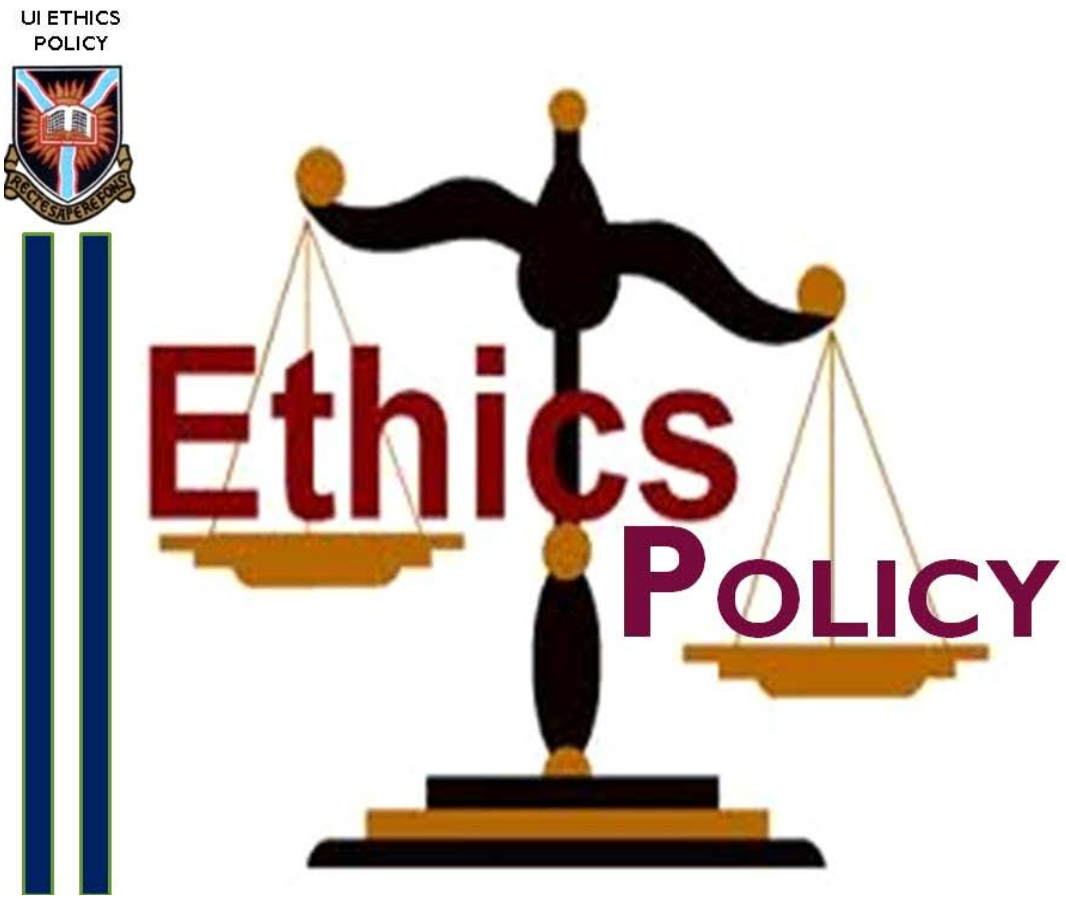
# CHAPTER ONE



## 1. INTRODUCTION

**PREAMBLE**

**The University of Ibadan (UI) was established in 1948 for teaching, research and service. It is the premier university in Nigeria with 14 faculties, 5 centres and 4 institutes. As of 2010, the undergraduate student population is 28,000 made up of 16,000 in the mainstream and 12,000 in the Distance Learning Centre while the postgraduate student enrolment is about 9,000. This is in accordance with the directive of the National Universities Commission (NUC) on annual 10% growth for the first generation Nigerian universities. There are several institutions affiliated to the University for which it provides oversight functions. The Institution is focused on increasing its research base through the 60:40 postgraduate to undergraduate ratio. With a rich history of engagement with the society, the University can boast of a conducive environment for multicultural activities and interactions. The University has a functional policy framework for staff, student and community activities.**

**THE VISION:**

- **To be a world-class institution for academic excellence geared towards meeting societal needs.**

***THE MISSION*:**

- **To expand the frontiers of knowledge through provision of excellent conditions for learning and research.**
- **To produce graduates who are worthy in character and sound judgement.**
- **To contribute to the transformation of society through creativity and innovation.**
- **To serve as a dynamic custodian of society's salutary values and thus sustain its integrity.**

**The University of Ibadan affirms that excellence in research, teaching and learning, professional conduct and services cannot be achieved without sound ethical standards. The aim of this policy is 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 UI are based on the principles enshrined in the Nigerian constitution as well as the National Health Research Ethics Code (NRHEC). This policy covers ethical issues as it affects staff, students and visitors to UI in research, teaching and learning as well as in professional conduct and services.**

**UNIVERSITY OF IBADAN RESEARCH ETHICS COMMITTEES**

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

- **Therapeutic procedures – interventions administered with the intent of providing direct benefit to the research participant.**

- **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 UI Policy, four new Research Ethics Committees (UIRECs) have been created in addition to the existing UI/UCH ERC now renamed Health Research Ethics Committee (HREC), Social Sciences and Humanities Ethics Committee (SSHREC), Animal Care and Use Research Ethics Committee (ACUREC), Plant Use and Conservation Research Ethics Committee (PUCREC), 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).**

**JUSTIFICATION FOR A UI ETHICS POLICY**

**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:**

- **The shortage of human, institutional and financial resources.**
- **The relatively low priority assigned to research.**
- **The impact of culture, religion and norms that undermine ethical requirements such as informed consent.**
- **The increase in volume of research in Nigeria has necessitated an ethics policy in UI, being a foremost research institution in the country.**

**The Ethics Policy will:**

- **promote the aims of research.**
- **encourage the values that are essential to collaborative work.**
- **ensure that researchers are accountable.**
- **build public support for research.**
- **promote social and moral values.**

# CHAPTER TWO

## 2. GOAL AND OBJECTIVES

**GOAL:**
**The overall goal of this Ethics Policy is to establish acceptable standard for research integrity, teaching and learning as well as professional conduct and services at the University of Ibadan.**

**THE OBJECTIVES INCLUDE:**

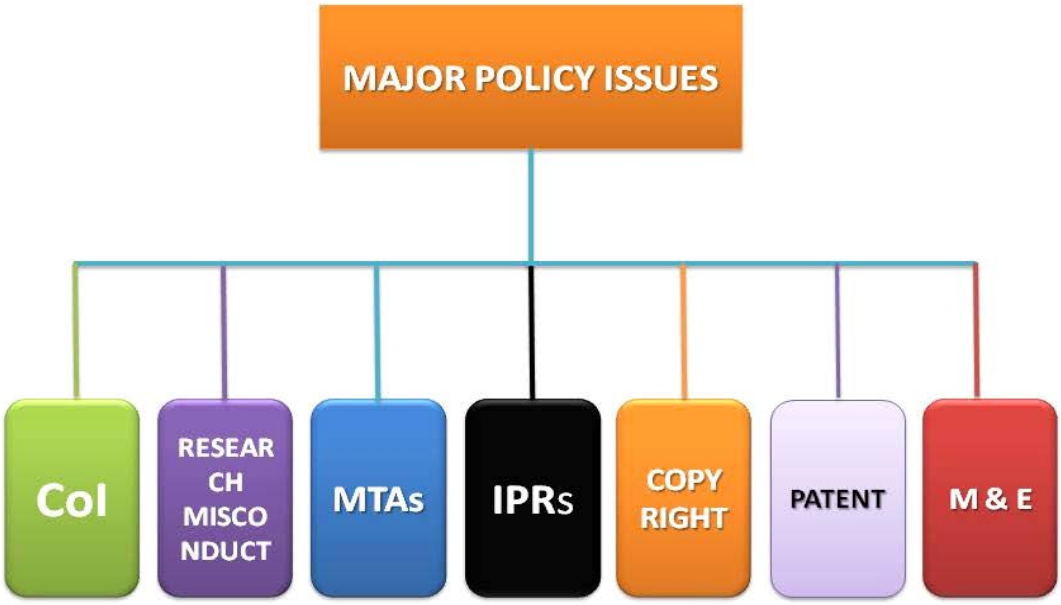
- **Providing guidelines for the conduct of research undertaken by staff, students and visitors.**
- **Establishing a framework for Ethics Review Committees.**
- **Developing an acceptable standard for teaching and learning.**
- **Maintaining and regulating different ethical practices and professional conduct.**

**HISTORY OF ETHICS AT UNIVERSITY OF IBADAN**
**The first Research Ethics Committee (UI/UCH Ethical Review Committee, ERC) was established in 1980, when the College of Medicine was founded. At inception, research protocols were allocated to one or two competent Faculty members to review after which approval was given executively by the Director of The Postgraduate Institute for Medical Research & Training (PIMRAT) now Institute for Advanced Medical Research and Training (IAMRAT) in the College of Medicine or the Chairman Medical Advisory Committee (CMAC) of the University College Hospital (UCH). Challenges during this period included the absence of a secretariat, infrastructural facilities, funds and standard operating procedure (SOP) for reviewing proposals. No formal meetings were ever held on proposal review.**

**However in 2002, a committee system was introduced, with the establishment of a functional Ethics Review Committee. In the same year, the UI/UCH ERC was registered with the Office of Human Rights Protection (OHRP) of the United States Department of Health & Human Services (DHHS), (Reg. No. IRB00002499) and renewed biannually. It also secured a Federal Wide Assurance of the USA (FWA) (FWA Reg. No. 403094-U Ibadan in Aug 2002) by Falusi and co-workers (2007).**

**The committee has been involved in the training of members and researchers within and outside Ibadan. Funding for the Committee has been mainly from external sources such as the Ralph & Marion Falk Cancer Trust, USA (a three-year subcontract from University of Chicago) and Internal Processing fees from Protocols Submission.**

# CHAPTER THREE



## 3. MAJOR POLICY ISSUES AND OPERATIONS

**Some major policy and operational issues common to the five ethics committees , teaching & learning as well as professional conduct now being established at UI will be addressed at this point to avoid repetition by each research ethics committee. These are Conflict of Interest, Research Misconduct, Monitoring & Evaluation, Material Transfers and Intellectual Property Rights.**

**CONFLICT OF INTEREST (CoI)**

- **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.**
- **Conflict of interest arises from a variety of impact of decisions made irrespective of validity of decision, of competence of the decider and irrespective of the degree of seriousness of 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 ends and methodologies. During data processing and reporting, integrity of editing, coding should be done to avoid prejudices.**
- **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).**
- **The review process focuses on the following areas of conflict which include 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. Desire for promotion, poor income and inducement of a trip, preferential choice of publication, international clout or institutional gain may result**

**in CoI. Anticipation of COI, training, emphasis to distort CoI, and effecting adequate supervision are keys to preventing CoI.**

**RESEARCH MISCONDUCT**

**Research misconduct refers to practices that seriously deviate from those that are commonly accepted within scientific community for proposing, conducting, or reporting research. It also embraces shortcomings in 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:**

