
# UNIVERSITY OF ILORIN
# ILORIN, NIGERIA

## RESEARCH POLICY

## APPROVED 2012
## REVISED 2024

# Foreword

This research policy was revised in 2024 to meet the changing dynamics and challenges of the 21st century scholarship. Indeed, critical issues of intellectual property, archival matters and environmental issues have been developed to become core policies by the university. This is in line with vision 1:10:500 of the current Administration.

**Professor Wahab Olasupo Egbewole, SAN**
Vice-Chancellor

# CONTENTS

# CHAPTER ONE

# 1RESEARCH SUPPORT SYSTEMS

## 1.1BACKGROUND

### 1.1.1UNIVERSITY OF ILORIN VISION AND MISSION

**Vision**

To be an international Centre of Excellence in learning, research, probity and service to humanity

**Mission**

To provide a world-class environment for learning, research and community service

**Identity Statement**

A community of scholars and technocrats who are committed to the production, collation and dissemination of knowledge for the transformation of society

**Philosophy Statement**

Promotion of probity, equity and other shared values of society

**Core Values**

Innovativeness, excellence and high ethical standards

### 1.1.2UNIVERSITY OF ILORIN RESEARCH MANDATE

The University of Ilorin Decree 1979 (Section 1 (3) (c)) and the University of Ilorin Act of 2004 (Section 1 (3) (c)) identified one of the objectives of the University in relation to research as "to encourage and promote scholarship and conduct research in all fields of learning and human endeavour." The University of Ilorin strategic plan (1st October, 2008-30th July, 2013) has the following strategies for achieving the research mandate of the University:

i. facilitating the conduct of relevant and incisive development oriented transdisciplinary research, with national and global applications;
ii. creating a conducive atmosphere for attracting external funds for research and project implementation;
iii. protecting and promoting researchers' interests; iv. encouraging staff to publish in highly-rated home-based, national and international journals;

v. ensuring that home-based outlets for publications are highly rated and become international;

vi. providing oversight to ensure quality, accountability and ethical standards in research; and



vii. developing appropriate copyrights and trademarks for the University through patenting and branding of research products.

### 1.1.3DEFINITION OF RESEARCH

Within the context of this Policy, research is defined as a methodical investigation into a subject in order to discover facts, to establish or revise a theory, or to develop a plan of action based on the facts discovered.

## 1.2STATEMENT OF NEED

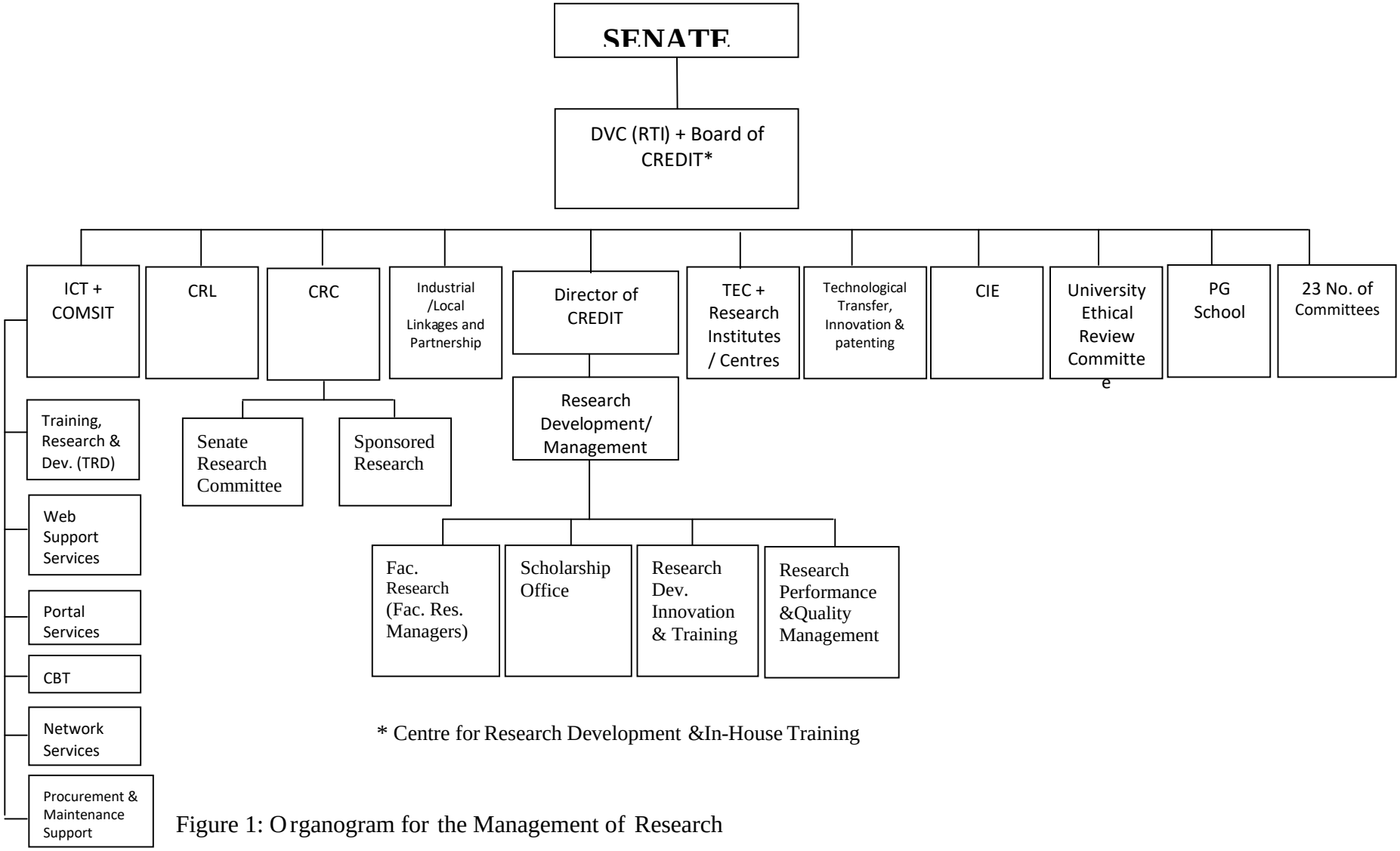
The need for a University of Ilorin Research Policy arises from a number of factors:

- requirement for a comprehensive policy on research;
- requirement for university-wide Ethical Committee for research within the University;
- evidence of government's interest in funding research;
- encouragement of the private sector to fund research;
- establishment of the Centre for Research, Development, Innovation and Training (CREDIT);
- competition for research funding from government and international agencies;
- support for the development for funding of competitive research proposals; and
- provision of institutional frameworks to support academic staff to develop and enhance their research skills, including collaborative research and publication.

## 1.3STATEMENT OF RESEARCH POLICY OBJECTIVES

The objectives of the University of Ilorin Research Policy are the following: To

- provide guidance for members of the University involved in research within and outside the University;
- encourage academic staff to conduct different types of research;
- encourage Faculties, Departments and Units in the University to develop research niche areas;
- develop and encourage multidisciplinary research culture to foster collaboration and cooperation within the University community; and
- meet the requirement for qualification for national and international funding for research.




* Centre for Research Development &In-House Training

Figure 1: Organogram for the Management of Research

## 1.4CENTRE FOR RESEARCH, DEVELOPMENT AND IN- HOUSE TRAINING (CREDIT)

### 1.4.1MANDATE

The Centre for Research, Development, and In-House Training (CREDIT) was established in 2008. It was approved by the University of Ilorin Senate at its 193rd Special Meeting of Friday, 20th June, 2008. The purpose of the Centre is to promote excellence in research, development and In-House training that will enhance optimum performance of the University's staff and students in its bid to attain a world-class status.

### 1.4.2VISION

To be a world-class centre for the promotion of research, development, innovation and training

### 1.4.3MISSION

To coordinate research, development and training activities that will enhance optimum performance of staff and students.

### 1.4.4RESEARCH OBJECTIVES OF THE CENTRE

The Centre is to:

i. Formulate new research policies and undertake periodic review of existing ones in line with international best practices and subject to the approval of the University Administration;

ii. process research project proposals submitted to the Central Research Committee (CRC) for peer review to improve their quality; iii.approve and monitor research funds from the Senate Research Grant and other available grants;

iv. source for and disseminate information on research grants and fellowships;

v. attract research grants from outside the University and outside the country;

vi. encourage the establishment of research niche areas in all Faculties in the University; vii. encourage and oversee research fairs and exhibitions;

viii. coordinate research discoveries and inventions, patenting and commercialization of research products;

ix. maintain a list of experts in the various disciplines from national and international sources and remunerate them for academic services provided to the University;

x. implement existing agreements between the University of Ilorin and other institutions of higher education or other bodies relating to research;

xi. cooperate with other national and international research centres; xii. organize research seminars and workshops for staff; and

xiii. create a database for research grant awardees to monitor individual researchers' progress according to approved timeline.

