe, in a language best understood by prospective participants, the objective(s) of the study; the research process and the participant's role; potential benefits and risks to individual participant, the community and humans in general. When children (or animals) are the prospective participants, the researcher would describe the study to parents or guardians or owners of the animals. It is after this that competent and mentally alert adults can freely decide/choose in writing with signature whether or not to participate in the proposed study. When researchers prepare informed consent form to be used for a proposed study, they must clearly indicate in it that results/findings of the study may be presented at seminar/conference or published in scientific journals without revealing participants' identities.

(vii) **Consideration of immediate/faraway community** – Besides directly impacting the participants, research activities in the College of Science, Engineering and Technology usually have far-reaching impacts beyond the immediate community where a given study was conducted. For instance, wastes generated in a microbiology laboratory are properly disinfected by autoclaving and then disposed of by incineration; otherwise they may be dispersed by air or sewage to constitute infectious hazards to people or other living things in faraway communities. A researcher must take due cognizance of this before embarking on a scientific investigation. His/her research proposal must therefore clearly describe how the hazardous wastes from research activities would be safely disposed of. For the University, we wish to suggest informing the Ministry of Environment on how UNIOSUN can safely and acceptably dispose of its wastes across campuses.

A researcher must seek to understand the cultural, religious and traditional practices of a community before engaging a subset of its animals/plants in research. When non-living components of a community are the subjects of research, investigators must obtain due consent of the community before the commencement of sampling or study.

(viii) Policy issues relating to research ethics in the College of Science, Engineering and Technology - Derived from legal and regulatory requirements of Nigeria, ethical standards stipulate that a researcher in the College of Science, Engineering and Technology accords and discloses any conflict of interest associated with his/her work(s). They must duly respect copyright, patents, trademarks and intellectual property rights by citing as appropriate, in published works, other researchers' works; or by formally requesting and getting approval that a resource or product be used. They must also respect material transfer agreement, as well as, monitoring and evaluation of on-going research activity.

2.0 RESPONSIBILITIES OF CSET's REC

Core responsibility of REC in the College of Science, Engineering and Technology is to appropriately review research proposals from any of its departments for ethical standard and scientific validity. In addition, it may have to participate in monitoring approved research protocols during execution. Consideration of all the above would therefore adequately equip the College of Science, Engineering and Technology's REC in expertise review of research proposal in the College and for decision-making post-review, after which it would recommend appropriate decision on the proposal to the ERRB.

3.0 COMPOSITION OF ETHICS COMMITTEE IN COLLEGE OF SET

As stated above, knowing that the College is diverse and multidisciplinary in its composition, the College will constitute a Committee (REC) to include representatives from all its departments in the College of Science, Engineering and Technology.

The College of Science, Engineering and Technology **REC shall have the following members:**

(a) Chair: A Professor to be appointed by the Vice-Chancellor on the recommendation of Deputy Vice-Chancellor, Academic, Research, Innovation and Partnerships (ARIP).
(b) One member of staff from each of the departments in the College, who shall not be below the rank of Senior Lecturer.
(c) College Representative in the University Ethics Committee
(d) Two lay people (male and female) from the immediate/local environment
(e) Any other relevant person on *ad-hoc* basis.

Members shall serve for two years.

Appendix VIIB

OSUN STATE UNIVERSITY, OSOGBO
Faculty of Basic and Applied Sciences

Date

SAMPLE OF INFORMED CONSENT FORM

Mr/Mrs./Dr./Chief..... as a participant in the study titled: SEROPREVALENCE OF HERPES SIMPLEX VIRUS (TYPES 1 AND 2) AMONG ADULTS IN OSUN AND LAGOS STATES, NIGERIA.

Name of participant .....

The following information applies to you as a participant in the research. A translator into local language will be used when necessary.

Are you currently participating in any research? Yes / No.

I, ..., a student in the above stated department, invites you to enrol in a research titled: SEROPREVALENCE OF HERPES SIMPLEX VIRUS (TYPES 1 AND 2) AMONG ADULTS IN OSUN AND LAGOS STATES, NIGERIA

I wish to find out if your blood sample contains antibodies against herpes simplex virus (types 1 and 2) (HSV-1 and -2), the viruses that cause blisters (known as cold sores) on the lips and ulcerative lesions in the genital areas in humans. You are selected as a possible subject in this study because you are an adult ($\geqslant$ 18 years), male or female attending the selected hospitals in Osun and Lagos States for medical care. You may be healthy or ill. The study will enable us to know how many persons attending the hospitals have been exposed to HSV-1 and -2. Your participation in the study is entirely voluntary. You are therefore free whether or not to enrol in the research; you are free to decline the use of your blood sample after giving it. Whatever your decision is, it will not jeopardize your right to medical care.

During your enrolment in the study, about 5 ml of blood will be taken from your vein thus: a tourniquet will be tied round your upper arm, following which a sterile needle (fixed to a sterile syringe) will be inserted by a doctor/nurse into the vein of your forearm. This procedure will give you bearable pains. Blood sample will be taken from you only once throughout the study period.

In addition, personal, clinical behavioural and epidemiological data will be collected, with permission of physician in charge, from you using interviewer-administered questionnaire form and when necessary from your medical record. Your medical data will be kept confidential and used solely for this research.

While your enrolment in this study is entirely free of cost, you may not receive direct benefit from the study, however, all Nigerians will ultimately benefit from the knowledge this study will provide.

The results of this study may be presented at scientific forum or published as Journal article; you will not be identified in any reports of the research. You will be assigned a number as your identification. Your records will be kept confidential as provided by the law and medical ethics; except when demanded by UNIOSUN, Ethics Committee (GEC).

In case you have further questions on the study you can reach me ..... on ..... or ..... on .....

Statement of nurse/person obtaining informed consent: I have fully explained this research to Mr./Mrs……, and I have given him/her sufficient information about risks and benefits involved to make an informed decision.

Date…….. Signature……

Name……..

Statement of research participant giving informed consent: The description of the research has been explained to me in the language I understand. I now have satisfactory information about the purpose, brief methods, risks and benefits of the research to allow me make informed decision. I understand that I may freely stop being part of the study at any time; and I have completed a copy of this consent form. I am also aware that results of the study may be presented at scientific forum or published in Journals. I therefore give my consent to participate in the study.

Date…….. Signature……

Name……..

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APPENDIX VIII

THE POSTGRADUATE COLLEGE POLICY ON RESEARCH ETHICS

1.0 PREAMBLE

Every researcher, whether faculty or graduate student, conducting research involving human and animal subjects has the obligation to be familiar with the Osun State University policies on research ethics. In an effort to avoid problems that may arise over questions of ethical conduct in research involving human subjects and in order to promote awareness of the issues involved, the Postgraduate College has prepared this document intended for students and their supervisors at Osun State University.

2.0 PRINCIPLES GUIDING ETHICAL CONDUCT

The guiding ethics principles express common standards, values and aspirations of the research community: respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, balancing harms and benefits, minimizing harm, and maximizing benefit.

3.0 TYPES OF RESEARCH REQUIRING ETHICAL REVIEW

(a) All research that involves living human subjects requires review and approval by a REB (Research Ethics Board) before the research is started, except as stipulated below.