- **complimentary authorship: a situation in which a person who has not made any contribution to a paper is cited as an author; submission of paper with sections lifted from other papers without acknowledgements,**
- **resubmission of previously published data with minor alterations and no acknowledgements,**
- **submission of papers by lecturer from students' dissertation without students' permission,**
- **Fabrication: making up data or results and recording or reporting them as true.**
- **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 proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books].**
- **Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.**

**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 dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies;**
- **adjudication, during which recommendations are reviewed and appropriate corrective actions determined.**

**MATERIAL TRANSFER AGREEMENTS (MTAs)**

***Material Transfer Agreements***

**Material may be defined as original tangible substance as well as modifications or derivatives made from the material that uses the owner's ideas. Biological and other materials and their derivatives that could be transferred include but not limited to:**

- **Human materials**
- **Cell lines**
- **Tissues**
- **Reagents**
- **Vectors**
- **Plant materials**
- **Archaeological Artefacts**

**Other materials include:**

- **Chemical compounds**
- **Software for e-learning**

**Ownership of materials indicates that:**

- **Human participants have the right over their genetic material**
- **Access must be defined by consent, contract or law**
- **Individual rights override community consent**
- **Group identity, culture, reputation, tradition, beliefs must be protected**
- **Compensation for indigenous/traditional knowledge in product development must be acknowledged.**

**Storage of Specimen must have:**

- **Identifiable information in genetic databanks**

- **Regulation of use of stored specimen**

- **Guidelines development to regulate previously stored specimens.**

**Material Transfer Agreement (MTA) describes the rights of the provider and the recipient with respect to materials and derivatives. Four types of MTAs are recognized as transfer:**

- **Across national boundaries**
- **Academic institutions**
- **Academia to industry**
- **Industry to academia.**

***MTA Guidelines:***

**For MTAs, the following guidelines should be adhered to:**

- **Materials to be transferred must have adequate description and documentation on source, date and physical form**
- **Agreements on the materials must go through the Legal Office for advice**
- **Agreements must be signed by the Vice Chancellor and the Provost/Dean of the University on behalf of the institution.**

**Material Transfer Agreements (MTAs) duly signed by the host and collaborating institution should be submitted to the host Ethics Committee for record purposes. This should serve as a binding document for the condition of transfer of any specimen and for patent right of both institutions and investigators. The Provider/Investigator could be prevented in some circumstances from using research results in further research, transferring them to other institutions, meeting the objectives of sponsors, or ensuring that the results are disseminated to the public domain.**

- **The UIEPC stipulates that MTAs should be guided by norms that govern ethics as detailed in Health Research Ethics Chapter and other guidelines in the University of Ibadan Ethics Policy Document.**

**INTELLECTUAL PROPERTY RIGHTS (IPRs)**

**The University's intellectual knowledge and technology are of extreme importance to its community. The University in encouraging research and development may have inventions that can be commercially tapped for the benefit of its inventors and the community. All research that may give rise to intellectual property must be in compliance with the University policy and International laws.**

**Intellectual property right (IPRs) is permission given to inventors/creators and owners of original works/endeavours that are the outcomes of intellectual creativity. The IPRs is to grant the inventor a time-dependent control over the use of their work in order not to deprive them of their reward. Rights require registration. It is the responsibility of the**

**inventor to make the product accessible to the public. The intellectual rights could be artistic, literary or scientific. Examples of intellectual property rights include:**

- **Copyright**
- **Patents**
- **Trade marks**
- **Design rights**
- **Confidential information**
- **Archeological artifacts**

**COPYRIGHT**

- **Protected by copyright under the Nigerian Act**
- **Recorded in some form – in writing, sound recording, on a computer disk, or in a printed form.**
- **The work meets originality requirement**

**Copyright is of utmost importance to the University of Ibadan, as a tertiary institution because of the mandate for teaching/learning to end-users, producers and disseminators of information by print as well as other multimedia including the Internet. Materials on the internet allows for the public dissemination of this information. Examples of copyrightable online materials are:**

- **Journals**
- **Internet content**
- **online databases**

**GUIDELINES ON COPYRIGHT**

**Many of these materials are available under certain terms and conditions stipulated by its rights holder such as the restriction to the public/other person(s):**

- **Copying the work in part or in whole**
- **Issuing copies of the work**
- **Renting or lending the work**
- **Performing, showing or playing the work**
- **Communicating the work to the public – in print or other media**
- **Making an adaptation of the work**

**PATENTS**

**The term *patent* refers to a right granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof. Examples of particular species of patents for inventions include biological patents, business method patents, chemical patents and software patents.**

**The procedure for granting patents, the requirements placed on the patentee, and the extent of the exclusive rights vary widely between countries according to national laws and international agreements. The exclusive right granted to a patentee in most countries is the right to prevent others from making, using, selling, or distributing the patented invention without permission. Patenting shall be encouraged and ownership shall be determined in accordance with the University of Ibadan patent policies and the Nigerian patency rights.**

**Under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, patents should be available in WTO member states for any inventions, in all fields of technology, and the term of protection available should be the minimum twenty years. Different types of patents may have varying patent terms (i.e., durations).**

**The inventors, their successors or their assignees become the proprietors of the patent when and if it is granted. If a patent is granted to more than one proprietor, the laws of the country in question and any agreement between the proprietors may affect the extent to which each proprietor can exploit the patent. For example, in some countries, each proprietor may freely license or assign their rights in the patent to another person while the law in other countries prohibits such actions without the permission of the other proprietor(s).**

**The ability to assign ownership rights increases the liquidity of a patent as property. Inventors can obtain patents and then sell them to third parties. The third parties then own the patents and have the same rights to prevent others from exploiting the claimed inventions, as if they had originally made the inventions themselves.**

**MONITORING AND EVALUATION (M&E)**

**Protocols approved by the Ethics Committee (EC) will be monitored and evaluated by the sub-committee on Monitoring and Evaluation yet to be established by the University of Ibadan to ensure compliance with good clinical practice, standard operating procedures and applicable regulatory requirements. The University of Ibadan ethics policy requires all M&E to report any unethical conduct of researches to the EC and eventually to the UI ERRB for necessary sanctions. However, it should be emphasized that the aim of M&E is to help and not to hinder investigators.**

**The followings are required for monitoring and evaluating research projects:**

- **Membership of the Monitoring Team (MT) should comprise some members of the EC and coopted members. Community representation are required to be part of the M&E**
- **Empowerment of the MT to scrutinize any part of the project with fair openness.**
- **Adequate funding should be provided for the activities of the MT by the University through the different communities.**
- **The working activities of the various M&E should be directed according to the flexibility of their schedule.**
- **Timing of the M&E should be as directed by the committee and be periodic with or without notice to the investigators.**

- **Investigators should submit progress reports, at least annually, to the EC which will be available for the MT.**
- **It is expected that investigators should not hinder or place mechanism in place to hinder the ethical work of the M&E members.**
- **It is expected that all the research participants should be accessible for interview by the MT.**
- **Part of the MT responsibilities is to observe clinical examination, laboratory methods, safety measures, and all information gathering instruments including questionnaires.**

# CHAPTER FOUR

## 4. UI 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.**

***ETHICAL RESEARCH REVIEW BOARD***

**The University shall establish and operate an Ethical Research Review Board (ERRB) under the Vice Chancellor's Office.**

***Functions of the ERRB***

**The principal functions of the ERRB shall be to:**

- **coordinate and regulate all matters pertaining to research ethics and integrity at the University of Ibadan**
- **oversee the activities of its ethical review committees**
- **advise Senate on policies and matters relating to research ethics and integrity**
- **prepare and submit annual report to Senate through the Vice-Chancellor.**

***Structure of ERRB***

**The ERRB consists of the following five research ethics committees:**

- **Health Research Ethics Committees (HREC)**
- **Social Sciences and Humanities Research Ethics Committee (SSHREC)**
- **Animal Care and Use Research Ethics Committee (ACUREC)**
- **Plant Use and Conservation Research Ethics Committee (PUCREC)**
- **Science and Technology Research Ethics Committee (STREC)**

***Composition of ERRB***

**The membership of the ERRB shall be as follows:**

- **Chair - Deputy Vice-Chancellor (Academic),**
- **Chairs of the five Research Ethics Committees**
- **One lay person from the public**
- **Head of the Legal Unit**
- **Director of RMO**
- **Principal Assistant Registrar (DVCO Academic Office), (Member and Secretary)**

# HEALTH RESEARCH ETHICS COMMITTEE (HREC)

## 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 well-being 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 deals 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 codes of conduct relating to subjects' rights 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 the review of protocols of research by properly constituted Research Ethics Committees (REC). The primary role of an REC 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 taken 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 advise on required modifications to research protocols. The REC also performs other functions, such as setting policies or offering opinions on ongoing ethical issues in research and educating researchers about the importance of ethics in research. All research conducted by staff, students and visitors to the University of Ibadan 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 University of Ibadan (UI) and the University College Hospital (UCH) Ethics Review Committees (UI/UCH ERC) now renamed Health Research Ethics Committee (HREC) was established in 2002 in accordance with the regulations setting up both institutions. The committee has a Federal Wide Assurance number FWA00003094-U Ibadan, which was**

**granted in May 2002 by the American Office for Human Research Protection (OHRP) and renewed biannually.**

**The Ethics Committee in reviewing research proposals 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 emphasises 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, culture or ethnic 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 (1947), the Belmont Report, the CIOMS (Council for International Organizations of Medical Sciences), International Ethical guidelines for Biomedical Research involving human subjects, the 45 CFR 46, the World Medical Association Declaration of Helsinki (1964; 1975; 1983; 1989; 1996; 2000), WHO Operational Guidelines for ethics committees that review biomedical research (2000) and the Nigerian National Health Research Ethics Code among others. These guidelines are based on four ethics principles which are of equal importance. These are:**

- **autonomy (respect for human dignity-ability to make decision for oneself)**
- **beneficence (obligation to 'do good' to participants/community)**
- **non-malfeasance (obligation to avoid harm to participants/community), and**
- **justice (distributing benefit 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 participants agreement to take part in the research without undue influence or coercion. Freely given 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, safeguarded and treated as strictly private in all circumstances of research.**

***Beneficence and Non-Malfeasance***

**Beneficence deals with the responsibility of researchers to maximise 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 benefit 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 not 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 to clinical studies, medical research, and it is an essential aspect of research bioethics. Clinical trial 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. Clinical trials (CTs) evaluate new drugs, medical devices, biologics, or other interventions on patients in strictly scientifically controlled settings. CTs are required by drug regulatory agencies (DRAs) such as NAFDAC in Nigeria and 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 new 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 for research purposes is one essential aspect of research bioethics. To this extent protocol submission and responsibilities of both sponsors and investigators are of utmost 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***

- **Ethical – This involves the following:**
  - **writing and submission of a protocol.**
  - **full and informed consent of human participants.**
  - **close supervision by appropriate Drug Regulatory Agencies.**
  - **all interventional studies must be approved by an Ethics Committee (IRB, ERC) before permission is granted to run the trial.**