### 1.4.5 MANAGEMENT BOARD OF CREDIT

i. DVC (RTI) - Chairman

ii. DVC (Academic) - Member iii. Registrar - Member iv. Bursar - Member v. University Librarian - Member vi. Dean, Postgraduate School - Member vii. Director, CREDIT - Member viii. Director, Academic Planning Unit - Member ix. Director, CIE Member x. Director, TEC Member xi. Faculty Research Managers - Member

xii. Centre Secretary - Secretary

### 1.4.6 CENTRAL RESEARCH COMMITTEE (CRC)

This Committee is theSenate Research GrantCommittee.

a. All research proposals for the central senate grant shall be submitted, in the first instance, to the Departmental Research Committee which will recommend to the Faculty Research Committee, which also will recommend to the Director, CREDIT, who will finally refer them to the Central Research Committee.
b. Comments from the Central Research Committee shall be sent to the Director, CREDIT who shall forward them back to the initiating Principal research applicants for revision, based on the comments.
c. Principal research applicants shall send revised versions of proposals to Director, CREDIT for the consideration and approval of the CRC.
d. Applications for externally funded research shall be processed through the Director, CREDIT on behalf of the CRC to the Deputy Vice- Chancellor (RTI) for consent.

### 1.4.7 FACULTY RESEARCH MANAGER

There shall be for each Faculty a Research Manager who shall normally be a Professor principally dedicated to the coordination of research activities in the faculty under the direct supervision of the Dean. He shall report Faculty research activities to the Director of CREDIT and represent the Faculty on the Board of CREDIT.

### 1.4.8 UNIVERSITY ETHICAL REVIEW COMMITTEE (UERC)

The University of Ilorin subscribes to the National Ethics and Operational Guidelines for Research on Human Subjects and the various International guidelines and Principles on researches involving human subject such as the Nuremberg code (1947); the World Medical Association Declaration of Helsinki (1964) and its amendments, and the Council for International Organization of Medical Sciences (CIOMS) guidelines

of 1993. The University's Ethical Review Committee (UERC) is charged with the responsibility of ensuring that human subjects are handled in accordance with National and International Regulations. In addition, the UERC will develop an Ethical Handbook to provide guidelines on how human subjects should be handled.

The main function of the University Ethical Review Committee (UERC) is to review the ethics of research proposals and projects involving human and animal subjects.

**Objectives**

i. Conduct prospective and progressive review of related research protocol involving human, plant and animal subjects to evaluate the risks and benefits to the subjects;
ii. review the adequacy of the informed consent document relating to human subjects concerning the description of the risks and benefits;
iii. provide channels for receiving reports of unanticipated problems, possible non-compliance and other pieces of information and incidents that might affect the Committee's approval of the protocol;
iv. evaluate reports received from various sources for use in approving the protocol; and
v. conduct spot reviews concerning possible non-compliance, especially concerning risks to human subjects or welfare of animal subjects.

### 1.4.9INNOVATION AND PATENTING COMMITTEE

The objectives of the Innovation and Patenting Committee are as follows:

i. identify the innovations generated from research projects carried out within the University for their worth, using national and international criteria;
ii. evaluate the innovations generated from research projects carried out within the University for their intellectual property and copyright values;
iii. assist researchers in patenting and copyrighting procedures; and iv.protect the innovations, intellectual property, copyrights and trademarks of researchers in the University. (See details in Chapter 4)

### 1.4.10ADMINISTRATION OF RESEARCH GRANTS

i. For all internally- funded research projects, the University and the Principal Investigator shall sign an agreement for purposes of accountability and management of funds, following approval by the CRC;
ii. the Deputy Vice-Chancellor (RTI) shall sign on behalf of the University while the Principal Investigator will sign on behalf of the research team;
iii. For externally- funded research projects, the Principal Investigator shall sign a contract with the donor agency and the DVC (RTI) and the DLU shall sign on behalf of the University. Copies of the contract will thereafter be deposited in the office of the Vice-Chancellor and the DVC (RTI);

iv. The University of Ilorin will charge 10% of the sum of Project Award for externally-funded research. This should have been negotiated and incorporated into the budget for the project at the proposal development stage. For any funding agency with policies at variance with this, the University must be informed and an agreement obtained on this variation before the signing of the contract with the funding agency. Upon signing of a contract concerning externally-funded research project, and after funds are released to the University, the funds will be disbursed as follows: a.Research----------90%

b.University ---------- 10%;

v. Of the 10% administrative charge, 5% will be retained by the central administration and 5% by CREDIT

vi. the Principal Investigator shall submit two copies of technical reports to the Director, CREDIT and the University Library.

## 1.5EXTERNAL RESEARCH ASSESSMENT (ERA)

The overall objective of the research policy document is to ensure that University of Ilorin becomes a research intensive institution. It is against this background that the External Research Assessment (ERA) was developed.

### 1.5.1PURPOSE OF EXTERNAL RESEARCH ASSESSMENT (ERA)

1. To get an objective review of the institution by a team of international academics with expertise in research assessment. This will provide independent advice to the University on the actions to be taken in the research policy and strategic plan to improve and increase research performance.
2. ERA is conceived by the University itself, it is therefore not driven by regulatory compliance. The exercise is conceived in terms of a learning organization model and a commitment to capacity-building and institutional improvement. It can however be predicted that in the near future, research funding bodies will introduce a form of funding related assessment of research performance. Therefore, whilst ERA will contribute to the University's own research development drive, it will also be preemptive of future external requirements.
3. ERA will seek to assess progress made in terms of research intensification of the University every two years. Although the assessment will be undertaken within the context of international benchmarks, it will take into account the distinctive characteristics of research in the African milieu.
4. ERA will be an international validation of the quality and status of University of Ilorin's research performance.

The responsibility for the implementation of ERA lies with CREDIT under the guidance of the Deputy Vice-Chancellor (RTI)

## 1.6DECLARATION BY THE RESEARCHER (APPENDIX A)

Researchers in the University of Ilorin will be required to be committed to the guidelines and values contained in the University Research Policy. They will be required to sign a declaration form at the time of submitting their research proposals (see Appendix A).

# CHAPTER TWO

# 2RESEARCH PRINCIPLES

## 2.1PREAMBLE

This chapter outlines the guiding principles for research being undertaken in the University of Ilorin with respect to eligibility , responsibilities, result output, quality control and the aspects of possible conflicts in research activities.

## 2.2ELIGIBILITY AND CRITERIA

Principal actors for research investigations in the University of Ilorin are restricted to academic staff members who are holders of Ph.D. or equivalent. The Principal Investigator (PI) should be a holder of a Ph.D. and a permanent staff of the University. Co-Researchers without Ph.D., are allowed to participate in the research. Apart from the co-researchers identified within a research group, associate-researchers may be co-opted into sponsored projects, where such researchers have been identified as being useful to the research and could drive the ultimate objectives of the project to successful completion. This category may include postgraduate students, research assistants and professionals in the industry.

## 2.3GENERAL PRINCIPLES OF UNIVERSITY OF ILORIN RESEARCH FUND

University of Ilorin Research fund is usually disbursed as University of Ilorin Senate Research Grant. The Federal Government annually provides funds for the University of Ilorin to administer on various research activities. This fund is used to undertake vibrant research that can demonstrate high level of potential to leverage external research funding for the University of Ilorin.

The following principles are considered in the disbursement of Senate Research Grants. It is expected that the proposed research;

a. is strategic, basic or applied and very productive;
b. shows evidence of solving community, national, regional and/or global problems;
c. is original and has potential for novel knowledge;
d. focuses on a new research project with high level of potential that will lead to academic and research excellence;
e. is trans disciplinary;
f. encourages international/ national linkage;
g. brings development to the community; and

h. leads to excellent research publications in reputable national and international journals and/or books.

## 2.4GUIDELINES FOR THE SENATE RESEARCH GRANT DISBURSEMENT

The University research fund shall be disbursed as follows:

a. Ninety per cent (90%) as research grant and 10% for Library and Publications Committee
b. Sixty percent (60%) of the net Research Grant shall be disbursed by the CRC
c. Forty per cent (40%) of the net Research fund shall be shared as follows:
   i. 50% on equal basis by Faculties, and ii. 50% on the basis of population of academic staff within the Faculty.

### 2.4.1 OTHER CONDITIONS IN THE GUIDELINES

Other inclusions in the guidelines are that:

i. all academic staff are qualified to apply and be considered for the two categories of the research grants (Central and the Faculty grants);

ii. a reasonable amount of fund shall be given to each researcher(s) by the Faculty for him/her to come up with a meaningful research, which will be of benefit to himself/herself and the University;

iii. each Faculty research manager on the Central Research Committee shall normally be a Professor as directed by Senate;

iv. each Faculty should have a research focus which shall be determined annually and on the basis of which applications shall be invited from researchers. Few viable proposals from outside the focus may be approved if the Faculty/Library so decides;

v. after the allocation to the beneficiaries, each Faculty shall inform the CRC and the Bursary Department of the beneficiaries, the sum, the topics and the duration of the projects;

vi. the Faculty shall indicate the percentage to be released at each of the specified intervals. The formats were distributed to representatives of all the Faculties/Library for onward delivery to the Faculties; vii.the Faculty Research Grants Committee shall consider the application as well as send a written assessment report after the research;

viii. the Faculty shall design a scoring assessment for the screening of the application;

ix. a period of four weeks shall be given for submission of applications;

x. all the completed application forms for the Faculty-based Senate Research

Grant shall be returned to the Faculty Research Committee for screening; xi. the Faculty Research Committee shall forward the list of successful applicants and their application forms to the CRC, within two weeks, after the closure of the application;

xii. the subsequent allocations to any Faculty/Library who fails to make returns to the Director, CREDIT would not be released;

xiii. the final report must be submitted not later than 3 months after the completion of the research, otherwise salary of the researcher(s) will be suspended;

xiv. Faculty Research Manager shall be present to form a quorum in any Faculty Research Grants Committee meeting.