(b) Research involving human remains, cadavers, tissues, biological fluids, embryos or fetus shall also be reviewed by the review committee.

(c) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.

(d) Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

4.0 TYPES OF RESEARCH INVOLVING HUMAN SUBJECTS

Research involving human subjects includes:

(a) Obtaining data about a living individual through intervention or interaction with the individual, or the obtaining of private personal information about the individual;

(b) Secondary use of data (i.e., information collected for purposes other than the proposed research) that contains identifying information about a living individual, or data linkage through which living individuals become identifiable;

(c) Naturalistic observation, except the observation of individuals in contexts in which it can be expected that the participants are seeking public visibility;

(d) Research involving human remains, cadavers, tissues, biological fluids, embryos, or foetuses.

5.0 RESEARCH TYPES WHICH MAY NOT REQUIRE REVIEW

(a) Assessment activities, such as quality assurance studies, performance reviews, or testing within normal educational requirements.

(b) Research involving only the use of published or publicly available information or materials, performances, or archival materials.

(c) Secondary use of data that contain no identifying information

6.0 PREREQUISITES FOR ETHICS REVIEW OF OSUN STATE UNIVERSITY GRADUATE STUDENT PROPOSALS/PROTOCOLS

The following prerequisites for ethical review of Osun State University graduate student proposal/protocols must be in place:

(a) A supervisor who has an appropriate School of Graduate Studies faculty appointment at the time of the ethics review protocol submission and for the duration of the research activity.

(b) In case of thesis research, it is required that the supervisory committee has been established, convened at least once, and has approved the thesis proposal. Members of the committee and the dates on which the committee has met must be recorded on ROSI. The date of approval of the thesis proposal must be recorded on the Ethics protocol cover sheet.

(c) The student must be registered in Osun State University graduate programme at the time of the submitting proposal for ethical review and must be registered in the postgraduate programme for the duration of the research activity involving human subjects.

7.0 IMPLICATION OF THIS POLICY ON GRADUATE STUDENTS AND FACULTY RESEARCHERS

(a) Every researcher using human subjects has the obligation to be familiar with the Osun State University policies on research.

(b) Graduate students performing research in one of the affiliated hospitals should submit research protocols to the REB of that hospital. If funding will go through the University or the research is non-clinical, a protocol must also be submitted to the appropriate Osun State University Ethics Review Committee.

(c) Human subject approval must be sought before the research commences. For students, they must either seek ethics approval for a new project or be certain that their research has already received ethics approval. This applies to student research as part of a graduate course, thesis research, and/or as part of research conducted by any student or faculty member at the Osun State University whether or not the research is funded and/or internally or externally funded.

(d) Faculty or graduate students intending to conduct interviews, or administer/distribute questionnaires, or in any way systematically gather any personal information from individuals (i.e. information that can in any way be construed to be “about” a person) must seek ethics approval.

(e) Ethics approval is required for all research involving secondary use of data (i.e., information collected for the proposed other than the proposed research) if the data contain information through which individuals can be identified.

(f) Ethics approval is required for all research involving naturalistic observation, except the observation of individuals in contexts in which it can be excepted that the participants are seeking public visibility (i.e., observation of participants in political rallies, demonstrations, or public meetings).

(g) Student research involving human subjects must be supervised by a faculty member (thesis supervisor or course instructor) who must sign the application and oversee the research.

(h) Graduate students with hospital approval should submit a copy of the letter and the approved protocol to the Ethics review Unit for documentation. A copy of the approval letter should also be sent to their departmental chair.

(i) The ethics Review Unit must have on file current valid approval for all graduate students and faculty members who have ongoing projects involving human subjects, animals, and/or biohazards.

(j) Approval can be granted only if the subject participating in the research has been given an opportunity for fair and informed consent, and it is clear that the result of the research will not identify the individual unless the individual prefers and consents to be identified.

8.0 Graduate students performing research in a hospital setting should apply to the hospital's REB for ethical review, not to the University's committees, unless:

(a) Funding will be administered through the University

(b) The research is non-clinical

(c) Recruitment is being done at the University

(d) Some aspect of the research will be done at the University.

In these cases, ethical review should be sought from both the University and the hospital.

Note. Students should submit a Statement of Intent and Ethical Review Protocol to the appropriate Ethical Review Departmental Coordinator, who will conduct a pre-review before submission to the UNIOSUN Research Ethics Review Board (URERB).

9.0 RESPONSIBILITIES OF THE ETHICS REVIEW COMMITTEE

The Ethics Review Committee shall ensure that:

(a) All sections of the protocol are complete

(b) The design of a research project that poses more than minimal risk is capable of addressing the question being asked in the research.

(c) All research involving human subjects are formulated from a participant-centred perspective, ensuring that all guiding principles are followed:

(i) respect for human dignity

(ii) free and informed consent

(iii) acknowledgement and protection of vulnerable persons

(iv) privacy and confidentiality

(v) respect for justice and inclusiveness

(vi) minimum harm and maximum benefits to participants.

10.0 RESPONSIBILITIES OF THE STUDENT INVESTIGATOR

The student investigator has the following responsibilities:

(i) Inform himself or herself and adhere to the relevant federal and University policies governing the ethical conduct of research and the use of human subjects.

(ii) Submit his or her research plans for ethics review;

(iii) Receive ethics approval before engaging in research activities that involve human subjects;

(iv) Report adverse events, apparent (or potential) conflicts of interest or observed non-compliance with ethical conduct guidelines that arise during the course of an approved research project; and

(v) Report any deviation from the project, originally approved, to the Review Committee for approval prior to its implementation.

11.0 ROLES AND RESPONSIBILITIES OF THE FACULTY "SPONSOR" OR SUPERVISOR

The faculty "sponsor" or supervisor has the following responsibilities:

(i) Ensure that the ethics review application and the proposed research project are compliant with those federal and University policies that govern research involving human participants;

(ii) Ensure that any activity (or change to activity/research) for which students require ethic review approval will receive appropriate review and approval prior to commencement of the activity;

(iii) Provide the necessary supervision to the student investigator to ensure that all procedures performed under the research project will be conducted in accordance with those federal and University policies that govern research involving human subjects;

(iv) Ensure reporting of adverse events, apparent conflicts (or potential conflicts) of interest or non-compliance with ethical conduct guidelines that arise during the course of an approved research project; and

(v) Professors responsible for a course involving any activity in which students obtain personal information from human subjects must ensure that the activity has received review and approval.

12.0 POST APPROVAL ACTIVITIES

Obtaining ethical approval is not the end of a researcher's responsibility. If any changes are made to the research involving human subjects after it has been approved, then the review committee must be apprised. Approval for the changes must be obtained before the revised research project can continue. As well, any adverse events (e.g. subject injuries or adverse drug reactions) must be reported to the review committee. Faculty and graduate students also have a responsibility to report to the review committee any apparent (or potential) conflicts of interest or observed non-compliance with ethical conduct guidelines that arise during the course of an approved research project.

The annual supervisory committee report on the progress of Doctoral or a Master student should include a statement of confirmation that the research has received, and continues to conform with ethical approval.

SECTION TWO

ANTI-PLAGIARISM POLICY

Plagiarism is using, without acknowledgement, someone else's words, ideas or work.