- **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 product and device must pass GMP requirements**

- **Good Clinical Practice (GCP) is 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 the administration of the drugs and in 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 methodologies that 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 trials are a novel concept in CTs involving testing small, non-therapeutic amounts of drugs to obtain preliminary pharmacokinetic information in animals. This helps to assist pharmaceutical companies in 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 in-patient 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 small 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:**

- **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).**

- **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.**

- **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 I assessments 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 large (possibly varied – multicentred) patient groups (300 - 3,000 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 drug 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 and 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 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:**

- **serve the interests of the parties actively involved in the research process.**
- **protect the rights and safety of subjects, including patients.**
- **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) – This is any undesirable experience occurring to a participant 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. There must be a qualified person legally allowed to practise medicine/surgery or a research scientist in 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, that allows verification.**

**Documentation**

**of 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 submissions and approval from the regulatory authorities and the Ethics Committee, investigator(s)' Curriculum Vitae, Consent Forms, Monitor Reports, Audit Certificates, Relevant Letters, Reference Ranges, 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***

- **It will be required that the protocol be 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.**
- **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.**
- **The investigator should ensure unbiased selection of the participants such that it is not based on other consideration apart from scientific criteria.**
- **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.**
- **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.**
- **Investigator(s) should be responsible for safe handling of drugs, apparatus, and instruments pertaining to clinical trial.**
- **All drugs and other investigational products must be duly accounted for and must be duly disposed off by the investigator(s).**

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

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

- **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.**

**RESPONSIBILITY OF STAKEHOLDERS**

***a.*** ***The Institution shall:***

- **Establish, nurture and maintain the committees**
- **Facilitate funding and support for the committee secretariat and Staff**
- **Share burden of protection of Human Participants and that of the investigator**
- **Educate staff and students about emerging ethical issues affecting human participants.**

**b.** ***The Ethics Review Committees:***

- **Understand and apply the rules/guidelines**
- **Review, approve, disapprove and modify proposals**
- **Conduct continuing review of approved projects**
- **Observe the consent process and verify changes**
- **Suspend or revoke approval where applicable**
- **Work with investigators to ensure that they develop ethically sound protocols**
- **Provide training/education as soon as possible for both members and investigators**
- **Provide effective communication of the decisions of the committee to investigators**
- **Report all adverse events and serious non-compliance to the University of Ibadan Research Management Board**

**c.** ***The Researchers*****:**

- **Accountable for the consequences of his/her research projects.**
- **Accountable to their professions, the University, staff and students involved in the project and project sponsors.**
- **Must be professionally competent.**
- **Must use 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.**

- **Must provide full information about the study to the ethics committee and Human Participants.**

**The information should include:**

- **Title/theme of research**
- **Required experience of Human subject participants**
- **Length of part participation**
- **Risk/injuries/distress involved in the study**
- **Benefits if any**
- **Compensation if any**
- **Voluntariness for participation and withdrawal with no reappraisal**
- **Notification of an alternative treatment e.g. in medical interventions**

- **Confidentiality of identity/information/data**
- **Transmission to local language of research protocol for the understanding of Human participants.**

**d.** ***The Participants*****:**

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

- **required experiences for participation**
- **the research procedure**
- **the purpose of the study**
- **the length of participation**
- **compensation if any**
- **the risk and injuries that may be involved**
- **potential benefits of the study and**
- **to clarify all doubts before accepting to participate in the study.**

**e.** ***The Communities*****:**

**The University of Ibadan 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 a project**

**inception. However, this community consent does NOT replace individual consent which is mandatory.**

**f.** ***Sponsors:***

**Most researches 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 University of Ibadan ethics policy submits as follows:**

- **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, the University of Ibadan) as well as the sponsor(s') country(ies).**
- **If a sponsor provides funding, a mechanism must be in place to ensure that the funds are being used in a manner that is ethically acceptable.**
- **However, the country in which the research is to be conducted must also be satisfied about the ethical acceptability of the research.**
- **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 an assurance that when such studies are no longer sponsored after the review process, a reimbursement of funds used should be made.**
- **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.**
- **If a 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.**

**COMPOSITION OF COMMITTEE**

***Membership:***

**Procedures for identifying and recruiting EC members are guided by the International and National Ethics Codes of Conduct. The responsibilities expected of the members should also be well outlined. Membership requirement should take note of the person responsible for making the appointment and the procedure for selection. 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 willingness of members to publicise their name, profession and affiliation. It should also include reimbursement to members for their work. A confidentiality agreement on meeting deliberations, applications, information on research participants 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 or a half of members). Stipulated professional requirement eg (physician, lawyer, statistician, and lay-person) must be included with gender and religious balance. Alternates are independent consultants appointed for their expertise in ethical, legal aspects, specific diseases, 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:**

- **Chair: Director of IMRAT appointed by the Vice Chancellor**
- **Co-Chair: Chairman Medical Advisory Committee (CMAC) (Statutory)**
- **Legal Officer: Nominee of Board of IMRAT (Statutory)**
- **Two academic staff members from each of the Faculties of the College of Medicine, namely: Basic Medical Sciences, Clinical Sciences, Public Health and Dentistry.**
- **One academic staff member from each of the Faculties of: the Social Science, Law and Pharmacy.**
- **One Statistician**
- **One member - UCH Pharmacy**
- **One member - Nursing Department**
- **Two Community Representatives – Laypersons, (1) Male and 1 Female**
- **Secretary (IMRAT Secretary)**
- **5 Alternates chosen on professional competence**

**Gender balance is observed in the Committee**

**Duration of membership**

**Membership is for a period of 2 years, renewable <u>once</u> thereafter.**

**STANDARD OPERATING PROCEDURE (SOP)**

- **Submission**
- **Review**
- **Approval/Disapproval**
- **Monitoring**

**GENERAL GUIDELINES FOR PROPOSAL SUBMISSION**

***A cover page specifying:***

- **Title, Full Names, Qualifications, Sponsors, Collaborating Institutions of Investigators, Corresponding Investigator, who must be the Project or Local PI of the protocol and bears responsibility for the research.**

***Background of Study***

- **A description of the state-of-the art of previous related research and current knowledge must be provided.**

***Rationale for the study***

***Objectives of the study***

***Methodology:***

- **Study design - stating clearly the nature of the study (descriptive, drug trial, experimental)**
- **Sample size determination**
- **Sampling/Interview detailing inclusion/exclusion criteria &frequency**
- **Statement on invasive sampling (blood, tissue etc); inclusion/exclusion criteria and frequency of sampling**
- **Data collection procedure**
- **Physical examination procedure if inclusive**
- **Follow up details, if required**
- **Laboratory procedures to be used**
- **Intervention statement to be included**
- **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 clearly addressed in the protocol as a separate section (See below).**

***Informed Consent Form***

***Where applicable, a translation of the questionnaire & Informed Consent*** **in the Local language of participants must be provided to facilitate clear understanding.**
**Each of the points listed below has to be explained in a few sentences to convey to the IRC, what steps the PI intends to take executing his/her research:**

- **Confidentiality of Data**
- **Translation of Protocol to local language and in the simplest level**
- **Compensation and/or Direct Benefits to Participants**
- **Non-Maleficence to Participants**
- **Issues of Equity and Justice in Participant Selection**
- **Right to Decline/Withdrawal from Study without Loss of Benefits.**

**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 undue pressure) and based on sufficient information as to the risks and benefits associated with participants in the project. Use of a *written consent* form is the preferred method of documenting informed consent. The written consent 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 addressed in the second person singular.**

**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:***

- **Information: Details provided to the participants must be comprehensive.**
- **Comprehension: Investigator must ensure that the informed consent process is clearly understood by the participant/ guardian before accepting to participate in the study.**
- **Voluntariness: All study participants must volunteer**
- **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:**

- **Name and Address of Principal Investigator**

- **Person to contact for answers to questions, or in event of research related injury or emergency should be clearly stated with full address and telephone numbers**
- **Purpose of Research must be clearly stated.**

- **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.**

- **Benefits expected to accrue from the research must be communicated to participants and the research community. In studies, evaluating drugs or other products, the participants should be advised as to the availability of the product after discontinuation of the study. Indicate possible cost implication or whether drug would be available to the patients free of cost.**

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

- **Length of time participant is expected to participate. If participant(s) is/are expected to participate over a long period of time, it should be clearly indicated. Any new information that develops during the study that may affect the participants' willingness to continue must be communicated to them. This would apply even when the intervention/investigation phase of the study has ended while monitoring continues.**

- **Treatment for adverse events. Explain what therapeutic measures 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.**

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

**CONFIDENTIALITY**

**The University of Ibadan 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:**

- **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.**
- **No description traceable to research participants shall be done without the necessary precaution.**
- **A comparable standard or mechanism should be in place to ensure the confidentiality and security of personal information concerning research participants.**
- **Information of research participants should be anonymised to a large extent.**
- **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.**
- **How long the data/samples will be kept should be adequately discussed in any submitted research protocol before approval.**

- **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.**

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

- **the professional knows or suspects that an individual is acting illegally.**
- **the researcher or professional knows or suspects that an individual is harming others.**
- **the researcher or professional knows or suspects that an individual might harm others in future.**
- **the researcher or professional knows or suspects that an individual is harming himself/herself**
- **the researcher or professional knows or suspects that an individual might harm himself/herself in future.**
- **the researcher or professional knows or suspects that a minor is being exploited or abused by others.**
- **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.**

- **The University of Ibadan Ethics Policy therefore requires that no research should be conducted against a person's wishes.**
- **His or her consent to participate in research must thus be obtained voluntarily.**
- **No potential participant in any research should be made to partake in any study by any form of coercion.**

***Participation/Right to Withdraw***

**The University of Ibadan 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**

- **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.**
- **Research participants have the right to request that their own 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/Thumb Print***

**The final stage in the process of Informed Consent is to append the signature or thump print. In case of participant's inability to append his/her signature due to the level of literacy or other considerations a proxy must sign or thumb print as a witness.**

**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; infants (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 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 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.**

**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 course of the study, the participant must notify the principal investigator as soon as possible.**

**REVIEW PROCEDURE**

***Committee Procedures***

- **The Committee meets once a month for proposal reviews and approvals.**

- **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 & Approvals*:**

**Ethics Committees 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)**

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

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

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

***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:**

- **Approved - If full approval is granted, the investigator may begin the research proposed in the protocol.**
- **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 formal approval has been obtained from the Committee.**
- **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.**
- **Rejection – A protocol may be rejected by the Committee if it has been deferred several times and the Committee feels that the problems have not been adequately addressed, or if the protocol is not justified and poses severe or unnecessary risk to the participants.**

***Conditions for Approval***

- **Approval is given for a specified period of 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.**

- **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.**

- **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.**

- **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.**

- **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**

- **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 are regarded as serious offences. Conflict of Interest can occur in research when the professional judgement is unduly influence by other interests such as financial gains or personal status. This sometimes is 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 articles, funding for facilities. Some of these issues have been addressed earlier under major policy issues and operations. These include:**