## 2.5OPENNESS IN RESEARCH

The primary responsibility of all categories of research in the University is to come up with publishable results of national and international standards. Therefore, except where stipulated otherwise in the proposal, the principle of openness in research is inherent in all proposals approved by the University. Theses and dissertations undertaken in the University of Ilorin are conducted with a drive to publishable results and openness.

Approval of grants and external funding are processed through the structures in place and announced by the University within the scope of policy-led research or policyrelevant research funding categories.

The University permits joint publications with project investigators in all categories of research with acknowledgements of the funding source(s).

## 2.6ACCESS TO RESEARCH DATA AND DATA BANKING

Research data basically include field and laboratory notebooks, questionnaires, tape recordings, specimens, samples and other records, e.g., artifacts that are necessary for the reconstruction and evaluation of the results of the research. The University guiding policy holds the Principal Investigator as having the primary responsibility for retaining the records of the research. Where a research is funded by an external agency by a contract agreement, such agreement will supersede the University's guiding policy. The Principal Investigator therefore, is responsible for the collection, management and retention of the research data. Such records will normally be retained for at least two years in the unit where results are generated.

## 2.7REPORTS AND PUBLICATIONS

It is the responsibility of the Principal investigator (PI) to design, conduct and make progress report of the research activities through the Director of CREDIT with the knowledge of the Co-Researchers and all participants in the project. As the business manager therefore, the PI control all the acquired properties for the research and reportage of the technical and invention aspects. All publications emanating from the research shall normally contain the names of all the participants.

# CHAPTER THREE

# 3MANAGEMENT OF RESEARCH GRANT

## 3.1PREAMBLE

This chapter treats how research funds are administered from the point of generation, disbursement, use and retirement. The functions of the various organs of the University responsible for each activity are clearly highlighted. As a critical aspect of research, the issue of accountability shall be given high priority by the University.

## 3.2DISBURSEMENT OF GRANTS

All grants funded by the University of Ilorin Senate Research Grant and/or external sponsors are offered in accordance with the deed of agreement between the sponsors and the University of Ilorin/Individual recipient.

### 3.2.1REQUIREMENTS FOR THE RELEASE OF FUND

The research grant recipients are required to complete a form or write a letter to the Bursar through their Heads of Departments and Deans of their Faculties. The amount requested must be retired before another new release of grant can be made. In the case of outside grants the release and retirement will depend on the agreement reached by the parties involved.

### 3.2.3PROGRESS REPORT

All successful applicants of Senate Research Grant must submit progress reports to the Senate Research Grant Committee through the Director, CREDIT as specified.

### 3.2.4FINANCIAL REPORT

All recipients are required to submit financial reports for each funded project on completion.

### 3.2.5RESEARCH GRANT VARIATION

Sometimes, the amount awarded may be insufficient to complete the project, in this case, a special request for more support may be made by the Principal Investigator of the project.

### 3.2.6FINAL REPORT

Final reports shall be submitted at the specified time and shall be submitted not later than three months after the completion.

## 3.3ROLE OF THE PRINCIPAL INVESTIGATOR IN THE RESEARCH MANAGEMENT

The Principal Investigator has overall duty for both the fiscal and technical management of any sponsored research. He has the responsibility of managing the project within funding limitations and to report the progress of the work, from time to time, to sponsor(s). The financial report and the outcome of the project must be made known to the sponsor at the specified time or when there is need to do so. He/ she is expected to effectively manage the fund of the sponsored research and must be in line with the budget approved by the sponsoring body.

On the other hand, the University requires all the Principal Investigators to review, from time to time, their expected obligations for stewardship of approved funds and must strictly comply with applicable regulations.

### 3.3.1BUDGET FOR SPONSORED PROJECTS

Accurate budgeting is expected from all the Principal Investigators. Some of the items that must be reflected in this part of the project are: i.list of specific requirements and their costs; ii.the consistency of these requirements; iii.the reliability of the costs; and iv.justification of these requirements.

### 3.3.2RESEARCH TIME EXTENSION

Sometimes, additional time may be needed to complete a project. The Principal Investigator is obliged to request for such an extension of the award. Request for extension is the prerogative of the principal investigator. He/ she is expected to initiate such an extension and process properly in accordance with the terms of the sponsored research award.

### 3.3.3OTHER RESEARCH FUNDS

Other sources of research funds include: industrial linkages, international and some national supporting agencies, international and national supporting agencies international institutional linkages and friends of the University.

### 3.3.4AWARDS AND INCENTIVES

Staff members are encouraged to attract external research funds. Appropriate incentives shall be given to such staff members.

Best Researcher Award shall be given annually to encourage deserving academic staff. There shall also be a prize for the Best Researcher of the Year at the Faculty level. The details of criteria for selection of nominees and the types of awards are as determined by the University Award Committee.

# CHAPTER FOUR

# 4. INTELLECTUAL PROPERTY

## 4.1SPONSORED RESEARCH AGREEMENTS

i. The University hereby creates the Sponsored Research Agreement (SRA) as a primary funding instrument used by the University to contract with companies or other nongrant-making entities that wish to sponsor faculty research, clinical or training projects.

   An SRA must be used in any of the following situations if:

   a. required by a sponsor;
   b. confidentiality of project results is desired;
   c. Intellectual property is likely to be created; and/or
   d. Students will be paid for work on the project.

ii. To retain maximum flexibility and achieve the desired goals of this Policy, the DVC (RTI) shall negotiate SRAs individually. The terms of such agreements shall vary, depending upon the project, the interests of the Sponsor, SRA recipient, and the University.

iii. An SRA and an intellectual property license may be negotiated simultaneously. Each of such negotiations is unique.

## 4.2DUTY TO DISCLOSE ON EXTERNAL GRANTS

i.Under the existing regulations and subsidiary legislations, the University must report all such Inventions to the funding agency and elect to file for a patent within a reasonable period of time. If the University elects not to file for a patent it must so inform the agency, which then has the right to take title. Inventors must report all Inventions to the Director of CREDIT who will notify the sponsoring agency; and ii.Creators whose works have been conducted under federal grants should be aware that the federal government retains a perpetual, non-exclusive license to all research results.

## 4.3WAIVER OF UNIVERSITY RIGHTS

The University may at any time waive its ownership rights in favour of the creator, subject to whatever terms and conditions it deems appropriate.

## 4.4 STUDENT RESEARCH AND SCHOLARSHIP

Students are subject to this Policy. A student employed by the University or works for a third party under SRA is a staff member within the meaning of this policy. Intellectual property

created by a student during such employment or course of study shall be owned by the University or by the entity so designated in the SRA.

In circumstances where a student originates intellectual property independently, using resources generally available to students, and without faculty supervision, such intellectual property is owned by the student.

Student Authors own the copyrights to their theses or essays, subject to the rights of any coauthor. Student Copyrights may be limited; however, when student manuscripts are based upon research conducted under an SRA. In those cases, the student's rights will be subject to the rights of the sponsor. Faculty has the obligation to ensure that students involved in sponsored research are aware of and understand the terms of any SRA. Acceptance of a thesis outline by a faculty member constitutes an assurance that the intellectual property created or otherwise acquired for the outlined research programme will remain reasonably available to the student for the duration of the proposed research. This assurance is granted only for the purpose of completing the proposed research and degree requirements. Thus, intellectual property agreements between the University and third parties under a grant or SRA should include such licenses as may be required to protect the interests of students and the realization of this provision.

Students are expected to maintain the confidentiality of proprietary information and trade secrets belonging to research sponsors and faculty. The University may require Students to sign and agree to be bound by confidentiality agreements, reasonable in their scope.

A Student working under an SRA violates this Policy and becomes subject to appropriate academic discipline, including termination from his or her academic programme, for the unauthorized oral, written, or electronic release of TRP to a third person not a party to the SRA. Such unauthorized release includes uploading such materials to any computer to which persons not a party to the SRA have access.

Students who believe that they may have been treated unfairly by faculty under this Policy should report such concerns to the DVC (Academic) for resolution as otherwise provided under this Policy.

## 4.5INNOVATIONS & TECHNOLOGY FORESIGHT

The University recognizes that science and technology are vital to our society as a developing economy because they cumulatively lead to wealth creation and improvement in the quality of life. As a policy, the University seeks to successfully exploit technological researches to achieve critical economic competitiveness of Nigeria in the regional and continental spheres.

The University shall adopt strategic technological development of forecasting and reliance in trend data extrapolations or applications of models to develop a unique future on the basic assumption that the future is an extension of the present.

Foresight exercises shall be conducted in specified research areas of earth sciences, the results of which shall be patented through appropriate laws and institutions in Nigeria. Regional and cross boundary studies shall be conducted with a view to making the University the Centre for Foresight in Nigeria.