1.0 Preamble

1.1 This policy is aimed at establishing a framework for determining, detecting, preventing and dealing with plagiarism to ensure academic excellence, honesty and integrity among students and the university community. While recognizing, supporting and encouraging the successful exploitation of intellectual property by its staff and students, UNIOSUN detests intellectual dishonesty and plagiarism in all forms.

1.2 The policy serves as a guide for all staff members and students of UNIOSUN to respect, observe and maintain high probity of academic standards, originality of academic publications, and to avoid academic dishonesty, cheating, stealing of others ideas and plagiarism.

1.3 The University is fully aware that effective production and management of intellectual property hinges on the quality and originality of all publications by staff and students. This is critical for the university to play its role in higher education. The University is also cognizant of the fact that plagiarism poses a significant challenge for academia worldwide and considers this as a serious form of academic impropriety which can result in rejection or withdrawal of theses/dissertations/long essays, publications or any piece of academic work produced by academic staff and students alike.

1.4 It shall also lead to disciplinary actions, such as expulsion from the university, postponement of promotion, rustication or any other form of discipline as stated in the relevant Statutes of the University, and as shall be determined by an impartial and independent committee set up by the authorities of the University.

1.5 For submission of students' projects, theses and dissertations, the similarity index threshold acceptable to Osun State University shall not exceed 20% excluding references and bibliographies. The Turnitin report of such work should be attached to the work before submission for defence. The University shall designate a body for the purpose of carrying out Turnitin; it shall be the exclusive preserve this body to do Turnitin on behalf of the University.

2.0 Definition of Plagiarism

2.1 Plagiarism is presenting someone else's work or ideas as your own, with or without their consent, by incorporating it into your work without full acknowledgement. All published and unpublished material, whether in manuscript, printed or electronic form, is covered under this definition. Plagiarism may be intentional or reckless, or unintentional. Under the regulations for examinations, intentional or reckless plagiarism is a disciplinary misconduct.

2.2 Plagiarism can also denote the re-presentation of one's own published or unpublished work, ideas, images, opinions, inventions, music or recordings, artistic works, or computer-

generated work without proper citing of source. This is generally known as self-plagiarism.

2.3 Plagiarism is a situation where one's ideas, expressions, words, methods, results, are used to describe these ideas, methodologies and outcomes are similar or expressed in the same way without appropriate acknowledgement.

2.4 Examples of plagiarism:

(a) Direct replication of one's work without duly acknowledging the original source.
(b) Reproducing or transcribing work from one language to another without acknowledging the source.
(c) Rewording of your own work or that of another without appropriately acknowledging the source.
(d) Piecing together sections of the works of others or one's own into a new whole.
(e) Resubmitting work that has hitherto been graded.
(f) Presenting a jointly produced work (in whole or in part) as one's own independent work.
(g) Presenting the works of students with or without their consent as one's own.
(h) Making use of professionals or professional agencies in producing one's work or submitting work which has been written on one's behalf.
(i) Cutting and pasting from the internet without clear acknowledgement.
(j) Paraphrasing the work of others by altering a few words and changing their order, or by closely following the structure of their argument.

2.5 Plagiarism is a serious academic fraud, intellectual dishonesty, theft, which is unethical and immoral, and a consequential manifestation of academic impropriety can lead to dismissal from the University.

2.6 Depending on the extent and the enormity of the plagiarism as well as the institutional requirements, the plagiarist may be disciplined according to the rules stated in the relevant Statutes of the University, or be forced to apologize publicly and withdraw the plagiarized materials.

2.7 In a situation where plagiarism is not detected early, appropriate sanctions shall still be applied when discovered later.

3.0 Types of Plagiarism

3.1 According to Turnitin.com and Research Resources, two types or categories of plagiarism are identified. These are; Intentional and Unintentional

3.2 Intentional plagiarism consists of Sources not cited and Sources cited (but still plagiarized).

A. Sources not cited: Examples of this include the:

(i) Turning in another's work, word-for-word, as if they are one's own.
(ii) copying significant portions of text straight from a single source, without alteration.
(iii) Trying to disguise plagiarism by copying from several different sources, modifying the sentences to make them fit together while retaining most of the original phrasing.

(iv) Retaining the essential content of the source whilst altering the paper's appearance slightly by changing key words and phrases.

(v) Paraphrasing most of the paper from other sources and making it all fit together. '

(vi) Borrowing' generously from one's own previous work which violates the policies concerning the expectation of originality adopted by most academic institutions.

B. Sources cited, but still plagiarized, these include the following:

(i) Obscuring sources/locations of consulted materials. For instance, providing an author's name for a source and neglecting certain important metadata of the referenced material

(ii) Providing insufficient information on the sources of referenced material, making it impossible to trace.

(iii) A situation where text is directly copied text is not put in quotation marks, although the source has been appropriately cited. In such situations, the writer falsely infers ownership of original information on himself.

(iv) When an author appropriately rewords, correctly uses quotations and cites all sources, but the work is entirely not original.

(v) A situation where the writer properly quotes and cites sources in some places, but goes on to paraphrase other arguments from those sources without citation. This way, the writer tries to pass off the paraphrased material as his/her own analysis of the cited material."

3.3 Non-intentional plagiarism is the situation where an author does not conform to orthodox standards for referencing. It is also a situation where the writer imitates a source text written in a language that the writer does not understand the technical and conceptual meaning and thus lacks the ability to present the ideas in his/her own words.

4.0 Evaluating Plagiarism

4.1 Plagiarism is a very complicated concept, no matter the form it takes. This makes it necessary for a proper assessment to be done when determining the quality of scholarly works produced by persons in academia.

4.2 Care must be taken when trying to measure the quality of scholarly material in the context of intentional and unintentional plagiarism.

4.3 The mixing of citation styles, lack of quotation and references are all strategies for assessing or establishing plagiarism of scholarly materials.

(a) Mixing of citation styles: There are several ways in which a work can be cited. Works can be cited in Harvard style, Chicago, APA, AAA, MLA, etc. Under no circumstance should a writer mix these styles in a text. Doing that indicates the amount of dishonesty exhibited by the writer; hence the work must be treated as a plagiarized material.

(b) Lack of quotation and references: Quoting a text without proper acknowledgement is a serious offense and so writers should make it a point to put such text in quotation marks and then cite accordingly in the required citation style. Scholarly works produced without references at the end of the work constitute plagiarism.

5.0 Institutional Responsibility

The University acknowledges the need to come up with a policy that seeks not only to punish but to help avert the issue of plagiarism among students and staff. In line with this, plagiarism and other similar issues shall form an important part of the academic curricula of the University. With this, the University shall make it one of its utmost priorities to:

(a) Educate the academic community on the dangers involved in plagiarizing,
(b) Acquiring appropriate software to check plagiarism in scholarly works and other researches,
(c) Supporting the various colleges, faculties and departments to enlighten their students on the issue of plagiarism,
(d) Handbooks given to students shall contain the University's stance on plagiarism,
(e) The University Library/Libraries shall be equipped with the necessary logistics and software to handle the plagiarism issues particularly with students' theses and dissertations.