- **Conflict of Interest**
- **Competence of Investigator**
- **Scientific Integrity and Misconduct**
- **Plagiarism**
- **Fabrication**
- **Intellectual Property Rights**
- **Disagreement between two ethics committees**

# SOCIAL SCIENCES AND HUMANITIES RESEARCH ETHICS COMMITTEE (SSHREC)


**4.2. SOCIAL SCIENCES AND HUMANITIES RESEARCH ETHICS COMMITTEE (SSHREC)**

**PREAMBLE**

**Research involving discipline in social sciences and the humanities shall be guided by four principles as produced by the *Belmont Report* (articulated by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in 1976).**

**These four principles include respect for persons; justice; beneficence and non-malfeasance. Please refer to the human participants' ethics committee section for detailed explanation of these ethical concepts (pp.17-18) .**

**Research offences in the social sciences and humanities shall include but not exhaustive of the following:**

- **Fabrication- Fabrication involves making up data or results and recording or reporting them as factual results.**
- **Falsification: falsification entails manipulating research materials, equipment, or process, or changing or omitting data or results such that the research is not accurately represented in the research record.**
- **Plagiarism. Plagiarism is the appropriation of another person's ideas, processes, results, words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts**

**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 handbook.**

**KEY AREAS COVERED BY THE COMMITTEE**

**The SSHREC shall function accordingly as follows:**

- **Communicate and enforce research ethics standards.**
- **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.**
- **Apply procedures to enforce breaches of research ethics standards.**
- **Must take responsibility for following the Guidelines for Research Ethics. They must have specific procedures to handle suspicions and accusations related to breaches of the Guidelines for example, by creating committees to deal with scientific dishonesty, under their own auspices**

**TO WHOM DOES THIS CODE APPLY?**

**The SSHREC guidelines contain standards that apply to:**

- **Teaching and non-teaching staff of the University of Ibadan, intending to engage in behavioural research.**
- **Diploma, undergraduate, and postgraduate students registered as students in the University of Ibadan, interested in behavioural research.**

- **Other researchers who are not members of the University of Ibadan community but intend executing any behavioural research within the university.**
- **Research institutions, financiers of research and other appropriating authorities in support of behavioural research affecting the University of Ibadan community.**

**COMPOSITION OF SSHREC**

**The membership of the *SSHREC* shall be as follows**

- **Chair: A Professor from the humanities or behavioural science (Appointed by the Vice Chancellor)**
- **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).**
- **One Statistician**
- **One Lawyer**
- **Two community representatives (lay persons; 1 male 1 female)**
- **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 generalizable knowledge; interviews of individuals that do not focus on things not people. (e.g. questions on policies).**

***Expedited Approval***

- **Expedited review procedures can be considered when research activities: present no more than minimal risk to human subjects, and involve only procedures that are not invasive (as listed below). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this 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 stick.***

**Prospective collection of biological specimens for research purposes by non-invasive means.**

- **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.**
- **Research involving materials (data, documents, records, or specimens), that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)**
- **Collection of data from voice, video, digital, or image recordings made for research purposes.**

- **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 criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, 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 consideration 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 shall enjoy continuous review process by SSHREC. Such projects through its principal investigator shall submit periodic report of 6 months 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 formal appointment (Teaching or Non-teaching) at the University of Ibadan, Nigeria, or registered students of the University. 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 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 of 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 clear statement of the research problems, objectives, and relevance; identifying the gaps in existing studies and showing the present state of knowledge.**
- **A precise description of the proposed research methods, including the design, setting, sample frame, size and sampling techniques, instrument for data collection, and procedure.**
- **A statistical plan**
- **The criteria for terminating the study, and**
- **Details of the procedure for obtaining informed consent and safety of participants**
- **The presumed benefits to participants and any possible risks involved in participating**
- **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.**
- **Describe how research outcomes will be evaluated and disseminated.**

**STANDARD OPERATING PROCEDURE (SOP)**

- **The review committee shall be lead by a Chairman**
- **The Chairman of the SSHREC must have been formally trained in Research Ethics, preferable with a certificate/diploma or degree.**
- **A minimum of two reviewers (three or more is preferred) shall review any proposal submitted.**
- **Consensus regarding the scientific acceptability of a submitted proposal (if there is not initial consensus, some group discussion regarding the proposal must take place)**
- **Student 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 own members as constituted by the Dean of the faculty**
- **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 human and subjects before it is initiated. This shall normally involve:**

- **A research protocol including a systematic investigation, research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.**
- **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.**
- **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 for completion of a course of study in the University or for expanding frontiers of academic knowledge.**

- **The procedures are performed with or involve the use of facilities or equipment belonging to the University; the research involves University patients, students, staff or faculty;**

- **The protocol narrative must be detailed to enable the SSHREC objectively evaluate the scientific merit of the proposed research and the potential risks and benefits to research participants.**

- **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 Names, 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:***

- **Brief literature review on the subject matter**
- **Statement of Research Problem**
- **Objectives of the Study**
- **Relevance of the Study**
- **Methodology**

***Study Design:***

- **stating clearly the nature of the study- descriptive, experimental, longitudinal, correlational, etc.**

***Participants:***

- **sample size determination, sampling techniques**

***Instrument for Data Collection:***

- **Describe the instrument, e.g. questionnaire, including standardization procedure. A sample of this should be included in the protocol.**
- **Data collection procedure, including pilot testing**
- **Data analysis package to be used**

***Ethical Considerations:***

- **this should be clearly stated in the protocol as a separate section**
- **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:**

- **introducing the theme or subject comprehensively with adequate information concerning the purposes, methods, demands, risks, duration and inconveniences of study.**
- **noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.**
- **obtaining appropriate consent from relevant community leaders and/or recognised spokespersons.**
- **ensuring that in a situation where a participant lacks the competence to consent, a person with legitimate authority to decide for that participant is provided with that information and may exercise that choice.**
- **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 situation of the study areas.**
- **obtaining letter of introduction from appropriate authorities/institutions.**

*Consent in Research and Power Relations*

- **The relations between researchers and informants are often characterised 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 Population*

- **Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is of sufficient competence. Otherwise, the person's guardian or any other legitimate authority must 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 organisation 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 parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years 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:**

- **Where there are changes in any part of the research protocol.**
- **Where there are changes in the named members of the research team.**
- **Where there are changes in research sites.**
- **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 submit 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 outcomes measures. Under no circumstances shall a 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:**

- **In accordance with the committee's requirements;**
- **In accordance with the existing legislation;**
- **In accordance with existing institutional guidelines; or**
- **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 University of Ibadan Ethics Research Review Board (ERRB).**

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

***Process for Revision of Suspension***

- **The Ethics Committee may reverse its decision to suspend research if the participant(s) of the action is resolved to committee's satisfaction.**

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

- **Where the ethics committee allows resumption of research, an oversight review of the research shall be carried out within ONE HUNDRED AND EIGHTY DAYS (180) days.**

*Process for Termination of Research*

- **Where the committee, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation of the precipitant, the committee shall terminate the research. The committee shall indicate the reason(s) for the termination of the research in writing within fourteen (14) days to the researcher(s), sponsor(s) and the University of Ibadan IERRB, 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 terminate research, the UI ERRB may at its discretion, take up such an appeal.**

*Where the appeal is sustained:*

- **The UI ERRB may with reasons, direct the ethics committee to approve the research and provide continuing oversight.**
- **The UI ERRB may mandate modifications, which if undertaken, can allow the research to proceed or resume, with the ethics committee providing continuing oversight.**
- **The UI ERRB may sustain the decision of the ethics committee and dismiss the appeal.**

*Conclusion*

**Research practice is prohibited if it is contrary to those required by morality or reasonable expectations and therefore, found unjustifiable within the research community. A research practice is said to be 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 known publicly.**

# ANIMAL CARE AND USE RESEARCH ETHICS COMMITTEE (ACUREC)

## 4.3. ANIMAL CARE AND USE RESEARCH 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 that 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 three Rs of Replacement, Refinement and Reduction (Russell & Burch, 1959). 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 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.**

**DEFINITION**

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

***Key Areas***

- **Evaluate and approve, subject to possible modification, or reject written proposals for animal studies submitted for ethical review.**

- **Monitor, inspect and assess the acquisition, transport, production, housing, care, use, humane killing and disposal of animals, including breeding stocks.**
- **Review research facilities' program for humane care and use of animals once every two years**
- **Develop acceptable standards for the establishment and maintenance of animal facilities for research, teaching and testing.**
- **Inspect research facilities and animal study areas at least every two years.**
- **Maintain a register of approved Projects and receive reports on their outcome.**
- **Review concerns and complaints involving the care and use of animals at the institution either from the public or research facility personnel.**
- **Make recommendations to the Ethical Research Review Board (ERRB) regarding any aspect of the institutions animal programme, facilities, or personnel training.**
- **Withdraw approval for any approved Project and/or authorise the humane killing formally of any animal which is being subject to unnecessary deprivation, fear, distress and pain.**
- **If an activity is suspended, the appropriate authorities in conjunction with ACUREC, shall review the reasons for suspension, suggest appropriate corrective actions.**
- **Prepare and submit annual reports to the ERRB.**
- **Training and retraining of all staff, students and visitors involved in animal use for research, teaching and testing.**

**These trainings include:**

- **Basic training for the first-time animal users.**
- **Annual refresher training for all animal users**
- **Training on roles and responsibilities of ACUREC**
- **Depending on the project, animal species, study models, ACUREC will recommend further appropriate trainings.**

**COMPOSITION OF ANIMAL CARE AND USE RESEARCH ETHICS COMMITTEE (ACUREC)**

**The membership of ACUREC shall be as follows:**

- **Chair: A Professor of Veterinary Medicine or Animal Science appointed by Vice Chancellor.**
- **One experienced scientist from each of the Faculties of: Veterinary Medicine, Agriculture (Animal Science and Wildlife and Fisheries), Social Science (Psychology), Science (Zoology), Pharmacy and Basic Medical Sciences.**
- **One Statistician**
- **One Lawyer**
- **Two community Representatives (Lay persons 1male 1 female)**
- **Head of the Research Ethics & Integrity Unit, (Secretary and member)**

**STANDARD OPERATING PROCEDURE (SOP)**

- **The Committee shall meet monthly over the following:**
- **Receipt of proposal**
- **Evaluation of proposal**

- **Approval/disapproval**
- **Monitoring (periodical physical inspection and recommendation of appropriate sanction/correction where necessary).**
- **Ensuring biosafety and best research/teaching practices as related to: Euthanasia in animals, Surgical procedures, Disposal of carcases (mandatory incineration), Clothing, Importation and exportation of animals, Housing and feeding of animals, Transport/transportation, Animal product handling, Monoclonal antibody production, Cancer research, Toxicity testing in mammals and fish, aging, pain research, infectious disease studies, vaccine trials etc.**

**CONCLUSION**

***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. It is the opinion of this committee that much will be achieved on the issue, if and when inter-university, national and international collaborations are sought and appropriate legislations (if any) are enforced.**