The researches in foresight technology shall be linked to the industry and then the society in order to complete the cycle of research, industry and society.

# CHAPTER FIVE

## 5HUMAN SUBJECTS IN RESEARCH

### 5.1PREAMBLE

This section provides comprehensive information about the organization, scope, authority and responsibilities associated with the University of Ilorin's programme for the protection of human research subjects. In this regard the University of Ilorin subscribes to the National Ethics and Operational Guidelines for Research on Human Subjects and the various International guidelines and Principles on researches involving human subject such as the Nuremberg Code (1947); the World Medical Association Declaration of Helsinki (1964) and its amendments, and the Council for International Organization of Medical Sciences (CIOMS) guidelines of 1993. The University's Ethical Review Committee (UERC) is charged with the responsibility of ensuring that human subjects are handled in accordance with National and International Regulations. In addition the UERC will develop an Ethical Handbook to provide guidelines on how human subjects should be handled.

### 5.2HUMAN RESEARCH PROTECTION PROGRAMME (HRPP)

#### 5.2.1SUMMARY

The Human Research Protection Programme (HRPP) policy is provided in an effort to give comprehensive information about the organization and focus of the human research protection programme to the members of the research community at the University of Ilorin and affiliated organizations. The HRPP will be conducted by the Centre for Research Development and In- House Training (CREDIT) or IRB in accordance with the principles and standards of the Association for the Accreditation of Human Research Protection Programmes. All members of the University community who engage in research involving human subjects must be knowledgeable about the requirements of the HRPP.

#### 5.2.2AUTHORITY AND RESPONSIBILITY

The Director of CREDIT and Chair of the University's IRB have been given the authority and responsibility to establish, maintain, and oversee the HRPP by the Vice-Chancellor of University of Ilorin. The Director of CREDIT will have the specific responsibility and authority to oversee the HRPP, while the Chair of the IRB will have the primary administrative responsibility for the day-to-day operation of the HRPP.

#### 5.2.3PARTICIPATING ORGANIZATIONS

The HRPP applies to the human subject research done at the University of Ilorin and also at affiliate organizations for which it has an agreement to provide services related to the HRPP. The organizations covered by and participating in the HRPP are:

- University of Ilorin
- University of Ilorin Teaching Hospital

This coverage includes any subsidiary entities listed in the Federal Wide Assurance filed by these organizations.

### 5.2.4HRPP POLICIES

The Vice-Chancellor and the Senate will approve the Policies that constitute the HRPP. These policies may be modified as necessary and appropriate to incorporate changes in the law and accreditation standards and to improve the effectiveness of protection for human subjects.

### 5.2.5COMPLIANCE AND MONITORING

The IRBs acting on behalf of the five organizations covered by the HRPP will institute a continual process for reviewing and monitoring human subject research and its compliance with the HRPP.

### 5.2.6ROLE OF THE UNIVERSITY ETHICAL REVIEW COMMITTEE (UERC)

The IRBs play a primary role in the HRPP through such activities as;

- prospective and continuing review of each research protocol involving human subjects, including an evaluation of its risks and benefits to the human subjects,
- reviewing the adequacy of the informed consent document, particularly as to its description of the risks and benefits,
- receiving, evaluating and conducting reviews concerning reports of unanticipated problems, possible non-compliance, and other information and incidents that might affect its approval of the protocol or the subjects' willingness to continue to participate.

### 5.2.7REGISTRATION AND CERTIFICATION OF THE UERC

In conformity with global standards, the UERC shall ensure currency of its accreditation by appropriate National and international accrediting bodies such as the National Ethics Committee, NAFDAC and the United States Office for Human Protection Services. In addition the UERC shall maintain current Federal Wide Assurance Certification by the US Department of Health and Human Services (DHHS) regulations for the protection of human research subjects

### 5.2.8COMPOSITION OF THE EURC

i. The EURC shall be a multidisciplinary Committee, comprising 10-15 members with at least 2 members who are not directly affiliated to the University representing community difference. Membership shall be drawn from health sciences, social sciences, humanities and central administration. There should be a bio-statistician

ii. The Chair of the UERC shall be a Physician appointed by the Vice-Chancellor upon the recommendation of the Provost of the College of Health Sciences.
iii. At least 25% of the membership shall be females
iv. The **tenure** of the Technical members of the EURC shall be 2 (two) years and renewable once
v. The EURC Secretariat shall be located in CREDIT.

### 5.2.9UERC REVIEW OF HUMAN SUBJECTS PROTOCOLS IN GRANT APPLICATIONS

For applications for Senate research grant in which the study protocol involves the use of human subject, the UERC review is not required until after peer review of the proposal by the Senate Research Grant Committee and the application appears to be in the fundable range. The University will in the long run develop guidance on how institutions and PIs can determine the fundable range based on an application's priority score/percentile. This is to relieve the burden on UERC by eliminating proposals that are unlikely to be funded.

For collaborative studies, involving other institutions, both within or outside the country, the UERC's approval or that of its affiliate institution (e.g. University of Ilorin Teaching Hospital) is required without prejudice to IRB approval's obtained elsewhere.

### 5.2.10GENERAL REQUIREMENT FOR THE INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in the language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

***Basic elements of informed consent***

Except otherwise stated in an approved guideline or elsewhere in this Policy, the basic elements of an informed consent for use of human subjects shall consist of the following: Study Description, reasonable foreseeable risks, benefits, alternative

procedure or treatment, confidentiality of records, compensation and treatment for injury, contact information, voluntary participation and number of subjects to be enrolled in the study.

### 5.2.11 TRAINING CONCERNING THE HRPP

University of Ilorin and its affiliates train and require documentation of training for all investigators, research staff, students, IRB members and staff, and others engaged in human subject research about the requirements of the HRPP, Good Clinical Practice (GCP) or equivalent training from the Social Sciences. An equivalent training from internationally recognized organizations by those engaged in research using human subjects may be acceptable in lieu of the University of Ilorin organized training. Refresher training is required once in every three years.

### 5.2.12 NON-COMPLIANCE

Anyone who knows that, or has reason to believe that human research is being conducted in a manner that is not in compliance with the HRPP must report the matter promptly to the Chairman EURC, Director of CREDIT, Provost College of Health Sciences or the Vice-Chancellor. All reported matters will be reviewed in a timely manner and, when possible, will be handled confidentially. Where appropriate, sanctions will be considered and imposed. Any attempt to retaliate against a person for reporting possible non-compliance with the HRPP may itself be considered a violation of the HRPP.

### 5.2.13 SANCTIONS

Non-compliance, protocol deviations, and violations of guiding principles on HRPP may, under certain circumstances, result in administrative, civil or criminal penalties against individuals and the organizations participating in the HRPP. These penalties include action by the FDA to suspend or terminate an investigator or an organization's ability to participate in clinical trials for investigational drugs, devices, and biologics, and action by the Senate or Federal Government to suspend funding for human subject research. Employees, students, and contractors of the participating organizations who are not in compliance with the HRPP in the conduct of human subject research or related activities may be subject to disciplinary action up to and including termination of employment, contract, or other relationship with the participating organization.

### 5.2.14 INFORMATION AND REPORTING

If any member of the University community has any questions about the HRPP or wishes to make a report related to human subjects in a research protocol, the Principal investigator of the relevant research protocol, the IRB, or the Research Compliance Office should be contacted. Contacting the IRB and Research Compliance Office, may be done anonymously.

## 5.3USE OF HUMAN SUBJECTS IN STUDENT PROJECTS AND PILOT STUDIES

This section discusses the responsibilities for use of human subjects in student projects and pilot studies, and describes conditions under which Administrative Panel review and approval is needed. In this regard three types of studies are considered, due to their uniqueness, to address the investigators' responsibilities and the need to obtain prospective review and approval of the Human Subjects Panel:

i.Student Projects
ii.Pilot Studies

These studies are sometimes less formal than other kinds of projects, and there can be confusion as to when or if they should be reviewed. Problems can arise when projects are not reviewed when they should be.

### 5.3.1HUMAN SUBJECT RESEARCH

#### *5.3.1.1Student Projects*

University of Ilorin supports a wide range of both undergraduate and graduate student research projects using human subjects--from course-related research exercises to Ph.D. dissertation studies.

Generally, student research involving human subjects falls into one of two categories:

1. RESEARCH PRACTICA the goal of which is to provide research training; and
2. Directed or independent RESEARCH PROJECTS (e.g., honours or graduate theses), which employ systematic data collection with the intent to contribute to generalizable knowledge.

RESEARCH PRACTICA do not require Ethical Review. RESEARCH PROJECTS do require prospective Ethical review and approval.

Research Practicum - A course of study that involves the supervised practical application of previously studied theories of research method (based on *Webster's New Collegiate Dictionary*)

A number of departments offer courses that require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these course projects is to train students and provide them with a closer view of social, educational, or psychological processes, and an opportunity to practice various research methods. Such projects typically do not lead to generalizable knowledge and are not undertaken with that goal in mind. Therefore, the Panel does not consider them to be research and Ethical review and approval are not required.

Although the UERC does not review such class projects, it is strongly recommended that instructors become fully familiar with each student's project(s), and to discuss it with the student. Experience has shown that time spent with students discussing matters such as courtesy, and avoidance of unnecessary discomfort or invasion of privacy, will be time well spent.