6.0 Student or Author Responsibility

6.1 Students and academic staff in the University shall heed to the following:

(a) Equip themselves with good writing skills
(b) Know what constitutes plagiarism and what needs to be done to avoid falling into the trap of plagiarism
(c) Know the accepted citation style of the institution

6.2 It is incumbent on all staff of the University to adhere to these responsibilities to ensure sanity in the academic environment thereby helping to reduce or prevent plagiarism. This shall help instil a sense of discipline among all who find themselves in academia.

7.0 Investigations and Sanctions

7.1 Plagiarism is not acceptable and shall be categorized as highly offensive by the University. Faculties are therefore obliged to observe the requirements and conditions set in this Policy. It is the responsibility of faculties to ensure students, and other staff receives the required training to prevent plagiarism. All materials suspected to have been plagiarized shall be required for investigations.

8.0 Investigation of plagiarism by students

8.1 When a lecturer responsible for a course suspects possible plagiarism by a student, he/she shall:

(a) investigate
(b) organize a meeting with the student in question
(c) present suspicions and available proof for discussion with the student
(d) solicit the student's opinion/defence on the matter

If the lecturer is satisfied that no misconduct has been committed, the matter may be closed

8.2 If the student is able to provide convincing and reasonable explanations of the accusation, and is discovered to have unconsciously plagiarized, it may be concluded that the

student committed an academic misdemeanour by referencing wrongly. A written warning is given.

8.3 However, if any suspicions about the originality of the work are confirmed, the issue can then be:

(a) settled at the departmental level or

(b) referred to the Dean of the particular Faculty, who shall then present a formal complaint to the Provost of the College. An initial investigation will be conducted by the said Dean at the request of the Provost of the College and a report submitted to the Vice-Chancellor through the Provost of the College.

(c) for further investigation, the Vice-Chancellor shall then refer the case to the suitable Disciplinary Committee

(d) upon conclusion of its hearing, the Disciplinary Committee shall report to the Vice-Chancellor on arrived conclusions and make propositions which he/she may implement per his/her considerations.

9.0 Plagiarism in a Course Assignment

(a) Any student accused of academic misconduct in a given assignment shall be reported to the Head of Department. He shall, in turn, adhere to the provisions stated in paragraph 8.1 and 8.3 above to resolve the matter through the appropriate authority.

(b) The processes of investigation and punishment of any student accused of plagiarism shall be in conformity with paragraph 8.1 to 8.3

9.1 Plagiarism in a Submitted Thesis

Alleged plagiarism in a thesis shall be reported to the Head of Department who shall immediately report to the Dean and an investigative committee will be set up by the Dean to examine the case. A report shall be submitted to the Vice-Chancellor on the findings detailing their recommendations.

9.2 The provisions made in 8.1 to 8.3 shall be adhered to in the process of examining and levying punishment on students.

10.0 Sanctions for Plagiarism by Students

10.1 The Penalty Scale for plagiarism applies to all works submitted for assessment.

10.2 One essential benchmark for assessing the gravity of misconduct is “quantity”; however, sanctions should be suitable for the level of severity of the incident.

10.3 The quantity, in this instance refers to the unaided professional judgment of the lecturer/supervisor and not the percentage generated from the TURNITIN originality report.

11.0 Investigating Plagiarism

When investigating a plagiarism incident, it is important to take note of the following:

(a) How significant the plagiarized content is on the grading of the work

(b) To what extent is the submitted work plagiarized

(c) The student's year and level

(d) The student's background

(e) Whether the student at any point, took the opportunity to participate in any of the activities provided by the University to enhance students' understanding of plagiarism
(f) Any previous incidence of plagiarism the student engaged in
(g) Any apparent intention by the student to mislead.

Plagiarism Scales for Postgraduate Programmes
Course Assignments/Term papers -Postgraduate Programmes

Degree of Seriousness	1st Incident	2nd Incident	3rd or more incidents
(More than 40% similarity index	Teacher explains UNIOSUN Research ethics •Resubmission accepted •Case reported at the Department Level•Advised to do a course on Academic Integrity.	Deducting some marks •Resubmission accepted •Case reported at the Department Level	Disciplinary hearing at Department Level •Record case in the registry at Faculty Level •No more Resubmission •Assignment failed •Case reported at the College Level
(More than 30% but less than 40% similarity index	Teacher explains UNIOSUN Research ethics •Resubmission accepted •Case reported at the Department Level	Teacher provides corrective advice •Deducting some marks •Resubmission accepted •Case reported at the Department Level	Disciplinary hearing at Department Level •Record case in the registry at Faculty level •No more Resubmission •Marked as it is with strong penalties •Case reported at the College Level
(More than 20% but less than 30% similarity index	Teacher provides corrective advice•Resubmission accepted	Deducting some marks •Final revision recommended •Resubmission accepted	Record case in the registry at Department Level •No more Resubmission •Marked as it is with soft penalties

Plagiarism Scales for Dissertations
Postgraduates

Degree of Seriousness	1st Incidents	2nd incidents	3rd incidents
(More than 40% similarity index	Examiner provides corrective advice •Resubmission accepted •Deducting some marks •Record case in the registry at Collegelevel •Required to do a training on academic integrity and research ethics	Deducting some marks •Resubmission accepted •Case reported at the College Level	Disciplinary hearing at University Level•Record case in the registry•Resubmission not accepted •Thesis failed •Case reported at the University Level
(More than 30% but less than 40% similarity index	Supervisor provides corrective advice •Resubmission accepted •Deducting some marks •Required to do a training on academic integrity and research ethics	Deducting some marks •Resubmission accepted •Case reported at the College Level	Disciplinary hearing at University Level •Record case in the registry at University Level •Resubmission not accepted •Thesis failed •Case reported at the University Level
(More than 20% but less than 30% similarity index	Supervisor provides corrective advice •Resubmission accepted	Deducting some marks •Resubmission accepted •Record case in the registryat College Level	Record case in the registry at the College Level •No more Resubmission •Marked as it is, with strong penalties •Case reported at the College Level

Adapted from University of Pretoria (2010)

12.0 Investigations and Sanctions for Plagiarism committed by Staff Members

12.1 Investigations

(a) The Head of Department shall report to the Dean in instances where a faculty member is alleged to have engaged in plagiarism. The Dean shall then present the matter and a detailed report expressing the suspicion of plagiarism to the Faculty Board.

(b) The complaint and report shall be forwarded to the Vice-Chancellor. The Vice-Chancellor shall refer the case to the appropriate Disciplinary Committee for action.

(c) Reports of plagiarism by faculty members from journals which are reported to the University will be forwarded to the appropriate Faculty or College Board Committees. The assigned committee shall investigate the accusation(s) and report sent to the Vice-Chancellor.

(d) The Vice-Chancellor, who shall in turn, refer it to the University Disciplinary Committee.

(e) The propositions of the Disciplinary Committee shall be forwarded to the Vice-Chancellor, who per his discretion may execute the recommendations or vary them. Where this academic misconduct may have contributed to the person's appointment or promotion, the Vice-Chancellor shall forward the investigation results and recommendations submitted by the Disciplinary Committee to the Appointments and Promotions Board reassess its decision.