# PLANT USE AND CONVERSATION RESEARCH ETHICS COMMITTEE (PUCREC)

## 4.4 PLANT USE AND CONVERSATION 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 humankind, it is important that plants which provide food and medicine are well managed such that their continued availability is ensured. One third of the land space in the University of Ibadan (ninety nine hectares) is made up of plants and vegetation. There is a large variety of plants that has served the community as food, research materials and ornamentals. In addition, the University has a well-laid out botanical garden.**

**In Switzerland, a Committee was set up to instil some ethics on plant use in the wake of biotechnology and cloning. 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[2].**

**As the saying goes, ethics is about choices and it continues to remain a moral issue. Sustaining the earth definitely will more or less be dependent on sustainability of all, made up of humans, other animals and the environment. Several questions arise:**

- **What do humans choose?**
- **Is it only what is beneficial?**
- **Is the earth going to drift away?**
- **What of the estimated 21st century projection of 9 billion people?**
- **What do we leave for the earth's future generations?**

**It is unethical to treat a plant or the environment with disrespect. The University of Ibadan agrees perfectly that there should be ethical guidelines on plant use and biodiversity conservation on her campus 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**

- **The University of Ibadan recognizes that plants on their own have intrinsic value apart from their usefulness to humankind and livestock as food, for aesthetics and raw materials for industries.**
- **The destruction, removal, acquisition and trade of plants native to the University of Ibadan require approval of the PUCREC of the University of Ibadan.**
- **Crop varieties developed by researchers in the University of Ibadan 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 other varieties.**

- **All requests to collect wild plants from their natural environment in UI must be submitted to and approval given by PUCREC before such collections can be undertaken.**
- **For researchers and other interested parties who are not employees of the University of Ibadan, the intent of use of plants collected in the University of Ibadan must be declared on the request for collection document.**
- **The University recognizes the role of the diversity of plant species in the functioning and productivity of ecosystems as well as stability of the latter; therefore it encourages the cultivation more varieties of plants on her campus.**
- **Collection of plants from the University of Ibadan must not endanger the plant species in question. As a guide, only a specified approved quantity any plant species (or seeds of such species) may be collected at any time and areas where collections have been made recently should be avoided as much as possible by the same or other people.**
- **Practices that will maintain and/or promote diversity of plant species are encouraged.**
- **The collection of endangered species is not allowed. Also, weak plants many not be collected for use, except for research.**
- **Rare or endangered species must be reported to the Ethics Committee for urgent steps at conservation.**
- **Reports of new diseases endangering plant species must be reported to the Ethics Committee.**
- **Plant/crop research and production practices must not endanger the diet and health of humans on the campus of the University of Ibadan and its environs and must not pose a threat to the environment.**

**GUIDELINES ON MEDICINAL PLANT USE**

**Plants have always played a central role in indigenous cultures, globally. Plant products are used as food, as sources of medicine, and as raw materials for the making of materials for clothes. 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 local 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 University of Ibadan recognizes 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:**

- **A compendium of plants of the University of Ibadan and their medicinal as well as other uses should be consulted before plant collection.**
- **Plants for research purposes should only be obtained from the University of Ibadan Botanical Garden or the Medicinal Plant Garden in order not to deface plants and thus the environment.**
- **Plants must be properly authenticated from standard herbaria and voucher specimens deposited.**

- **After use for research, resulting plant residue (marc) should be properly incinerated.**
- **No new species of plants can be introduced into the campus of the University of Ibadan, without the approval of the Committee.**
- **Plants shall not be transferred to other biodiversities without the approval of the Committee in addition to approvals of other governmental agencies.**
- **It is prohibitive to embark on bush fires and pesticide use without approval.**
- **It is unethical to fell a plant without consulting the Tree management Committee and PUCREC.**
- **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.**

- **The University of Ibadan will promote the responsible use of technology to advance the welfare of humans and ensure the protection of the environment.**
- **The use of any transgenic plant for research must first be documented with PUCREC.**
- **Adequate care must be taken to prevent contamination of the environment with vectors carrying genes for antibiotic resistance or other reported genes.**
- **Disposal of wastes from laboratories where genetic transformation research is undertaken must conform to the standard safety practice for such laboratories worldwide.**
- **Testing of transgenic/genetically modified plants must be done first in containment facilities before field trials and a risk assessment undertaken.**
- **Field trials require approval of PUCREC.**

**GUIDELINES ON CONSERVATION OF ENVIRONMENT**

**The conservation of natural ecosystems is of great importance for many reasons, including the fact that it conserves ethnobotanical 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 a part of the human life. On these lines, it is clear that they should also be associated with our guiding principles as well as our moral and ethical values. The University of Ibadan recognizes the fact that the environment needs to be conserved and so some guidelines are listed below:**

- **Replacement of natural ecosystems with crop fields and tree farms should be respected.**
- **Groundwater pollution should be avoided.**
- **Soil erosion, aquifer depletion, soil degradation, should be avoided or kept at the barest minimum.**
- **Pesticide use must not endanger the environment.**
- **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 Conversation Committee shall comprise of:**

- **Chair-A professor of Agriculture or Forestry or Botany or Pharmacognosy appointed by the Vice Chancellor.**
- **One experienced scientist from each of the Faculties of Science (Botany), Agriculture and Forestry, Technology (Environmental Scientist), Pharmacy (Phytomedicine).**
- **One Statistician**
- **One Lawyer**
- **One Curator**
- **Two Community Representatives (Laymen 1male, 1 Female)**
- **Head of Research Integrity Unit, ( Secretary & member).**

**STANDARD OPERATING PROCEDURE (SOP)**

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

- **Submission of Protocols**
- **Reviews**
- **Responsibilities of Stakeholders**
- **Approvals**
- **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 (plants, animals and other living organisms) together with their environment, functioning as a unit.**

**Ethnobotany: Ethnobotany is the study of the relationships 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. Ethnobotanical surveys of habitats provide valuable information on the number, kind, and health of species present. (Britannica Concise Encyclopaedia)**

**Environmental Ethics: 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 reintroduction 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.**

**CONCLUSION**

**Plants, 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 human generations. Conservation of natural resources is important for today as well as the future and is the duty of all.**

# SCIENCE AND TECHNOLOGY RESEARCH ETHICS COMMITTEE (STREC)


## 4.5 SCIENCE AND TECHNOLOGY RESARCH ETHICS COMMITTEE (STREC)

**PREAMBLE**

**Scientific and technological ethics is geared towards developing sustainable solutions. Sustainability implies cultural, social and economic restructuring simultaneous with scientific and technological 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:**

- **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 slow. Imbedded in this trust is a responsibility of researchers to mentor the next generation who will build their work on the current research discoveries.**

- **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.**

- **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 have 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 University of Ibadan Science and Technology Research Ethical 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 two fundamental issues viz:**

- **scientific and technological research is a social process and not a discrete set of fragmented tasks.**

- **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 scientist, engineers and technologists operate.**

- **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. In 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 evaluating relevant information and arriving at relevant recommendations and 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 training must be documented and certified. The University should ensure that the training programme 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 programme 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:**

- **Measures workers can take to protect themselves from hazards including any operational specific procedures they have implemented; appropriate work practices to be followed in the laboratory; emergency procedures; and personal protective equipment to be used.**
- **Overview of the contents of the standards and where workers can get access to the standards.**
- **Knowledge of permissible exposure limits to chemicals.**
- **Location and availability of reference material on hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory.**
- **Methods and observations that may be used to detect the presence or release of a hazardous chemical.**
- **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 these broad principles, research ethics in science and technology must include the following key issues:**

- **Professional Competence**

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

- **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.**

- **Legal Obligations**

  **The researcher must be honest in stating claims or estimate 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.**
- **Social Responsibility**

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

- **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 of Ibadan uses chemicals in their activities. There is therefore the need for proper description of operation of the Chemical Safety Programme 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 in certain reference materials 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 campus Radiation Safety 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 programme 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 of Ibadan 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 which will minimize the exposure of people to radioactive materials.**

**There are four key components to radiation safety programme:**

- **The Radiation Safety Committee**
- **The Environmental Health and Safety Office**
- **The Authorized User**
- **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 programme 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 Authorized 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 Authorized User***

**Authorized 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 authorized user is granted approval to possess and use specific isotopes only for the uses described in the authorization application and is issued a possession limit for each of those isotopes.**

**Each authorized user is responsible for:**

- **The health and safety of anyone using or affected by the use of radioactive materials under his or her direction or supervision.**
- **Personally attending initial and annual refresher training and ensuring that his/her employees, staff and visitors receive appropriate training.**
- **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:**

- **Complete the initial radiation safety training programme and, for open source users, attend annual refresher radiation safety training to be organised by the University.**
- **Be familiar with the isotopes in use; know their radiological, physical and chemical properties, methods of detection, and the types of hazards presented by each one, and the specific precautions and handling requirements for each isotope.**
- **Be familiar with all the relevant procedures of the radiation safety program, including isotope purchasing and waste disposal procedures.**
- **Know how to use the appropriate radiation survey metre properly .**
- **Know how to use radiation monitoring badges and exchange them promptly at the end of the monthly or quarterly wear period.**
- **Maintain appropriate inventory, disposal and survey records.**
- **Secure radioactive materials by making sure that radioactive materials are locked away or are under immediate supervision within the laboratory.**
- **Inform coworkers and visitors to the work area about the presence of radioactive materials and of any precautions they should take.**
- **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 of 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 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 the 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:**

- **"hazardous materials" defined as select carcinogens, acute toxins and reproductive toxins.**
- **Explosive or highly flammable chemical use.**
- **radioisotopes.**
- **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.**

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

- **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.**
- **Face shields - Full-face shields 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.**

- **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.**

- **Personal hygiene - Hands should be washed frequently throughout the day, after glove removal, before leaving the lab, after contact with any hazardous material, and before eating, drinking, smoking, or applying cosmetics.**

- **Respiratory protection - Fume hood or other local exhaust ventilation must be used when working with materials that produce hazardous vapours or fumes.**

***Spills & 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; protect the environment; protect University facilities. It is the responsibility of the department to provide and ensure that:**

- **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.**
- **lab workers are informed about what to do in the event of a chemical spill.**
- **immediate steps are taken in situations that are life threatening or 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. Because 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 minimisation 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 standardised 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 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 materials. (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 any significant environmental impact. The Institution has direct responsibility for managing air emissions from their equipments as well as discharges to wastewater systems. Chemical fume hoods should not be used as a disposal method for hazardous materials such as volatile solvents. Chemicals 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

- **Biosafety guidelines are related to issues raised at the conference of the parties to the Convention on Biological Diversity (CBD). This was adopted a supplemenntary agreement to the convention on January 29, 2000. The agreement is known as the Cartagena Protocol on Biosafety.**
- **Protocol is designed to protect biological diversity and human health from potential risks arising from genetically modified organisms (GMOs).**
- **It provides a clear legal framework for transboundary movement of the GMOs.**
- **Unexpected interactions between modified organisms and the environment or other organisms produce risks to the environment and public health.**
- **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**