#### *5.3.1.2Pilot Studies*

As the UERC interprets the concept, a PILOT STUDY is a preliminary investigation of the feasibility of a study, usually done on a small scale (usually fewer than 10 subjects) and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. At the point of academic discussions, e.g., "how could this survey question be misunderstood?," such a pilot would not contribute to generalizable knowledge and therefore is not considered research and does not require Ethical review.

However, the Panel has encountered cases in which information derived from pilot studies has been considered or used for research purposes, i.e., publication. The Panel urges investigators preparing pilot studies to weigh the likelihood that the pilot data will actually be used for research purposes. In those instances or where collection of body fluid is a component of the pilot study, Panel Ethical review and approval is required before data collection commences.

#### *5.3.1.3Other Types of Research*

Research conducted in conjunction with programme evaluations or quality assurance measures may or may not fall under the jurisdiction of the Human Subjects Panel. If such a project is conducted with the intent to develop or contribute to generalizable knowledge, it should be submitted to ERC for review.

## 5.4WOMEN AS SUBJECTS IN RESEARCH

This section presents requirements for the participation of women with child-bearing potential in research trials, including clinical trials

### 5.4.1INTRODUCTION

Historically, there have been concerns about the participation of women with childbearing potential in research trials due to potential risks of fetal harm should a woman become pregnant. Such apprehension has resulted in guidelines or policies from Federal agencies that called for special protection for women. In 1977, for example, the FDA published a guideline that excluded most women with childbearing potential from the early phases of drug trials. An exception was made for studies involving women with serious and life-threatening diseases.

Over the past decade, however, questions have been raised by professional, consumer, and governmental groups about whether clinical treatments are adequately tested in various populations that are the recipients of such therapies. In terms of drug development, the FDA began to consider information available pertaining to the safety and effectiveness of drugs for women and subpopulations such as the elderly and diverse racial groups. In 1988, the Agency issued a guideline that called for safety and efficacy profiles for these groups as part of new drug applications (NDAs). (*FDA Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications, 1988)* Then, in 1993, following broad public discussion about participation of women in clinical trials, FDA issued a new guideline that eliminated the restriction on participation of women with childbearing potential from all phases of drug trials. It detailed procedures to minimize the risks of pregnancy in women participants such as contraceptive counselling, pregnancy tests, timing of short-term studies in relation to the menstrual cycle, and the process of informed consent. The guideline underscored that while FDA remained involved in general risk/benefit determinations for subjects entering various phases of clinical trials, initial determinations about whether fetal risk is adequately addressed are properly left to patients, physicians, local IRBs, and study sponsors. The new guideline also called for gender analyses with special attention to factors affecting pharmacokinetics, e.g. the role of the menstrual cycle and exogenous hormone therapy in relation to the drug, as well as the influence of the drug on oral contraceptives.

The NIH has also examined carefully the issue of participation of women in research. It has determined that since the primary aim of biomedical and behavioural research is to provide scientific evidence leading to a change in health policy or a standard of care, it is imperative to determine if the intervention or therapy being studied affects men and women differently. As stated in its new guideline, (58 Federal Register 39406 -39416, 7/22/93 and NIH Guidelines On The Inclusion of Women and Minorities as Subjects in Clinical Research. NIH Guide, Vol. 23, No. 11, 3/18/94) the agency has concluded that the inclusion of women in research is sufficiently important that the only justifiable reason to exclude women of child-bearing potential from federally funded research is compelling evidence that the proposed project would be inappropriate with respect to the health of the subject or the purpose of the research.

The following policy statement pertains primarily to the inclusion of women as subjects in clinical trials, i.e., medical research. However, the inclusion of women in behavioural research studies is also important and must be accomplished unless

there is a compelling rationale which establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

Significant portions of the text below are presented verbatim as published in the Code of Federal Regulations and the Federal Register.

University of Ilorin endorses these changes and has adopted the following policy regarding the inclusion of women as subjects in human research as a guideline to researchers.

### 5.4.2PREGNANT WOMEN AS HUMAN RESEARCH SUBJECTS

Drug research using pregnant women as subjects is governed by federal regulations. University of Ilorin considers it prudent to apply these requirements to clinical research involving pregnant women, as follows:

"No pregnant woman may be involved as a subject in a human clinical research project unless (1) the purpose of the research is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

“Research involving the use of pregnant women as subjects” may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if (1) the purpose of the research is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or

(4) the pregnancy resulted from rape."

### 5.4.3WOMEN OF CHILDBEARING POTENTIAL AS HUMAN RESEARCH SUBJECTS

Women should not be excluded from any phase of research unless the science of the project or the health of the subject will be compromised. Regarding clinical drug research, Phase I, II, and III trials should have the proportion of women in the study which at least reflects the proportion of women in the population which will receive the drug when it is marketed, and should enrol numbers adequate to detect clinically significant sex differences in drug metabolism and response.

#### *5.4.3.1Risk to Fertility*

It is expected that experimental subjects will be informed about potential risks to their fertility including the development of any abnormalities or abnormalities in function of reproductive organs as a consequence of the proposed study intervention.

"Where abnormalities of reproductive organs or their function (spermatogenesis or ovulation) have been observed in experimental animals as a consequence of the proposed study intervention, the decision to include patients of reproductive age in a clinical study should be based on a careful risk-benefit evaluation, taking into account the nature of the abnormalities, the dosage needed to induce them, the consistency of findings in different species, the severity of the illness being treated, the potential importance of the drug, the availability of alternative treatment and the duration of therapy. Where [women] of reproductive potential are included in studies of drugs showing reproductive toxicity in animals, the clinical studies should include appropriate monitoring and/or laboratory studies to allow detection of these effects. Long-term follow-up will usually be needed to evaluate the effects of such drugs in humans."

#### *5.4.3.2Risk to Fetus and/or Infant*

**i. General Guidelines:**

"Appropriate precautions should be taken in research studies to guard against inadvertent exposure of fetuses to potentially toxic agents and to inform subjects and patients of potential risk and the need for precautions. In all cases, the informed consent document and investigator's [drug information] brochure should include all available information regarding the potential risk of fetal toxicity. If animal reproductive toxicity studies are complete, the results should be presented, with some explanation of their significance in humans. If these studies have not been completed, other pertinent information should be provided, such as general assessment of fetal toxicity in drugs with related structures or pharmacological effects. If no relevant information is available, the informed consent should explicitly note the potential for fetal risk. In general, it is expected that reproductive toxicity studies will be completed before there is large-scale exposure of women of child-bearing potential, i.e., usually by the end of phase II and before any expanded access program is implemented."

**ii. Minimizing the Possibility of Fetal Exposure:**

Pregnancy testing may be used to detect unsuspected pregnancy prior to initiation of study treatment. Timing of the start of the study to coincide with or immediately follow the onset of menses is also an adequate indication that the subject is not pregnant. The investigator should ascertain that the subjects will responsibly employ a reliable method of contraception or abstinence for the duration of the drug or treatment exposure, which may exceed the length

of the study. If requested, the investigator should be able to refer the subject to a knowledgeable counselor or physician for contraceptive advice.

**iii. Inclusion of Women in Early Clinical Trials (Phase I and early Phase II):**

"In some cases, there may be a basis for requiring [inclusion] of women in early studies. When the disease under study is serious and affects women, and especially when a promising drug for the disease is being developed and made available rapidly under FDA's accelerated approval or early access procedures, a case can be made for requiring that women [be allowed to] participate in clinical studies at an early stage. When such a drug becomes available under expanded access mechanism (for example, treatment IND or parallel track) or is marketed rapidly under subpart E procedures (because an effect of survival or irreversible morbidity has been shown in the earliest controlled trials), it is medically important that a representative sample of the entire population likely to receive the drug has been studied, including representatives of both genders. Under these circumstances, clinical protocols should not place unwarranted restrictions of the participation of women."

**iv. Risk to Infant of Nursing Mother:**

The potential for harm from exposure to a drug with unknown risks exists for nursing infants as well as fetuses. Therefore, this policy applies to breast feeding female subjects who are potential subjects in a drug trial in the same manner in which it applies to gestating women.

#### *5.4.3.3Active Recruitment of Women*

In order to assure that adequate numbers of women are included, researchers are encouraged to actively recruit women into their trials.

### 5.4.4SAMPLE INFORMED CONSENT FOR A POTENTIALLY TOXIC DRUG STUDY

The following language is recommended when women of child-bearing potential (non-pregnant) will be enrolled into a potentially toxic drug study:

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this drug study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk [or state specific risk].

To confirm to the extent medically possible that you are not pregnant, you agree [to have a pregnancy test done before beginning this research study] [to begin the study after the onset of your next menstrual period] (choose one). You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

### 5.4.5PROTOCOL RENEWAL

Investigators applying for a renewal of their research protocols are encouraged to comply with these new guidelines to the extent that the science of their project is not compromised.

## 5.5GUIDELINES FOR STUDIES INVOLVING HUMAN VOLUNTEERS RECEIVING POTENTIALLY ADDICTING DRUGS

In developing and testing new drugs with therapeutic potential it is usually necessary to conduct studies on human volunteers. This remains true for drugs, including but not limited to opiate analgesics, which are known to have significant potential for addiction in some individuals. In order to serve the goal of minimizing potential risk to human subjects, these guidelines review special features of studies involving human volunteers receiving potentially addicting drugs.