12.2 Sanctions

(a) Sanctions to be applied to any offending staff shall be in harmony with the University policy.

(b) Any Member declared guilty of academic impropriety/plagiarism shall be downgraded to the next lower rank for a first misconduct and in case of subsequent misconducts may be dismissed. In a situation where the faculty member has not yet been promoted, his/her salary shall be dropped to the next lower scale.

13.0 False Accusation of Plagiarism

No student, staff or faculty member shall wrongly or falsely be accused of academic dishonesty. Any incident of this nature shall be reported by the appropriate person in-charge of that particular Department to the Vice-Chancellor and later on referred to the Disciplinary Committee of the University.

GUIDELINES FOR WRITING PROJECT REPORTS FOR DIPLOMA AND THESES FOR HIGHER DEGREES OF OSUN STATE UNIVERSITY

INTRODUCTION

This publication is intended to create a set of guidelines that will ensure uniformity in the presentation of Projects Reports for Postgraduate Diploma, Long Essays and Theses for Higher Degrees of Osun State University. It will therefore be a very useful guide to all our Postgraduate students in the course of writing and typing their project reports and theses in a manner that will make them and Theses Supervisors as well as Examiners to measure compliance of students with the set guidelines.

SEQUENTIAL ARRANGEMENTS OF MATERIALS IN PROJECT REPORTS AND THESES:

A typical Long Essay, Project Report or Thesis submitted for any Postgraduate Diploma or Higher Degree of Osun State University shall contain all or some of the following materials arranged in the following sequential order:

(a) Title Page
(b) Authorization to Copy
(c) Certification Page (by Supervisor(s))
(d) Attestation
(e) Dedication (Optional)
(f) Acknowledgements
(g) Table of Contents
(h) List of Tables
(i) List of figures
(j) List of Plates (where applicable)
(k) Glossary (where applicable)
(l) Abstract
(m) Chapter One: Introduction (with subsections as applicable)
(n) Chapter Two: Review of Literature (with subsections as applicable)
(o) Chapter Three: Method/Methodology
(p) Chapter Four: Results and Discussion
(q) Chapter Five: Conclusion and Recommendations
(r) List of References and Bibliography
(s) Appendix A (Raw Data)
(t) Appendix B (Published papers from the thesis, if any)

The items listed (a) to (t) can be divided into three parts namely, the Preliminaries, (a) – (i), main body of thesis (m – q) and Reference Matters (r –t) all these shall follow the cover page.

THE COVERAGE

The cover page shall bear the full title of the project report/thesis, the full name of the student, the qualifications of the student at the time of submission of thesis/project report, the month and year of submission. All letters of the title and name of the author shall be capitalized

(surname last, first name, other names) and printed in gold. Font type shall be Time New Roman font size 14 (see Appendix 1)

THE PRELIMINARIES

Title Page: This is the first page after the cover page. It should not bear any page number but shall contain the full title of the Project Report/Thesis and the full name of the student (Surname in capital letters with no comma thereafter but other names should be typed with the, initial case in capital), the student's matriculation number, qualifications of the candidate at the time of submission of thesis, the Department and Faculty of which the Project Report/thesis is submitted also indicating the degree and area of specialization, the month and year of submission. (see Appendix 2).

Authorization to Copy: This page shall contain the authorization by the author to the Osun State University Library to copy the thesis in whole or in part in response to request from individual researcher or organizations for the purpose of private study or research. (see Appendix 3).

Certification Page: This page shall have a statement signed by the Supervisor(s) indicating that the materials contained in the Project Report/Thesis is a product of the research carried out by the student under supervision by the signees. (see Appendix 4).

Attestation: The attestation page shall be signed by the Head of Department where the research work was done. In a case where the Head of Department is also the Supervisor, another Faculty member appointed by the Faculty Postgraduate Committee and who shall serve as the Chairman of the Panel of Examiners shall sign the attestation page in place of the Head of Department (see Appendix 5).

Acknowledgement: The acknowledgement of the aids provided by others to the student in the course of the research work and during the preparation of the thesis shall follow the attestation page.

Table of Contents: This shall contain the contents of the thesis starting from the title page and indicating the first pages of the items listed with specific mention of the subject headings.

List of tables: This is a complete list of tables showing table number, title of the table and the pages where they appear in sequential order in the text of the thesis.

List of Figures: This is a complete list of figures which shall include graphs, charts, drawings, diagrams, maps and computer print-outs arranged sequentially.

List of Plates: A complete list of plates of which references have been made in the text of the Project Report/Thesis shall be stated. This should normally include pictures.

Glossary: Where applicable, a Glossary of items, foreign words and abbreviation used in the Project Report/Thesis shall appear immediately after the list of plates. Efforts should be made by the students to adhere strictly to the standard list of abbreviations for the specific discipline of the student.

Abstract: Each thesis shall have a short abstract which is a concise summary of what the Project Report/thesis is all about. It should not be more than 500 words and shall have **four (4)** paragraphs. The first paragraph shall be a brief introduction stating what the research work is all about, the specific objectives and the envisaged contributions to knowledge while the second paragraph shall summarize the methodology employed in the research work which shall include the method employed in the research work which shall include the method of collecting primary and secondary data, laboratory work (where applicable), analytical techniques, method of data analysis and statistical techniques (where applicable). The third paragraph shall list specific findings and implications of such findings (if any) while the fourth paragraph shall be the conclusion and recommendation(s) if any.

MAIN BODY OF PROJECT REPORTS/THESES:

The form of presentation of the main body of Project reports/Theses may vary with the subject matter and the discipline. However, it is very important and necessary that the stipulated format in the Department/Faculty is strictly adhered to. The Main Body of any thesis submitted for any postgraduate diploma or higher degree in Osun State University shall not be less than five chapters out of which the first three chapters as highlighted below are imperative and in typing the theses, each chapter must begin on a new page.

Chapter One: Introduction:

The introduction shall, depending on the discipline, contain among other things, an overview of the study, a definition of the problem/scope of the research including the statement of the research problem, justification, aim and objectives, and any other relevant information.

Chapter Two: Review of Literature:

This section shall highlight the work of previous researchers/workers in the student's area of research carried out anywhere in the world. At the end of the literature review, a student should be able to clearly indicate the existing gap in knowledge which he/she intends to fill with the research work he/she has embarked on. Presentation of this chapter could be done by creating sub-sections as applicable in the write-up.

Chapter Three: Methodology/Materials and Methods:

This chapter shall discuss types and source of data, methods of data collection and techniques of data analysis and as it is peculiar to the student's discipline. Presentation of this chapter can be done with sub-sections as may be applicable to the student's discipline.

Chapter Four: Results and Discussion:

This chapter comprises the presentation of the findings of the research work, summarizing the findings of the research and their implications in comparison with existing literature stating clearly how they agree with, depart from or provide better explanations for what had hitherto remain unexplained before his/her research work.

Chapter Five: Conclusion and Recommendations:

This is the final chapter of a Project Report/Thesis and it is a concise overview of the research work shall also highlight the contribution(s) to knowledge. A recommendation for further work on the subject matter could be made at this point.

Tables, Figures and Plates

Tables, Figures, Citations, illustrations etc. generally appear in the body of the thesis. To ensure uniformity in presentation across disciplines, the under listed is recommended without prejudice to certain styles native to each discipline. All these are to ensure consistency.