- **They can evolve beyond their functionality and elicit unprecedented side-effects on the environment and other organisms.**
- **The use of modified living organisms must therefore address biosafety issues when they have consequences for ecology and human health.**

- **Risk assessment procedures and methods must be established to safeguard human health and the health of the environment.**
- **Potential harzards associated with GMOs must be identified.**
- **Risk analysis profile of such hazard must be done.**
- **Development and application of biosafety regulatory framework is very necessary.**
- **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:***

- **Chair-A Scientist/Engineer of the rank of Professor appointed by the Vice Chancellor**
- **One experienced Scientist from the Faculty of Science,**
- **One experienced Engineer from the Faculty of Technology,**
- **A Representative from each of the Faculties of Law, Social Sciences and the College of Medicine (Preclinical).**

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

f. **Two community representatives (1 Male, 1 Female)**

g. **Head of the Research Integrity Unit (Member & Secretary).**

**STANDARD OPERATING PROCEDURES (SOPS)**

**The key area of operations of the STREC is defined within the overall policy document of the University Ethics Research Review Board (ERRB) and includes the following major aspects:**

- **Receive research proposals for scientific and technological research.**
- **Define research themes in areas of science and technology within National science and technological policies and developmental frameworks such as the Vision 20 -2020.**
- **Develop acceptable standards and procedures for the establishment and maintenance of science and technological facilities for research, teaching and testing.**
- **Inspect the research facility and structures at least every three years.**
- **Make recommendations to the Ethical Review Board (ERRB) regarding any aspects of the Institutions Science and Technological programmes, facility or personnel training.**
- **Review and approve required modifications (to secure approval) or withhold approval of proposed activities related to scientific and technological research.**

- **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.**
    - **resolve problems arising from questionable practices.**

- **Prepare and submit annual reports to the ERRB**

**Conclusions**

**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 a basic and fundamental knowledge for conducting appropriate research in science and technology.**

# ETHICS OF TEACHING AND LEARNING (ETL)

## 5. ETHICS OF TEACHING AND LEARNING (ETL)

**PREAMBLE**

**Teaching and learning is a core component required by the University of Ibadan 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 potential and become knowledgeable and proud graduates of University of Ibadan. All ethical issues relating to the section are under the purview of the UI ERRB.**

**The University of Ibadan among its vision to upgrade standard in education has two goals**

- **Teaching component-the creation of knowledge, its dissemination and how such knowledge are preserved**

- **Research component-the creation of knowledge through exploration and discovery-represents in its broadest sense the learning component of university life.**

***Principles of Good Teaching & Learning***

- **to promote good teaching and learning practice (GTLP) that will encourage quality assurance measures that ensure quality outcome at all levels in the university**
- **to ensure high quality teaching and learning experiences for all students and teachers in the university**
- **to provide a framework for teaching and learning that will permit flexibility and creativity**
- **to create awareness of how teaching and learning should take place**
- **to create a basis for monitoring and evaluating teaching and learning process in the university**
- **to highlight rules, regulations and sanctions guiding teaching and learning**
- **to identify specific areas of responsibility at the institutional, teacher and student levels.**

***Roles and Responsibilities of the Institution***

***The University should*:**

- **introduce quality assurance measures into the 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.**

- **promote regular review of curriculum in line with the NUC standards and internationally acceptable standards.**

- **provide funds for upgrading teaching aids, laboratories and facilities for teaching, learning and research.**

- **sponsor teaching development programmes for academic staff with little or no teaching experience especially for newly recruited staff.**

- **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.**

- **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 moderate.**

- **establish a framework or mechanism for validating teaching and learning activities.**

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

- **should acquire software that can be used to detect plagiarism by both staff and students.**

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

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

- **ensure and uphold that there is reciprocal respect between lecturers and students.**

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

- **implement sanctions to 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 THE TEACHER**
**The teacher should:**

- **ensure that effective teaching is conducted with reference to the university's vision and mission.**

- **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 this noble responsibility should show from time to time to have proven ability for sustainable intellectual and skill development**

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

- **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; their 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.**

- **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.**

- **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. In such a climate, 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.**

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

- **understand that physical appearances of both lecturers and students shall be of utmost ethical element in the University. To this extent, appropriate dressing that dignifies the respect for person within a learning environment should be upheld by the teacher within the university.**

- **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.**

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

- **encourage students to develop independent learning skills by providing appropriate tasks to develop analytical and critical thinking skills.**

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

- **not use students as guinea pigs in their realisation of their personal goals**
  **For general conduct of examination regulations and discipline refer to the Student Information handbook 2008-2009 Chapter 5**

**RESPONSIBILITIES OF THE STUDENT**

**The student should:**

- **be willing to take a major responsibility for one's own learning and should motivate self to participate in an active learning community that challenges and stimulates intellectual, scholarly, personal and interpersonal growth.**

- **strive for tolerance and integrity; acknowledge their personal responsibility for their own value judgements; and ethical behaviour towards others.**

- **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.**

- **Work effectively and purposefully to achieve their goal of learning.**

- **come fully equipped and prepared to maximise the learning opportunity in the university.**

- **should dress appropriately or in accordance with any approved dress code in such a way that promotes the respect for person within a learning environment.**

- **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.**

- **avoid the use of foul and obscene language against lecturers and other students.**

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

**Conclusion**

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

# ETHICS OF PROFESSIONAL CONDUCT (EPC)


## 6. ETHICS OF PROFESSIONAL CONDUCT (EPC)

**PREAMBLE**

**Professional Conduct is a set of rules that prescribe baseline standards of acceptable behaviour and rules of conduct as well as professional responsibility for members of an association or organisation. These rules are binding on every member of the organisation. However, having a common set of Model Rules facilitates a common discourse on ethical issues, and simplifies professional responsibility training as well as the day-to-day application**

**of such rules. The application of Standards of Ethical rules cut across all disciplines and all members of the university community, including the Senate, Officers of the University, faculty and other academic personnel, staff, students, ad-hoc staff, contractors, agents and others associated with the university. Organizationally, the standards apply to faculties, the laboratories, the Office of the Vice-Chancellor, Units, campus organisations, foundations, alumni associations and support groups. All ethical issues relating to the section are under the purview of the UI ERRB.**

**PURPOSE OF THE PROFESSIONAL CODE OF ETHICS**

**The pursuit of the University of Ibadan mission of teaching, research and public service requires a shared commitment to the core values of the University as well as a commitment to the ethical conduct of all University activities. In that spirit, *the Standards of Ethical Conduct* are a statement of our belief in ethical, legal and professional behaviour in all of our dealings inside and outside the University. The following rules of professional conduct could be adopted by the University of Ibadan:**

1. ***Fair Dealing***
   **Members of the University community are expected to conduct themselves ethically, honestly and with integrity in all dealings. This means that the principles of fairness, good faith and respect for person, consistent with laws, regulations and University policies should govern our conduct with others both inside and outside the community. No unlawful practice or practices at odds with these standards can be justified on the basis of customary, expediency, or achieving a "higher" purpose.**

2 ***Individual Responsibility and Accountability***
   **Members of the University community are expected to exercise responsibility appropriate to their position and delegated authorities. They are responsible to each other, the University and the University's stakeholders both for their actions and their decisions not to act. Each individual is expected to conduct the business of the University in accordance with the *Core Values* and the *Standards of Ethical Conduct*, exercising sound judgment and serving the best interests of the institution and the community.**

3. ***Respect for Others***
   **The University is committed to the principle of treating each community member with respect and dignity. The University prohibits discrimination and harassment and provides equal opportunities for all community members and applicants regardless of race, color, national origin, religion, sex, gender identity, pregnancy, physical or mental disability, medical condition (cancer-related or genetic characteristics), ancestry, marital status, age, sexual orientation, citizenship, or status as a covered veteran. Further, romantic or sexual relationships between faculty responsible for academic supervision, evaluation or instruction and their students are unacceptable and should be discouraged. The University's health centre is especially committed to**

**the ethical and compassionate treatment of patients and has established policies and statements of patient rights in support of this principle.**

4. ***Conflicts of Interest or Commitment***
   **Employee members of the University community are expected to devote primary professional allegiance to the University and to the mission of teaching, research and community service. Outside employment must not interfere with University duties. Outside professional activities, personal financial interests, or acceptance of benefits from third parties can create actual or perceived conflicts between the University's mission and an individual's private interests. University community members who have certain professional or financial interests are expected to disclose them in compliance with applicable conflict of interest/conflict of commitment policies. In all matters, community members are expected to take appropriate steps, including consultation if issues are unclear, to avoid both conflicts of interest and the appearance of such conflicts.**

5. ***Ethical Conduct of Research***
   **All members of the University community who engaged in research are expected to conduct their research with integrity and intellectual honesty at all times and with appropriate regard for human and animal subjects. The University prohibits research misconduct. Members of the University community engaged in research are not to: fabricate data or results; change or knowingly omit data or results to misrepresent results in the research record; or intentionally misappropriate the ideas, writings, research, or findings of others. All those engaged in research are expected to pursue the advancement of knowledge while meeting the highest standards of honesty, accuracy, and objectivity. They are also expected to demonstrate accountability for sponsors' funds and to comply with specific terms and conditions of contracts and grants.**

6. ***Records: Confidentiality/Privacy and Access***
   **The University is the custodian of many types of information, including that which is confidential, proprietary and private. Individuals who have access to such information are expected to be familiar and to comply with applicable laws, University policies, directives and agreements pertaining to access, use, protection and disclosure of such information. Computer security and privacy are also subject to law and University policy. Information on the University's principles of privacy or on specific privacy laws may be obtained from the respective units or laboratory information privacy office. The public right to information access and the individual's right to privacy are both governed by state and federal law, as well as by University policies and procedures. The legal provisions and the policies are based upon the principle that access to information concerning the conduct of the people's business is a fundamental and necessary right of every person, as is the right of individuals to privacy.**

7. ***Internal Controls***

**Internal controls are the processes employed to help ensure that the University's business is carried out in accordance with these *Standards*, University policies and procedures, applicable laws and regulations and sound business practices. They help to promote efficient operations, accurate financial reporting, protection of assets and responsible fiscal management. All members of the University community are responsible for internal controls. Each business unit or department head is specifically responsible for ensuring that internal controls are established properly documented and maintained for activities within their jurisdiction. Any individual entrusted with funds, including principal investigators, is responsible for ensuring that adequate internal controls exist over the use and accountability of such funds.**

8. ***Use of University Resources***

***University resources* may only be used for activities on behalf of the University. They may not be used for private gain or personal purposes except in limited circumstances permitted by existing policy where incidental personal use does not conflict with and is reasonable in relation to University duties (e.g. telephones). Members of the University community are expected to treat University property with care and to adhere to laws, policies and procedures for the acquisition, use, maintenance, record keeping and disposal of University property.**

9. ***Financial Reporting***

**All University accounting and financial records, tax reports, expense reports, time sheets and effort reports, and other documents including those submitted to government agencies must be accurate, clear and complete. All published financial reports will make full, fair, accurate, timely and understandable disclosures as required under generally accepted accounting principles for government entities, bond covenant agreements and other requirements. Certain individuals with responsibility for the preparation of financial statements and disclosures, or elements thereof, may be required to make attestations in support of the *Standards*.**