### 5.5.1INFORMED CONSENT

Human volunteer subjects who may receive drugs with significant potential for addiction (examples include but are not limited to opiates, cocaine, alcohol) in a study must be informed that the drug(s) they may (or will) receive are known to have a significant potential for addiction in some individuals. If the magnitude of the risk of addiction in relevant populations is known it should be specified.

### 5.5.2EXCLUSION OF SUBJECTS WITH A HISTORY OF ADDICTION

With some exceptions, potential volunteer subjects who have a known history of addiction should be excluded from studies of drugs with a significant potential for addiction. The informed consent should indicate that potential subjects should NOT participate in the study if they have any history of addiction to a drug or to alcohol. Subjects should be asked to check off a box on the consent form to indicate that they do not have such a history.

Furthermore, investigators may wish to incorporate a confidential pre-screening questionnaire about prior drug use history in such studies. Investigators may also

choose to perform urine drug screening of subjects. If pre-screening questionnaires or urine testing is utilized, subjects should be informed as to how the confidentiality of these data will be maintained, and to whom they may be released.

The exceptions to this exclusion policy are those protocols which require the participation of addicted patient subjects to answer a scientific question (e.g., the effect of moderate doses of alcohol on a biologic variable which might predict subsequent relapse or give insight into the etiology of the disorder.) The justification for experimental ingestion or intoxication must be included in the application.

### 5.5.3EXCLUSION OF SUBJECTS WITH DIRECT ACCESS TO THE CLASS OF ADDICTING DRUG UNDER STUDY

Potential volunteer subjects who have direct physical access to and routine handling of addicting drugs in the regular course of their work duties should be excluded from studies of drugs with a significant potential for addiction and to which the subject has access.

# CHAPTER SIX

## 6USE OF ANIMALS IN RESEARCH

### 6.1PREAMBLE

Advances in the biomedical sciences have always been attributed to combination of results of experimentation at all levels from the molecular to the clinical. Advances in molecular biology have revolutionized the experiments that can be done in sub-cellular systems and those that can be performed in test tubes. Tremendous progress has even been made by the application of cell culture techniques in *in vitro* experiments. Although these advances have changed the questions being asked in experimentation with intact organism, be it animal or human, they do not seem able to replace and do not seem able to replace *in vivo* experimentation.

### 6.2ETHICS OF ANIMAL RESEARCH

There shall be a framework within which judgments about acceptable practice must be made. The key elements of this ethical framework are that:

i. The likely benefits of the work must be weighed against the harms likely to be caused to the animals;
ii. It must be shown that there is no alternative means of achieving the purpose of the work; and
iii. pain, distress and discomfort to the animals must be minimized.

#### 6.2.1PRINCIPLES

i. Animal experiments are to be undertaken only with the purpose of advancing knowledge. Consideration should be given to the appropriateness of experimental procedures, species of animals used, and number of animals required.
ii. Only animals that are lawfully acquired shall be used in the laboratory, and their retention and use shall be in every case in compliance with federal, state and local laws and regulations, and in accordance with the Institute for Laboratory Animal Research (ILAR) Guide for Care and Use of Laboratory Animals.
iii. Animals used in research and education must receive every consideration for their comfort; they must be properly housed, fed, and their surroundings kept in a sanitary condition.
iv. The use of animals must be in accordance with the ILAR Guide for Care and Use of Laboratory Animals. Appropriate anaesthetics must be used to eliminate sensibility to pain during all surgical procedures, Drugs that produce muscle

paralysis are not anaesthetics, and they must not be used alone for surgical restraint, but may be used in conjunction with drugs known to produce adequate anaesthesia. The care and use of animals shall be such as to minimize discomfort and pain. All measures to minimize pain and distress that would not compromise experimental results may be employed.

v. If the study requires the death of an animal, the most humane euthanasia method consistent with the study must be used.
vi. When animals are used by students for their education or the advancement of science, such work shall be under the direct supervision of an experienced teacher or investigator.

## 6.3KEY PRINCIPLES FOR PROMOTING ANIMAL WELLBEING

The key principles for promoting the wellbeing of animals and the quality of scientific outcomes are *Replacement, Reduction and Refinement*, known as the **3Rs**. These principles aim to reduce the impact of scientific activities on animal wellbeing.

The 3Rs are defined as follows:

i. **Replacement**: If a viable alternative method exists that would partly or wholly replace the use of animals in a project, the Code requires investigators to use that alternative. Examples of alternative methods include in vitro techniques and computer models.
ii. **Reduction**: A project must be designed to use no more than the minimum number of animals necessary to ensure scientific and statistical validity. However, the principle of reducing the number of animals used should not be implemented at the expense of greater pain and distress for individual animals.
iii. **Refinement**: Studies must be designed to avoid or minimise both pain and distress in animals, consistent with the scientific objective. Investigators must also be competent in the procedures they perform. Project design must take into account:
    - the choice of animals, their housing;
    - management and care and their acclimatization;
    - the choice of techniques and procedures;
    - the appropriate use of sedatives, tranquillisers, analgesics and anaesthetics;
    - the choice of appropriate measures for assessing pain and distress;
    - the establishment of early intervention points and humane endpoints; adequate monitoring of the animals; and appropriate use of pilot studies.

Other key principles in addition to the 3Rs include Justification and Responsibility:

**Justification:** The University required that projects using animals to be performed only after they are justified, weighing the predicted scientific or educational value of the project against the potential effects on the wellbeing of the animals. Thus, the justification must take into account all aspects of the project that may have an adverse impact on the animals.

**Responsibility**: The University requires that investigators who use animals for scientific purposes have personal responsibility for all matters relating to the wellbeing of the animals. They have an obligation to treat the animals with respect and to consider their wellbeing as an essential factor when planning or conducting projects. To meet these responsibilities, it is essential that investigators are knowledgeable about all factors associated with the project that may affect the wellbeing of the animals they use, mechanisms to minimize these effects, the monitoring and assessment of adverse effects on animal wellbeing, and appropriate actions to take if adverse effects are observed.

## 6.4 WELLBEING, STRESS, DISTRESS AND PAIN

### 6.4.1 WELLBEING

**Animal welfare:** This encompasses the different ways in which an animal may respond to its circumstances, ranging from a positive state of wellbeing to a negative state of distress. Criteria that define wellbeing and distress provide a basis for the critical evaluation of how an animal is coping in a given situation, and hence also provide evidence that informs our judgment about their welfare.

**Animal wellbeing**: This relates to evidence of how an animal is coping with a given situation and a judgment as to how the animal feels in these circumstances. Wellbeing is an internal state involving quality of life that is affected by responses to internal and external factors. These factors may be good or bad, positive or negative. Individuals experience wellbeing differently, because of their different needs, goals, motivations and preferences.

In addition, wellbeing in one individual can vary from time to time, and changes may or may not be orderly or predictable. As a protective mechanism, departures from optimal wellbeing generally cause normal adaptive coping responses designed to return the animal to its normal state of wellbeing. Ineffective responses may result in distress, disability, disease or death.

#### *6.4.1.1 Physiological and Behavioural Indicators of Wellbeing*

Assessment of wellbeing involves using a combination of behavioural and physiological measures that indicate:

- the animals health status
- evidence of species-specific behaviours
- the status of the key indicators of the physiological and behavioural responses to a stressor

Animal behaviour is an important indicator of how an animal is interacting with its environment: changes in patterns of behaviour are often the first pointer as to how

an animal is responding to and coping with change. Animal behaviour can be assessed by observation and during interactions with the researcher or animal care provider. A number of factors can influence individual responses. Therefore, knowledge of species-specific behaviours as well as prior history is important.

Documentation of the range and level of activities such as eating, drinking, play, grooming, sleeping, resting, interactions with conspecifics and exploration of the environment can be used to describe patterns of behaviour indicative of wellbeing. Species-specific differences will be seen in the types and levels of activities. Individual responses within this framework may be modulated by prior experiences.

Indicators of an animal's state of health include general appearance, posture, coat condition, clinical signs (e.g. temperature, heart rate, respiratory rate), haematological and biochemical measurements, responses to handling, demeanour, temperament, maintenance of bodyweight or, in immature animals, rate of weight gain, and reproductive performance. Although requiring sophisticated methods, the pattern of circadian rhythms in the physiological, immunological and neuroendocrine indicators of the stress response is a sensitive indicator of physiological adaptation.

Researchers and animal carers must be familiar with species-specific indicators of wellbeing; these are the basis for assessment of evidence of pain and distress. Absence of signs of disease or abnormal behaviours, together with positive evidence of health status and behaviour, indicate that an animal is probably coping with its current situation.

### 6.4.2STRESS

Stress is the response of the animal to a stressor (external events or internal factors, including pain) and is a normal feature of life, serving important adaptive functions. The stress response consists of a combination of four general biological responses: behavioural, autonomic, neuroendocrine and immunological. The nature of this biological response varies between individuals and is influenced by factors such as previous experience, genetics, age and physiological state. Regardless of the combination of biological responses, the result is an alteration in the animal's normal biological function as it attempts to adapt to or cope with the stressor, behaviourally and/or physiologically.