Tables

(i) Each table shall be numbered and shall have a suitable heading which must be self explanatory;

(ii) The word "Table" typed in sentence case and followed by an Arabic number shall appear at the centre on top of the Table;

(iii) The descriptive title of the table shall be centred above the body of the table and the letterings in the Table should be at least 2mm high to ensure that the information presented in table is easy to read;

(iv) Only the first word and proper names shall begin with capital letters and shall be underlined.

(v) Tables shall be numbered consecutively in the order of appearance within the Project Report/Thesis with the chapter number first, then numbered sequentially within each chapter. For example, Tables in chapter 1.1, Table 1.2, etc. while tables in chapter 2 are sequentially numbered as Table 2.1, Table 2.2 etc.

(vi) Each table shall have a box and shall be ruled;

(vii) Each table shall be place on a fresh page within the chapter immediately following first reference to them;

(viii) Units of measurements must be clearly indicated in the appropriate column of the table;

(ix) In case a table could not be contained in one page, such a table should be split at an appropriate place such as just before a new sub-heading;

(x) For a split table, headings must be repeated on the second and subsequent pages of tables that split over two pages or more with the word continued abbreviated as "contd." appearing immediately after the Table number and before the description title of the table;

(xi) Explanatory footnotes to table must be indicated by means of standard footnote reference marks (*, x,,+) placed after words or numbers to which footnotes refer. Footnotes may also be indicated by use of superscript letter (a, b, c, etc.), placed after words or before numbers in the table. The footnotes must however, appear below the table on the same page.

Figures

(i) Every figure (graphs, charts, histograms, maps etc.) included in the main body of the thesis shall be numbered and suitable self-explanatory title of the figure shall immediately follow the number;

(ii) The acronym "Fig." typed in sentence case followed by an Arabic number and then the descriptive title (not centred) shall appear at the bottom of the figure;

(iii) Labelling on the figures must be clear and accurate, scales and keys to maps must be clearly indicated by any of the accepted methods;

(iv) Graphs, histograms and charts must be clearly divided up and suitably labelled and units of measurement clearly indicated;

(v) Figures shall be numbered consecutively in order of appearance within the Project Report/Thesis with the chapter number first, then numbered sequentially within each chapter. For example, figures in chapter 1 are numbered sequentially as Fig. 1.1, Fig. 1.2 etc. while Figures in Chapter 2 are sequentially numbered as Fig.2.1, Fig. 2.2 etc.

(vi) Each figure shall be placed on a fresh page within the chapter immediately following first reference to them;

(vii) Explanatory footnotes to figures must be indicated by means of standard footnote reference marks (*, x,,+) or by means of superscript letter (a, b, c, etc.) on the appropriate places on the figures and shall appear below the figure title on the same page.

Plates

(i) All plates (photomicrographs, pictures etc) shall be given number and suitable titles which shall be self-explanatory without references to the text;

(ii) the word "Plate" typed in sentence case and followed by an Arabic numeral and then descriptive title (not centred) shall appear at the bottom of the plates;

(iii) Labelling on the plates must be clear and accurate with scales and keys clearly indicated by any of the acceptable methods;

(iv) plate shall be numbered consecutively in order of appearance within the project report/Thesis with the chapter number first, then numbered sequentially within each chapter. For example, plates in chapter 1 are numbered sequentially as plate 1.1, plate 1.2 etc. while plates in chapter 2 are sequentially numbered as 2.1, plate 2.2 etc.

(v) Each plate shall be placed on a fresh page within the chapter immediately following first reference to them.

(vi) The legends for letter labels superimposed on photomicrographs for example, shall be given below the plate title on the same page.

(vii) Where necessary, the magnification of the plate shall be given.

It is important to note that a consistent format for titles and captions of tables, figures, plates and other illustrations must be used throughout the thesis. Reference to figures, tables and plates on the text shall be made by number and never by headings or titles, where reference is made to a table or figure by stating the facts shown by the figures or tables, the reference shall be in parenthesis as close as possible to the first point of mention.

Citation of References in the Text

The style used shall vary from one discipline to another. While thesis writers in the Medical Sciences, Biological Sciences, Earth Sciences, Physical Sciences, Chemical Sciences and other disciplines related to these fields usually prefer the Harvard Referencing Format, where the author's name is followed by the year of publication in parenthesis, other disciplines in the Humanities, Social Sciences and sometimes Education may prefer the Chicago Reference System where references are referred to in the text by superscript numerals (footnote citation). It is however important, that the author should maintain a consistent style throughout the thesis.

Citation of Quotations in the Text

(i) All quotations in the text of the Project Report/Thesis should correspond exactly with the originals in wording, spelling, capitalization and punctuation;

(ii) If a quotation is less than two lines, double quotation marks are placed at the beginning and end within the text;
(iii) A quotation which is two or more lines in length shall be indented and typed in single space;
(iv) If the author is desirous of pointing out an error in a quotation, the word "sic" in parenthesis should immediately follow the observed error. The error could be grammatical, spelling mistakes or both. If more than one error is observed, the word "sic" must appear immediately after all the errors observed.
(v) Where a part or parts of a quotation are left out , such omitted part(s) must be indicated by three (3) dots (…) only no matter how long, to show that something from the original has been omitted;
(vi) Appropriate source of the quotation must be indicated using the referencing format adopted by the author.

REFERENCE MATTERS

General:

(i) References for Project Report and these shall come after concluding chapter and should start on a fresh page andl8 titled "References";
(ii) Each item cited in the reference list must have been cited in the text and must be arranged alphabetically by surname;
(iii) The reference list should be typed double-spaced with handing indents used for the second and subsequent lines of each entry. There should however, be no line spaces between references;
(iv) Italics is the preferred format for title of books, journals and videos. Article and chapter titles are not italicized or put in quotation marks. Volume numbers should also be typed in italics but issue numbers and page numbers are not.

Method of Citing According to the Format of Graphic Communication

Journal Articles with Single and Multiple Author

In references to journal articles, the following essential information shall be given in the order shown below:

(i) Author's surname followed by initials;
(ii) Year of Publication in Parenthesis;
(iii) Title of Paper/Publication;
(iv) Name of Journal in full and in italics;
(v) Volume number of the journal in Arabic numerals typed in italics;
(vi) Issue number in Parenthesis and in Arabic numerals;
(vii) Pages in Arabic numerals;

Examples

Bashiru, K.A. (1990). Diaphragm muscle glycolysis in iron-deficient rats. Bioscience Research Communications, 2(2):163-172.

Adeneye, A.A., Olagunju, J.A., Benebo, A.S., Elias, S.O., Adisa, A.O., Idowu, B.O., Oyedeji, M.O., Isioye, E.O., Braimoh, O.B., Oladejo, O.O., and Alana, E.O. (2008). Nephroprotective effects of the *aqueous* root extract of Harunganamadagascariensis(L) in acute and repeated acetaminophen renal injured *rats*. International Journal of Applied Research in National Products 1(1):6-14.

Please note that all generic names of plants and animals shall be typed in italics.

Books/Manuals/Monographs/Reports

The following order of referencing is recommended for books, monographs, technical reports, etc.