10. ***Physical Violence***

**Physical harm inflicted pain on students/staff in any form and constitutes a breach of rules of ethical behaviour. Consequently:**

i. **Staff and student are not expected to resolve into any physical violence or any act that inflicts physical pain or injury on the, or causes physical harm to students or staff such as pushing, pulling, hitting and/or flogging.**
ii. **Members of the university community are not expected to, intentionally or unintentionally, cause harm to any student/staff.**
iii. **Members of staff are not expected to threaten any student with the intention to put that person in fear or harm.**
iv. **Members of staff or student are not expected to assault any member of the University community.**
v. **Members of staff are not expected to subject students to or encourage other students to subject a student to torture or other cruel, inhuman or degrading**

**treatment or punishment including any cultural practice that dehumanizes or is injurious to the physical and mental well-being of the student.**

**11.** ***Psychological Violence***

- **i. No act of staff/students is expected to create a negative psychological effect on any member of the University community. Therefore, no staff in the course of his/her duty is expected to intimidate, insult, harass, threaten, snub or discriminate against any student.**
- **ii. No staff is expected to use the physical challenges of students to intimidate or ridicule them.**
- **iii. No staff is expected to use any acts or means to pester or coerce students into activities of which they do not have a clear understanding of.**
- **iv. No member of staff is expected to emotionally manipulate any student to his/her advantage.**

**12.** ***Sexual Violence***

- **i. Staff/students are not expected to do anything directly or indirectly that may constitute sexual harassment.**
- **ii. Staff/students are not expected to cause or encourage the seduction, carnal knowledge or prostitution or an indecent assault upon any member of the University community.**
- **iii. No member of staff is expected to detain any student for immoral purposes.**
- **iv. No member of staff/student should publicly or in secret, intentionally or intentionally commit any act of indecency towards any member of the University community.**

**13** ***Non-Discrimination***

- **i. No member of staff should discriminate against students on the grounds of sex, race, age, religion, disability, health status, custom, ethnic origin, background, socio-economic status or personal misunderstanding.**
- **ii. Members of staff are not expected to do anything that suggests or create the impression that a student is more favoured than the other.**

**14** ***Staff Performance Appraisal***

- **i. Every staff is expected to carry out his/her duty in accordance with the University rules and regulations.**
- **ii. Any staff member whose performance is proven through staff appraisal to be below the set standard is to be warned and given all necessary encouragement by indicating to him/her the improvement he/she is required to make within a reasonable time frame.**
- **iii. Staff members, who after two warnings of proven poor performance without improvement, may be sanctioned.**

iv. **Members of staff are not expected to forge or falsify any document or impersonate any other person with the intent of misleading the University and general public.**
v. **Members of staff are not expected, through any act of negligence, cause unacceptable loss, damage or injury, to another person.**

**15** ***Absence from Duty***

i. **Members of staff are not expected to go on leave without the permission of the HOD and approval of the University authority.**
ii. **Members of staff are not expected to be absent from duty on ground of ill-health for more than five working days without informing the head of department/unit.**
iii. **Members of staff are not expected to leave the country without a written permission to the Vice Chancellor.**

**16.** ***Protection of the Interest of the University***

i. **Members of staff are not expected to divulge privileged or classified information or document to any other person or body that is not entitled to have access to such information or document.**
ii. **It is not expected of any staff member, in the course of his/her duties, to disobey, disregard or wilfully default any lawful instructions, reasonable orders or directives given by any person or body having authority to give such lawful instructions.**
iii. **No member of staff/student is expected to engage in any act that brings the University into disrepute.**
iv. **No staff or student is expected to cause a deliberate damage to the property of the university.**
v. **No staff/student is expected to disrupt the peace and harmony of the University through blockade of roads closure of gates or obstruct free flow of traffic in and out of the University campus.**
vi. **Members of staff and students are not expected to use the name or property of the University for personal benefit or advantage.**

**17.** ***Health and Safety Rules***

i. **Members of staff and students are not expected to infringe on health and safety rules within and outside the university environment.**
ii. **Members of staff and students are expected to refer any major outbreak, infection, injury, disease or observed hazard to health to the University Health Centre promptly.**

**18.** ***Unauthorized Collection of Moneys, Fees or Levies***

i. **No staff is expected to collect unauthorized monies, fees or levies from any student or from any other person.**

**19.** ***Drinking, Drunkenness and Smoking***

i. **Members of staff and students are not expected to drink alcohol or be found drunk during official / school hours.**
ii. **Members of staff and students are not expected to smoke in the classroom during lecture hours or in any public place while on the University campus.**
iii. **No member of staff is expected to involve any student by sending him/her to purchase alcoholic beverage or cigarettes.**
iv. **No staff is expected to involve students directly or indirectly in drinking any alcoholic beverage and/or in smoking any kind of cigarette while on the University campus.**
v. **It expected of every member of staff to preserve the dignity and honour of his profession and also maintain his/her own dignity, honour and integrity.**

**20.** ***Role Modelling***

i. **Every staff is expected to serve as a role model to students showing high degree of decency in speech, mannerism, discipline, dressing and general performance of his/her roles.**

**21.** ***Misappropriation of funds***

i. **Every staff/student is expected to render proper account of public funds in his/her possession or care.**
ii. **No staff/student is expected to misappropriate public funds.**

**22.** ***Adverse Internal or External Audit Report***

i. **An Adverse Internal or External Audit Report against any staff may constitute a prima facie charge against him/her and the staff may be made to explain why disciplinary action should not be taken against him/her.**

**23.** ***Giving and Receiving Bribes***

i. **No staff/student is expected to give or demand/receive a bribe or any benefit whatsoever from any person before rendering his/her normal duties.**
ii. **Financial embarrassment impairs the efficiency of any staff and may result in disciplinary proceedings being taken against him/her.**
iii. **All cases of proven financial embarrassment are referred to the appropriate organ of the University.**

**24.** ***University Examinations***

i. **No staff acting as an invigilator or a supervisor is expected to offer assistance to students during university examinations with the intent to cheat.**
ii. **No staff is expected to leak examination questions to any student.**
iv. **No staff is expected to connive or condone collusion or copying during University examinations.**
v. **No staff is expected to indulge in or encourage any act of impersonation during any examinations.**

**25.** ***Publications***

**The misappropriation of the written work of another and its misrepresentation as one's own original work. Others are:**

**26.** ***Improprieties of Authorship***

**Members of staff are not expected to Improperly assign credit, such as excluding other authors; inclusion of Individuals as authors who have not made a definite contribution to the work published; or submission of multi-authored publications without the knowledge of all authors.**

**27.** ***Anonymous Letters***

**i. Members of staff are not expected to write or circulate anonymous letters with malicious intent.**

**28.** ***Prompt Action on Disciplinary Matters***

- **All acts of misconduct by a staff are expected to be dealt with promptly.**

**29.** ***Compliance with Applicable Laws and Regulations***

**Institutions of higher education are subject to many of the same laws and regulations as other enterprises, as well as those particular to public entities. There are also additional requirements unique to higher education. Members of the University community are expected to become familiar with the laws and regulations bearing on their areas of responsibility. Many but not all legal requirements are embodied in University policies. Failure to comply can have serious adverse consequences both for individuals and for the University, in terms of reputation, finances and the health and safety of the community. University business is to be conducted in conformance with legal requirements, including contractual commitments undertaken by individuals authorized to bind the University to such commitments.**

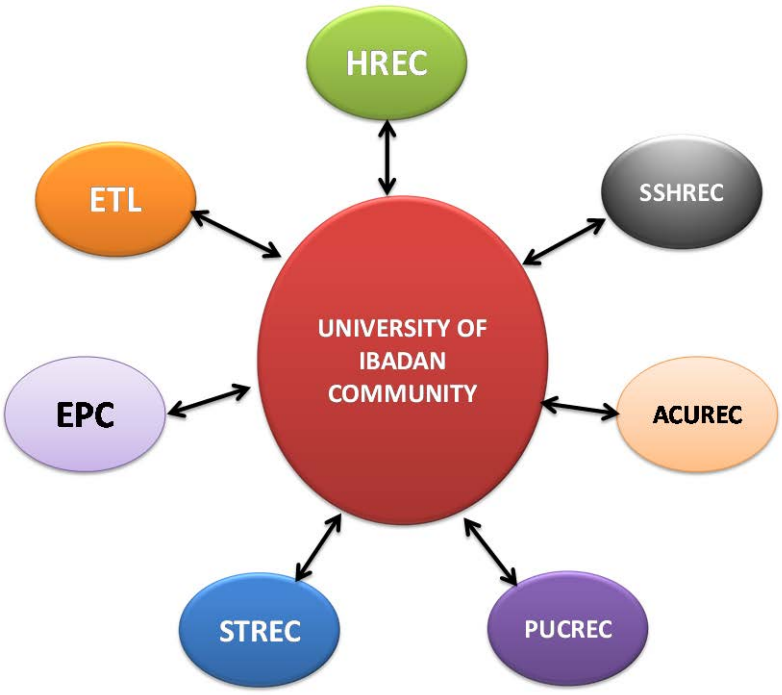
**The Legal Office has responsibility for interpretation of legal requirements.**

**30.** ***Compliance with Applicable University Policies, Procedures and Other Forms of Guidance***

**University policies and procedures are designed to inform our everyday responsibilities, to set minimum standards and to give University community members notice of expectations. Members of the University community are expected to transact all University business in conformance with policies and procedures and accordingly have an obligation to become familiar with those that bear on their areas of responsibility. Each member is expected to seek clarification on a policy or other University directive he or she finds to be unclear, outdated or at odds with University objectives. It is not acceptable to ignore or disobey policies if one is not in agreement with them, or to avoid compliance by deliberately seeking loopholes.**

**In some cases, University employees are also governed by ethical codes or standards of their professions or disciplines—some examples are attorneys, auditors, physicians and counseling staff. It is expected that those employees will comply with applicable professional standards in addition to laws and regulations.**

# RECOMMENDATIONS



## *7.1:* RECOMMENDATIONS

**In line with global standards, the University of Ibadan Ethics Directorate (UI ERRB) should be established and located under the Vice-Chancellor's Office. In addition, the following recommendations are made:**

- **The Ethics Policy should be periodically reviewed within a minimum of 3 years**
- **The University of Ibadan Ethics Policy should be made available on the University website as soon as possible.**
- **Each of the five Research Ethics Committees must register with the National Health Research Ethics Committee (NREC)**
- **Each Research Ethics Committee must develop a full Standard Operating Procedure (SOP) for its internal committee usage.**
- **The Research Ethics Committees should 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.**
- **Person appointed as Committee Chairs should be knowledgeable in ethics in the specific area(s) and possess proven leadership qualities and interest in ethics.**
- **The University should put modalities in place for training on online access towards the policy guidelines implementation.**
- **All undergraduate students of the University should be made to go through a course in Ethics under the General Studies Programme.**
- **Ethical committees should report any unethical conduct of research to the appropriate University of Ibadan authority for necessary sanctions.**
- **Faculty ethics committees to be created are to review undergraduate and other projects earmarked for expedited reviews. This will facilitate decentralisation and reduction in the time required for more complex proposals. However, such Faculty decisions should be approved or ratified by the relevant Ethics Committee.**
- **The University should construct a standard incinerator for proper carcass disposal.**
- **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.**