In most cases, this altered biological function has a minimal effect on the animal's wellbeing; the stressor is either brief or it is eliminated, so biological function soon returns to normal. However, if the stress is not alleviated or if the stressor is large

enough, the animal is forced into a prepathological state that makes it vulnerable to pathology such as disease, abnormal behaviour, reduced growth or some other type of undesirable shift in biological function.

During this time, the animal experiences distress, and its wellbeing is threatened. The degree and context of the stressor are crucial in determining whether distress occurs. The existence of subclinical stress may not affect normal biological function, but may make the animal vulnerable to the effect of a second subclinical stress; either stressor alone would have no effect on biological function, but their accumulated biological cost could result in distress.

### 6.4.3 DISTRESS

Distress occurs when, in magnitude or duration or both, the stress response is such that significant changes in biological function must occur for the animal to survive. For example, distress in animals results when a stressor (or a number of stressors) overwhelms the animal's ability to cope with or manage a situation. Such a failure, from the animal's point of view, arises directly from its capacity for sentience and the role of feelings and emotions in that experience.

Distress is not necessarily associated with pain, although pain will cause distress. Various unpleasant experiences are often described and grouped together under the notion of suffering, including pain, distress, anxiety, fear, boredom and frustration. Suffering is the negative emotional state associated with distress; it can be due to adverse physical, physiological or psychological circumstances and is moderated by the cognitive capacity and experiences of the individual.

#### *6.4.3.1 Physiological and Behavioural Indicators of Distress*

The overall response of an animal to a stressor (which may or may not include a painful stressor) involves a variety of responses that are complex, closely integrated and complementary. The response may be modified by external or internal modifiers, such as experience, genetics, age, biological rhythms, the physiological or psychological state of the animal, the number of stressors (single or multiple) and their duration (acute or chronic), or the presence or absence of subclinical stress. The result is significant variation in responses among animals. Stress responses are broadly divided into behavioural, autonomic nervous system, neuroendocrine and immunological responses:

- Behavioural responses to a potential aversive stimulus are often the animal's first line of defense. Some responses may be as simple as a reflex withdrawal or the flight or fight response to protect the animal from injury; some convey the experience to others of the same or other species. Various species (e.g. prey species) may manifest tonic immobility (freezing), and avoidance behaviours can

result from the animal learning from its experience. The nature of the behavioural response is determined by the species of animal, the location and intensity of any pain, and the environment. Acute, intermittent and chronic pain will produce different behavioural responses. Different individuals of the same species will behave differently in response to an identical pain stimulus. The absence of behavioural abnormalities does not necessarily imply that an animal's psychological and physiological equilibrium is not disturbed.

- Autonomic nervous system responses (the flight or fight response) can have marked, albeit short-term, effects on many biological systems. The results (increased metabolic rate, oxygen consumption, respiratory rate, heart rate, blood pressure etc) enable the animal to make quick physiological adjustments in response to sudden, short-term threats. Simultaneously, anabolic processes such as digestion, growth, reproduction and immune function are depressed. Learning and memory are also improved, enabling animals to react more adequately to similar stressors on subsequent exposures.

### 6.4.4PAIN

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain tolerance varies between individuals and is influenced greatly by environmental conditions and mental state. The inability to communicate verbally does not negate the possibility that a person or animal is experiencing pain and needs appropriate pain-relieving treatment.

#### *6.4.4.1Causes of Pain*

Pain is a complex phenomenon involving the following components:

- transmission to the brain of a signal that identifies the site and intensity of a noxious stimulus
- interpretation by the brain that the noxious stimulus at that site is pain
- transmission of signals from the brain that will result in behaviours to withdraw from the noxious stimulus, promote recovery and enable social communication release of substances that will modify the response to, and experience of, pain experience of unpleasant feelings, including anxiety and fear.

Pain is caused by the detection of a noxious stimulus by the peripheral nerves, which send a signal along the sensory nerve fibres to the spinal cord, and up the spinal cord to the brain. This results in conscious awareness of pain.

Many factors moderate the experience of pain. In some instances, suppression of the signal from the noxious stimulus by the brain prevents the individual from being

totally overwhelmed by a particularly intense pain and therefore allows some form of escape behaviour.

Levels of anxiety also have a significant influence. Various chemicals released during an inflammatory response to tissue damage may expand the area of pain and increase its intensity. In addition, the inflammatory response can lead to greater sensitivity to a light touch that would not normally be painful (peripheral sensitisation). Repeated pain impulses to the spinal cord (e.g. following surgery, injury, illness or disease) may result in hyperexcitability of the nerves within the cord and a persistent state of pain (central sensitisation). Once this happens, high doses of analgesics are required to relieve the pain.

#### *6.4.4.2Physiological and behavioural indicators of pain*

The physiological and behavioural changes associated with distress will also be evident when an animal experiences pain. However, the specific neurophysiological mechanisms that enable the experience of pain, and which underpin the sensory, motor and motivational, affective components of that experience, differentiate pain from other sensory inputs that cause distress.

Consequently, animals will display a range of pain-related behaviours that are directed towards alleviating their experience of pain and promoting recovery. Painrelated behaviours vary with the circumstances and the level of injury and provide the basis for the differentiation of pain from other causes of distress and for the evaluation of the efficacy of pain management.

## 6.5EFFECTS OF ANIMAL WELLBEING ON SCIENTIFIC OUTCOMES

Good experimental design is essential, but challenging, when complex biological systems are studied. The aim is to use animals that are in a stable and defined physiological state so that the response to the variable of interest is not confounded by unwanted influences. Studies in animals where there is not a stable baseline for reference can lead to incorrect interpretation of data due to the effects of a treatment being masked or confounded. Given the complexity and range of the physiological and behavioural responses associated with stress, distress and pain, there is a high risk of these effects confounding the collection and interpretation of data.

In addition to the potential effects of specific research procedures on their wellbeing, animals can experience a range of stressors that are part of their daily living conditions and social environment. Animals may experience physiological and behavioural perturbations associated with stress, distress or pain, which are induced as part of the experimental protocol, in which case the magnitude of the effect must be minimised commensurate with

the aims of the study (humane endpoints). However, when these effects are incidental and not part of the experimental design, factors that cause such perturbations should be eliminated or controlled so as not to confound data collection and interpretation of results. Any response to stressors that results in fluctuations in physiological and behavioural measurements, however transient, may influence the reliability and interpretation of data.

If an animal's wellbeing is compromised, the consequences can include:

- greater variability in the data
- a need for increased numbers of animals
- data that cannot be reproduced
- data points that are missing
- reduced credibility of data
- data that cannot be applied to other situations
- unpublishable data

Clearly, in the design and execution of protocols, avoiding unintended effects on animal wellbeing involves much more than the selection of the appropriate anaesthetic or analgesic agent. It is in the interests of good scientific practice to maintain the wellbeing of animals used in scientific activities and to identify, control and, if possible, eliminate factors likely to cause physiological or behavioural responses associated with stress, distress or pain.

Reduced variability between animals should lead to reductions in the number of animals needed to achieve statistical significance. When stress, distress or pain are a predicted or unavoidable consequence of a research procedure, strategies to minimise or control these effects are an essential component of good experimental design. Part II of this document outlines strategies that investigators can use to maximise wellbeing and minimise pain and distress in animals, thereby reducing variability in scientific data.

## 6.6PLANNING, CONDUCTING AND REVIEWING RESEARCH PROTOCOLS

### 6.6.1PLANNING NEW RESEARCH PROTOCOLS

This section provides information to help investigators decide whether animal experiments are needed to meet the aims of a specific research project. For projects that do require the use of animals, information is provided on all stages of the research process, such as choosing the right animal to use; sourcing, transporting and housing animals; designing the experiment; predicting and minimising pain and distress; training personnel; and publishing the data.

### 6.6.2 ARE ANIMALS NEEDED TO MEET RESEARCH AIMS?

Scientists using animals in scientific procedures have an ethical and legal obligation to ensure that the principles of Reduction, Refinement and Replacement are used wherever possible. Before developing a new research protocol using animals, the investigator should consider:

- whether the use of animals is justified
- if similar projects have been performed elsewhere
- whether the same results could be obtained using tissue culture or computer modelling or other alternatives to animals.

Investigators must weigh up whether the potential benefits of the scientific knowledge gained will outweigh harm to the animal.

If animals are required for the research, the information in this section must be considered before submitting a proposal to the University's Animal Ethics Committee

### 6.6.3 CHOOSING THE RIGHT ANIMAL

It is important to choose the right animal for a proposed research protocol. Biological variability can reduce the power of a research protocol to detect treatment effects, and increase the number of animals needed to maintain an adequate level of precision. On the other hand, biological variability itself may be important to the research. The most suitable animal to achieve the required outcomes must be used, and the reasons for choosing a particular species must be clear in the proposal.