(i) Author's surname followed by initials;
(ii) Year of Publication;
(iii) Title (with initial letter capitalization for all main words);
(iv) Place of Publication;
(v) Publisher's information;

Full title of books/monographs etc. shall be written exactly as the original in wording and punctuation. There shall be no translation of titles from one language to another.

Examples

Michal, J. (1970). Inorganic Chromatographic Analysis. London, England: Van Nostrand Reinhold Company. 217pp.

Dickerson, R.E., Gray, H.B., and Haight, Jr., G.P. (1970). Chemical Principles.New York , USA: W.A. Benjamin, Inc. 873pp.

Edited Books/Chapter in a Book

The order of listing shall be as indicated for books but abbreviation of editor (i.e. "ed" for single editor and "eds" for multiple editors) should be after the title. In case of "compilers", the abbreviation "comp" is used for a single compiler while "comps" is used for multiple compilers. This is in recognition of the fact that editors and compilers are regarded as authors.

If only a single chapter or passage of a book is referred to, the form of reference shall be such that the cited parts are related to the whole book. A word or phrase (such as "in") shall be added to indicate the relationship of the part to the whole.

Examples

Balogun, A.A. (2011). Ogedengbe Agbogungboro of Ilesha: A 19th Century Yoruba Warlord. In: S. Oyeweso (ed), Ijesha Icons and the making of the Modern Nigeria: Essays in Honour of Ogbeni Rauf Aregbesola, Osogbo Nigeria: Osun State University, 3 35.

Trzaskos, J.M. (1992). Biosynthesis and Utilization of Isoprenoids In: W.D. Nes, E.J. Parish, and J.M. Trzaskos (eds) *Regulation of Isopentenoid Metabolism,* Washington, DC, USA: American Chemical Society, 2 – 7.

Books in Parts

A work published in several volumes under one general title but with separate titles for the individual volumes shall be cited with the general title also indicated. For such books, volume should be indicated after the title of the books.

Example

Massry, S.G. and Glassock, R.J. (1995). *Massy and Glassock's Textbook of Nephrology,* 3rd Edition, Volume 2, Baltimore, USA: Williams and Wilkins, 2025p.

Conference Proceeding

The order of citation shall be the same as journal article up to the title of the article then followed by Proceedings of the specific conference, the place and the pages.

Example

Olagunju, J.A., Loremikan, E.A. and Gbile, Z.O. (1998). Hypoglycaemic and lipolytic activities of isosaline extract of the leaves of *Anthrocleist adjalonensis* A. Chev in the rat, *Proceedings* of the *1st International Workshop on Herbal Medicinal Products,* University of Ibadan, Ibadan, 157 – 163.

Newspaper Articles

Citation of newspaper articles shall be listed, following the underlisted order:

(i) Title of Article:
(ii) Name of Writer:
(iii) Name of the Newspaper:
(iv) Date of Publication starting from the year and the date in that order:
(v) Pages:

Example

Nigeria's Political Rolling Stones, Sote, Lekan, *The Punch,* 2018, August, p. 47

Article in Encyclopaedic Works

References to articles in encyclopaedic works shall be brief, omitting the editor, publisher and place of publication but shall include in the order listed, the followings:

(i) Author(s) of the article or chapter:
(ii) Year of publication in parenthesis:
(iii) Title of the article or chapter:
(iv) Title of the Encyclopaedia:
(v) Imprint of the Encyclopaedia from which the work being cited is published:
(vi) Number of pages:

Example

Pacific Islands (2007). *The World Book Encyclopaedia,* Vol. P, 3 – 13.

Thesis and Dissertations

In citing unpublished theses and dissertations, the order of listing shall be as follows:

(i) Name followed by initials;
(ii) Year of submission of thesis or dissertation in parenthesis;
(iii) Title of thesis or dissertation;
(iv) Types of thesis or dissertation (M.Sc., M.Tech., PhD) prefixed by the word "unpublished" and typed in italics;
(v) Name of the University to which the thesis or dissertation was submitted;
(vi) Number of pages where applicable.

Example

Olagunju, J.A. (1991). *Nature of Interferon Induced in Swiss Mouse Embryo Primary Tissue Culture by Synthesized Polyriboadenylic acid: polyribo – 5 – azidouridylic Acid,* Unpublished Ph.D Thesis, Obafemi Awolowo University, Ile-Ife, 252p.

Corporate Author

Publications of societies, institutions, international organizations or other corporate bodies, which do not carry the names of personal authors are entered under the name of the corporate body in its official language. For international organization having official names in more than one language, the name shall be given in English with the main words in the names of the corporate bodies beginning with capital letters.

Examples

Osun State University (2020). *Students' Handbook,* New Edition, Osun, Nigeria: Osun State University Press, 166p.

World Health Organization (2013). *WHO Traditional Medicine Strategy: 2014 – 2023,* Geneva, Switzerland: World Health Organization, 76p

Government Agency as Author

Government publications are usually listed under the name of the official agency responsible for their publication. In citing such works, the reference shall include:

(i) Name of the country, state, city, town or other government districts;
(ii) Name of the major divisions of government from which the publication emanated from and if available, further subdivision such as the Office of the Accountant General etc.;
(iii) Year of publication in parenthesis
(iv) Title of the publication;
(v) Place of publications;
(vi) Pages.

When a personal author appears on the title page of a government publication, the work shall be listed under the name of the author.

Example

Federal Government of Nigeria: Federal Ministry of Justice (2010). *Laws of the Federation of Nigeria.* Abuja, Nigeria: Federal Republic of Nigeria Printers and Publishers. 2018p.

Adedeji, A. (1960). *A survey of Highway Development in the Western Region of Nigeria,* Ibadan, Nigeria: Government Printers, 68p.

Anonymous Works

An anonymous work is one in which the author's name does not appear anywhere in the book or represented by initials, asterisks or other typographical devices. Citations involving an anonymous work shall be in the following order:

(i) Title of publication;
(ii) Date of publication;
(iii) Place of publication;
(iv) Publisher's information
(v) Number of pages

Example

The Maxwell Leadership Bible, Nashville, USA: Thomas Nelson, 1649p.

Titles of Nobility

Traditional rulers and members of Religious Orders who do not use their surname are entered under the personal names officially adopted by them and are cited as follows:

(i) Title of the Traditional ruler or Religious Leader;
(ii) Date of publication;
(iii) Title of the publication;
(iv) Place of publication;
(v) Publisher's information
(vi) Number of pages.

Example

Aroyinkeye I, Orangun of Oke-Ila (2018). *From Ila-yara to the Present Oke-Ila Orangun,* Osogbo, Nigeria: Government Press, 150p

Electronic Publication

Electronic publications shall be cited by providing the following information in the order shown below:

(i) Author's surname followed by initials or the name of a corporate author;
(ii) Year of publication in parenthesis;
(iii) Title of the publication;
(iv) URL address;
(v) Date assessed.

Example

Brownile, D. (2007). Toward effective poster presentation: An annotated bibliography. *European Journal of Marketing, 41,* 1245 – 1283. Doi: 10.1108/030905607 10821161. 2008/05/06

APPENDICES

The appendices, where applicable, shall come after the listing of the references and shall be arranged alphabetically in the order of which they were cited. e.g., APPENDIX A, APPENDIX B, APPENDIX C, etc.