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

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

- **Functional contact telephone lines should be activated in the entire University.**

- **Emergency Response Guidelines books which list incident contact phone numbers and procedures should be posted in every laboratory for contacts in emergencies.**

- **In order to make T and L easier for highly subscribed courses it is recommended that class sizes are regulated to a maximum of 200 students**

- **Students should submit a proposal of their projects detailing timeline and financial implications to a facility based ethics committee.**

**7.2: POLICY IMPLEMENTATION & 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 fulfill their oversight responsibilities.**

***2.*** ***Infrastructure Development and Administration***

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

**3.** ***Capacity building including personnel and infrastructure development***

**All Ethics Committees must 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 would also encourage acceptable conduct among 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 evaluation to determine the impact of the policy on the University community. A periodic review of the document is also recommended.**

6. *Ensuring compliance with the guidelines of this 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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## 9: APPENDIX - 1

**INFORMED CONSENT FORM FOR PARTICIPATION IN RESEARCH**
**(Qualitative research by interview, focus group discussions, experiment and so on)**

**I…….. being an adult over the age of 18 years hereby consent to participate as requested in the ……for the research project on…….**

- **I have read and fully understand the information provided by the researcher (s).**
- **I have been given details of procedures for the research and risks have been explained to my understanding and satisfaction.**
- **I give consent and approval to audio/video recording of my information and participation.**
- **I am fully aware that I should keep a copy of the Information Sheet and Consent Form for future reference.**
- **I understand that:**
    - **I may not directly benefit (materially or otherwise) from taking part in this research;**
    - **I am free to pull out from the project at any time and I am free to refuse to answer particular question (s);**
    - **While the information gathered in this research will be published as discussed with me, I will not be identified, and individual or personal information will remain confidential;**
    - **Whether I participate or not, or withdraw after participating, will have no impact on any treatment or service that is being offered to me;**
    - **Whether I participate or not, or withdraw after participating, will have no effect on my progress in my course of study, or results gained; and**
    - **I could request that the recording/observation be terminated at any time, and that I may pull out at any time from the session or the research without any disadvantage whatsoever.**

- **I agree/ do not agree *to the tape/transcript* being made available to other researcher(s) who are not members of this research team, but who are assumed or adjudged by the research team to be doing related research, on condition that my identity is not revealed. **delete as appropriate****
- **I have discussed taking part in this research with a family member, colleague or friend.**

**Participant's Signature……..Date……..**

**I certify that I have explained the study to the volunteer and consider that s/he understands what it entails and freely consent to be a participant in the research.**

**Researcher's Name…….....**

**Researcher's Signature……Date…….....**
***NB: Two signed copies should be obtained. The copy retained by the researcher may then be used for authorisation of items 8 and 9, appropriately.***

- **I, the volunteer participant whose signature appears below, have read a transcript of my information and consent to its use by the researcher as discussed.**

**Participant's Signature…….....Date…….....**

- **I, the participant whose signature appears below, have read the report of the researcher(s) and agree to the publication of my information as reported.**

**Participant's Signature…….....……Date.....……**

**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:**

- **introducing the theme or subject comprehensively with adequate information concerning the purposes, methods, demands, risks, duration and inconveniences of study.**

- **noting that there is sufficient capacity for the participant to exercise a voluntary choice of participation.**
- **obtaining appropriate consent from relevant community leaders and/or recognised spokespersons.**
- **ensuring that in a situation where a participant lacks the competence to consent, a person with legitimate authority to decide for that participant is provided with that information and may exercise that choice.**
- **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 situation of the study areas.**
- **obtaining letter of introduction from appropriate authorities/institutions.**

**Consent in Research and Power Relations:**

**The relations between researchers and informants are often characterised 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 Population:**

**Informed consent to participate in research by a person with mental or physical impairment must be obtained wherever the person is of sufficient competence. Otherwise, the person's guardian or any other legitimate authority must 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 organisation 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 parent or guardian. However, the University may consider approving participation by those aged 16 and 17 years without parental consent in specific circumstances."**

**PARENTAL INFORMED CONSENT FORM FOR CHILD PARTICIPATION IN RESEARCH**

**I…….. being over the age of 18 years hereby consent for my child…….. participating, in the ……..for the research project on ……..**

- **I have read the information as contained in the document.**
- **Details of procedures and any risks have been well discussed with me.**
- **I approve the audio/video recording of my child's information and participation.**
- **I agree that I should retain a copy of the Information Sheet and Consent From for future reference.**
- **I understand that:**
    - **My child may not benefit from the research**
    - **My child is free to withdraw from the research at any time and is free to decline to answer particular questions**
    - **While the information derived from this research will be published, my child will not be identified. S/he information remain confidential.**
    - **Whether my child participates or not, or withdraws after participating, will have no effect on any treatment or service offered to him/her.**
    - **My child may request that the recording/observation be stopped at any time, and s/he may withdraw at any time from the session or the research without disadvantage.**

- **I agree/do not agree*to the tape/transcript* being made available to other researchers who are not members of this research team, but who are deemed by the research team to be carrying out related research. *delete as appropriate.**

**Participant's Signature…..Date.....**

**I certify that I have explained the study to the volunteer and consider that s/he understands what is involved and freely consents to participation.**

**Researcher's Name……..**

**Researcher's Signature…….……..Date…..……**

- **I, the participant whose signature appears below, have read a transcript of my participation and agree to its use by the researcher as explained.**

**Participant's signature…….....Date…..……**

- **I, the participant whose signature appears below, have read the researcher's report and agree to the publication of my information as reported.**

**Participant's Signature…….……Date…….....……**

**INFORMED CONSENT FOR OBSERVATION OF SOCIAL AND PROFESSIONAL ACTIVITIES**

**We/I hereby grant consent to…….....**
**a researcher/student in the Department of .....……Faculty of ……..University of Ibadan, whose signature appears below, to observe and record our/my (meeting, festival, celebration, social event, relaxation, work etc) as part of his/her study.**

**We/I give permission for the use of the data as observed and other information which we/I have agreed may be obtained or requested, in the writing up of the study, under the following conditions:**

**Our/my participation in this research is voluntary, and we/I understand that we/I could withdraw from the research at any time.**

**Signatures:**

**Participant(s)…….....Date…….....……**

**Researcher(s)…….....Date…..……**

**APPENDIX - 2**

**NUREMBERG CODE - 1947**

- **The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be**

**able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.**

- **The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.**
- **The experiment should be so designed and based on the results of animal experimentation and acknowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.**
- **The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.**
- **No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.**
- **The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.**
- **Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.**
- **The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.**
- **During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.**
- **During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.**

***Ref: Nuremberg Code of Ethics: Reprinted from*** **Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.. *Washington, D.C.: U.S. Government Printing Office, 1949.***

**APPENDIX - 3**

**THE BELMONT REPORT - 1979**

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

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

**Agency: Department of Health, Education, and Welfare.**

**Action: Notice of Report for Public Comment.**

**Summary: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behaviourals research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioural research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.**

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

**Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and**

**Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.**

**APPENDIX - 4**

**DECLARATION OF HELSINKI - 1964**

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

**It is not a legally binding instrument in international law, but instead draws its authority from the degree to which it has been codified in, or influenced, national or regional legislation and regulations (Human and Fluss 2001). Its role was described by a Brazilian forum in 2000 in these words "*Even though the Declaration of Helsinki is the responsibility of the World Medical Association, the document should be considered the property of all humanity*" (Human and Fluss 2001).**

**Principles**

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

**Basic principles**

**The fundamental principle is respect for the individual (Article 8), their right to self determination and the right to make informed decisions (Articles 20, 21 and 22) regarding participation in research, both initially and during the course of the research. The investigator's duty is solely to the patient (Articles 2, 3 and 10) or volunteer (Articles 16, 18), and while there is always a need for research (Article 6), the subject's welfare must always take precedence over the interests of science and society (Article 5), and ethical considerations must always take precedence over laws and regulations (Article 9).**

**The recognition of the increased vulnerability of individuals and groups calls for special vigilance (Article 8). It is recognised that when the research participant is incompetent, physically or mentally incapable of giving consent, or is a minor (Articles 23, 24), then allowance should be considered for surrogate consent by an individual acting in the subject's best interest. In such cases their assent should still be obtained if at all possible (Article 25).**

**Operational principles**

**Research should be based on a thorough knowledge of the scientific background (Article 11), a careful assessment of risks and benefits (Articles 16, 17), have a reasonable likelihood of benefit to the population studied (Article 19) and be conducted by suitably trained investigators (Article 15) using approved protocols, subject to independent ethical review and oversight by a properly convened committee (Article 13). The protocol should address the**

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

**Ref: Declaration of Helsinki - Current (2008) version**

**APPENDIX – 5**

**COUNCIL FOR INTERNATIONAL ORGANIZATION OF MEDICAL SCIENCES (CIOMS) – 1993**

**CIOMS serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for the ethical conduct of research, among other activities. CIOMS promulgated guidelines in 1993 entitled *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. These 15 guidelines address issues including informed consent, standards for external review, recruitment of participants, and more. The Guidelines are general instructions and principles of ethical biomedical research.**

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

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

## 10: MEMBERS OF THE ETHICS POLICY DRAFTING COMMITTEE

| | | |
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| **Adeyinka Falusi** | **IMRAT** | **Coordinator/Chairperson** |
| **S.O. Adedeji** | **Educational Management** | **Member** |
| **Edith Ajaiyeoba** | **Pharmacognosy** | **,,** |
| **B.O. Olley** | **Psychology** | **,,** |
| **Chinedum Babalola** | **Pharmaceutical Chemistry** | **,,** |
| **A.S. Jegede** | **Sociology** | **,,** |

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| **A.A Oni** | **Medical Microbiology & Parasitology** | **,,** |
| **Comfort Aiki-Raji** | **Microbiology & Parasitology** | **,,** |
| **E.A. Iyayi** | **Animal Science** | **,,** |
| **S.B. Olaleye** | **Physiology** | **“** |
| **Chuks Diji** | **Mechanical Engineering** | **,,** |
| **A. Ipeaiyeda** | **Chemistry** | **,,** |
| **V. O. Adetimirin** | **Agronomy** | **”** |
| **A. Ajuwon** | **Health Promotion & Education** | **,,** |
| **E.A Okewole** | **Veterinary Medicine** | **,,** |
| **B.O. Ehigie** | **Psychology** | **”** |

**<u>With support from:</u>**

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| **Oka Obono** | **Sociology** |
| **Eme Owoaje** | **Community Medicine** |
| **M.A. Kehinde** | **English** |
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