GENERAL CONSIDERATIONS:

Language and Style

The Project, Long Essay or Theses shall be written in English Language and must be scholarly in content. Tense expression throughout the text must be in the third person with accurate expressions. Attention must be paid to correct spelling, punctuation marks, sentence structure, capitalization and appropriate use of italics. The use of dictionary, thesaurus as well as Equator of Editor (where applicable) is highly recommended when writing a Project Report, Long Essays and Theses. Consistency in language, style and spelling (British preferable) is highly required.

Paper and Typing Instruction

The size of the paper for Project Reports, Long Essays and These word-processed shall be A4 (21.0 x 29.7cm) except for Drawings and Maps on which no restriction is placed. The paper used shall be of good quality. The margin on each sheet shall not be less than 38mm (1.5 inches) and 25mm (1 inch) on the left- and-right hand margins respectively. A margin of 25mm (1 inch) shall be allowed at the top and bottom of the sheet. Typing shall be done on only one side of the sheet and double-spaced except for indented quotations that shall be typed in single line spacing. The typing should be in Times New Roman and font size 12.

Chapter or Section Heading

The main chapter and section heading shall be capitalized and written centrally at the top of the first page of the chapter or section. The main chapter or section heading shall not be underlined but scientific names of plants and animals if these appear in the headings, shall be typed in italics.

Sub-Headings

Sub-headings shall not be capitalized but shall appear towards the left margin and shall be underlined. Only the first letters of each main word and proper names in a sub-heading shall be in capital letters. In other levels of sub-headings (i.e. sub-sub-heading), the first letter of the first word shall be in capital letter. All forms of sub-headings shall be typed in bold letters.

Numbering

The Project Report, Long Essay or Theses shall have all the pages numbered except the title page. The page number shall be at the bottom of each page with the preliminary pages numbered using lower case Roman numerals (e.g. i, ii, iii, etc.) while subsequent pages from chapter 1 shall be numbered using Arabic numerals (i.e., 1, 2, 3, etc.).

Thesis Title

The title of Project Reports, Long Essays or Theses shall not be more than nineteen words.

Binding of Thesis

(i) For Ph.D. qualifying examination, M.Phil./Ph.D. conversion examination and before the external examiner's assessment of Master Theses, Projects, Long Essays and PGD Project Reports, all Project Reports, Long Essays and These shall be soft-bounded with light green cardboard. Spiral bound copies will not be accepted;

(ii) Upon successful oral examination, all Project Reports, Long Essays and These shall be finally bound in hard cover only;

(iii) The colour of the cover of a successful Postgraduate Diploma Project shall be Navy Blue, Master Thesis/Project Report shall be Green while Doctor of Philosophy (Ph.D) Thesis shall be black;

(iv) The title and names on the cover page shall be in gold letters and all names fully written with the surname last. The title shall bear the officially approved one and the candidate's name as registered. The month and year of submission shall be indicated below on the cover page;

(v) Candidate's name with initials preceding surname, title of degree (M.SC., Ph.D., MBA, etc.) and year of award in that order shall be on the spine of the thesis from top to bottom.

(vi) Photographs and other illustrations shall be in colour while mounting, by the use of cellotape and similar materials are not acceptable. Unfastened documents (especially CDs), shall be properly kept in an adequately guarded pocket at the end of the Long Essays, Project Report or Thesis with the name of the student and diploma or degree programme clearly reflected on the documents.

Statement of Integrity

All theses, Project Reports or Long Essays shall be accompanied by a statement of Integrity duly signed by the student.

Submission of Thesis

Six copies of the hard-bound thesis shall be submitted to the Postgraduate College and shall be sealed and dated by the Secretary of the Postgraduate College after the approval of the Board. Four (4) copies of the thesis shall be returned to the Faculty for distribution to the Dean, Department, Supervisor and Student. A copy shall be forwarded to the University Library while the Postgraduate College keeps a copy for its records. A candidate who has Co-Supervisors shall submit additional copies depending on the number of Co-Supervisors, to be processed along with the six (6) copies.

CONCLUSION

All Postgraduate Student of Osun State University shall be expected to comply with all the guidelines highlighted in this document in writing and preparing their Long Essays, Project Reports and Theses. Failure to so do shall lead to rejection of such Long Essays, Project Reports or Theses.

APPENDICES

Appendix 1 (Cover Page)

DEVELOPMENT AND EMPIRICAL APPLICATION OF A CLIMATE CHANGE EDUCATION MODEL

ZULUM NWACHUKWU ADEDOLAPO

UNIOSUN PG Matric Number:

B.Sc. (Ed.) Chemistry, M. Ed. Science Education (UNIOSUN)

September2020

NOTE:

If the degrees were obtained from different Universities it be written as B.Sc. (Ed) Chemistry (UI), M.Ed. Science Education (UNILAG)

Appendix 2 (Title Page)

DEVELOPMENT AND EMPIRICAL APPLICATION OF A CLIMATE CHANGE EDUCATION MODEL

ZULUM NWACHUKWU ADEDOLAPO

UNIOSUN PG Matric Number:

B.Sc. (ED.) Chemistry, M.Ed. Science Education (UNIOSUN)

A Thesis Submitted to

The Global Affairs and Sustainable Development Institute in Partial Fulfilment of the Requirements for the Award of Doctor of Philosophy (Ph.D.) Degree in Sustainable Development Practice of Osun State University

September 2020

NOTE:

If the degrees were obtained from different Universities, the conditions as stipulated in Appendix 1 shall apply.

Appendix 3 (Authorization Page)

AUTHORIZATION TO COPY

AUTHOR:

TITLE OF THESIS/PROJECT REPORT/LONG ESSAY

DEGREE:

YEAR:

I, Zulum Nwachukwu Adedolapo hereby authorize the Osun State University Library to copy my thesis in whole or in part in response to request from individual researcher and organisations for the purpose of private study or research,

_____ _____

Signature **Date**

Appendix 4 (Certification Page)
CERTIFICATION

This Thesis with the title *"Development and Empirical Application of a Climate Change and Sustainable Development"*
Submitted by Zulum Nwachukwu Adedolapo was carried out under my Supervision at Osun State University, Osogbo.

_____ _____

Professor Olaide Gbadamosi **Date**
Supervisor

If there is more than one Supervisor, the text and the signature place should so indicate.

Appendix 5 (Attestation Page)
ATTESTATION

I hereby attest that this research work was carried out at the Department of Global Affairs and Sustainable Development Institute, Osun State University, Osogbo, Nigeria.

_____ _____

Head of Department **Date**
Professor Aminu Ngozi Adeleke
(B.Sc., M.Sc., Ph.D.)
Professor of Development Practice

BIBLIOGRAPHY

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(iv) Covenant University Policy on Plagiarism and Other Forms of Academic Dishonesty (2006) http://eprints.covenantuniversity.edu.ng/id/eprint/6973

(v) University for Development Studies UDS Library https://www.udslibrary.net/wp-content/uploads/2019/01/UDS_Plagiarism-Policy-2.pdf.

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