The following are issues to consider when deciding whether the animal is appropriate:

- ***Species:*** Ensure that the species is the most appropriate for the proposed research protocol.
- ***Breed, strain and genetic variability***: There can be wide variation between breeds of all species. Variability can be reduced by choosing the most appropriate animal model.
- ***Outbred strains*** are mainly used in toxicology research; however, their phenotypic variability reduces precision and increases the number of animals required.
- ***Inbred strains*** have a more uniform phenotype than outbred strains, allowing detection of smaller treatment responses and reducing the number of animals required.
- ***Health:*** Ensure that the animal is free from disease, has a health status appropriate for the research purpose, and that, if it has been sourced from another facility, the source colony is of equivalent health status.
- ***Behaviour***: Ensure that the animal is behaviourally suited to the research environment.

Investigators should select domesticated species and animals that have been habituated or accustomed to humans and the human environment.

### 6.6.4EXPERIMENTAL DESIGN

All research protocols should be well designed. However, given the ethical considerations associated with using animals in research, it is particularly important that studies using animals are well designed. The aim is to use as few animals as possible to get meaningful data, without using too few so that the study needs to be repeated or gives inconclusive results. This is the principle of Reduction, one of the 3Rs, along with Replacement and Refinement.

Studies must be designed to ensure that valid data can be obtained. A good experimental design means that the experiment should be:

- unbiased (for example, the treated and control groups have the same environment)
- precise (so that the chance of detecting treatment effects is as high as possible).

To achieve this, investigators must ensure their experimental design, objectives and hypotheses are thoroughly considered and completed before they start any research involving animals.

Before starting a research project, the experimental design must be approved by the relevant University Animal Ethics Research Committee that include the following:

- clearly stated objectives and hypotheses of the research
- in the case of animal models, an explanation of why the model was chosen
- a good understanding of relevant scientific literature (including similar studies already done and reasons why more research using animals is required)
- precise details of the study design
- precise details of the statistical methods that will be used to analyse the data.

### 6.6.5METHODS USED

Before starting the research, it is also important to make sure that the methods used are designed to ensure the animals' wellbeing. Also it is important that random (uncontrolled) variables; from biological variation of the species selected and housing conditions, are taken into consideration. Unnecessary stress and discomfort can cause increased variation, affecting the accuracy of the results.

Other variables, such as circadian rhythms, measurement errors, and the age and quality of reagents, need to be considered. Contingency plans for unexpected animal deaths during the research are essential. For example, how will they affect the final results, taking into account the sample size; how can the maximum amount of information be salvaged (eg bodyweight, age, sex)?

### 6.6.6DATA MANAGEMENT

When designing the experiment, the final stages (eg writing up the results) should be considered. The methods, data and analyses must be accessible to other investigators. This information should be presented clearly, precisely, and in enough detail to allow it to be easily understood and replicated, including:

- the experiment's objectives and hypotheses
- the animals used (e.g. species, strain, source, type, health status)
- animal transport conditions and the length of the acclimatization period before the experiment
- animal housing, dietary and water conditions
- the statistical methods used to analyse the data.

Overall, investigators must keep in mind that poorly designed studies using animals, or inappropriate statistical analysis of results, are a waste of animals, and this is unethical.

.

## 6.7THE INSTITUTIONAL ANIMAL CARE COMMITTEE

It is essential that the necessity for and the benefits of effective control in the care and use of experimental animals be recognized. Regardless of whether this control is "voluntary" or legislated, each institution has a commitment to be cognizant of the nature of all experiments involving animals in their establishments and to ensure their propriety. This responsibility is best met by an effective local ACC, reporting to the appropriate senior administrative officer of the institution. The local ACC should be responsible for formulating and implementing policy on all matters concerning the general care and use of animals as outlined below.

### 6.7.1TERMS OF REFERENCE FOR UNIVERSITY ANIMAL CARE COMMITTEES (UACC)

**i. Membership**

The UACC should comprise between 15-20 members. The complements should include:

a. Scientists and/or teachers experienced in animal care and use, who may or may not be actively using animals during their term on the ACC; there should be a minimum of two such members, and representation of all the major animal-using divisions of the institution must be ensured;
b. A veterinarian, normally experienced in experimental animal care and use;
c. An institutional member whose normal activities, past or present, do not depend on or involve animal use for research, teaching or testing;
d. At least one, and preferably two or more, person(s) representing the University;

e. Technical staff representation (either an animal care, an animal facility or an animal research technician) actively involved in animal care and/or use within the institution;
f. Student representation (graduate and/or undergraduate), in the case of institutions that have programmes where students use animals; and
g. The ACC coordinator (the institutional employee who provides support to the ACC).
h. The UACC Chair shall be appointed by the Vice Chancellor upon the recommendation of the Director CREDIT
i. Provision should be made to co-opt other persons to the ACC as the need arises. A reasonable quorum, such as a majority of the members, should be established for ACC meetings, and the quorum should include community and veterinary representation. Meetings should be scheduled at times that are convenient for all members, including community representatives.

**ii. Tenure of members:**

The Tenure for the members shall be for a term of two years, renewable once to make a maximum of 4 consecutive years. This does not apply to ACC members who must be part of the ACC because of their role within the institution (ex officio members): the ACC Coordinator, the veterinarian(s) and the animal facility manager.

**iii. Authority**

The UACC will have the authority, on behalf of the Vice Chancellor or Director CREDIT to:

**a.** Stop any objectionable procedure if it considers that unnecessary distress or pain is being experienced by an animal;

**b.** Stop immediately any use of animals which deviates from the approved use, any non-proved procedure, or any procedure causing unforeseen pain or distress to animals; and

**c.** Have an animal killed humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated. The Chair of the ACC and the veterinarian(s) must have access at all times to all areas where animals are or may be held or used.

**d.** Establish procedures for post-approval monitoring of animal use protocols, and define the roles and responsibilities of the members of the animal care and use programme in the monitoring process.

**e.** Delegate to the veterinarian(s) the authority to treat, remove from a study or euthanize, if necessary, an animal according to the veterinarian's professional judgment. The veterinarian must attempt

to contact the animal user whose animal is in poor condition before beginning any treatment that has not previously been agreed upon, and must also attempt to contact the ACC Chair, but the veterinarian must have the authority to proceed with any necessary emergency measures, whether or not the animal user and ACC Chair are available. A written report should be sent by the veterinarian to the animal user and to the ACC following any such event.

**iv. Responsibility**

It is the responsibility of the ACC to:

**a.** Ensure that no research or testing project or teaching programme (including field studies) involving animals be commenced without prior ACC approval of a written use protocol; further to this, that no aenimals be acquired or used before such approval. This includes internally funded projects;

**b.** Ensure that no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written animal use protocol, except where current guidelines provide for exemptions. The ACC should also be aware of other animal-based activities, such as commercial or recreational activities, within the institution, and should work with the persons responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures;

**c.** Require all animal users to complete an animal use protocol form and ensure that the information therein includes the following points, clearly presented in a form that all members of the ACC can readily understand. To facilitate the work of both protocol authors and ACC members, appropriate SOPs should be referred to as much as possible;

**d.** Ensure that approved protocols and SOPs should be readily available in the areas where animal-based work is taking place.

**e.** Ensure that each research project has been found to have scientific merit through independent peer review before approving the project;

**f.** Review and assess all animal use protocols, with particular emphasis on the University Research Policy statement on: ethics of animal investigation

**g.** Ensure that animal users update their protocols with any modifications they intend to make, and approve any modifications to a protocol before they are implemented. Minor modifications (e.g., 1 or 2 animal users added or removed, a small number of animals

added, etc.), as defined by the UACC, can be approved by the Chair of the ACC or a delegate.

For any major changes to a protocol, it requires that a new one be submitted. ACCs should define, in writing, their own criteria as to what constitutes a major change to a protocol (e.g., a considerable increase of the number of animals required vs. the number in the original protocol, a change of species, use of more invasive or more frequent procedures, use of entirely new procedures, or other criteria). Ensure that animal users report any unanticipated problems or complications, as well as on the steps they have taken to address the problem(s), to the ACC;

**h.** Review all protocols annually, i.e., within a year of commencement of the project; annual renewals should be approved by at least a scientist, a veterinarian and a community representative and should be brought to the attention of the full UACC for its information.

**i.** Document all ACC discussions and decisions in the committee minutes and on attachments to the protocol forms;

**j.** Define an appeal mechanism that can be used by the author of a protocol in the event that animal use is not approved by the UACC. This mechanism should include appropriate expertise and ensure a separate, fair and impartial process. The National Ethics Committee may be called upon for information purposes; however, appeals cannot be directed to the National Committee;

**k.** Ensure that all UACC members and animal users have the opportunity to become familiar with the National/ University Guide and policy statement on: ethics of animal investigation and all other guidelines and policy statements that may apply;

**l.** Ensure appropriate care of animals in all stages of their life and in all experimental situations. Veterinary care must be available. Formal arrangements must be made to obtain the services of a veterinarian, at least on a consultative basis, if they are not readily available within the institution. These formal arrangements must be based on the elements contained in the Standards of Veterinary Care of the Laboratory Animal Medicine (2004), which define the roles and responsibilities of veterinarians involved in scientific animal care and use programmes;

**m.** Establish procedures, commensurate with current veterinary standards, to ensure that:

1. unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;
2. anesthesia and analgesia are properly and effectively used; the only exception to this may be when agents must be withheld as a scientifically justified requirement of the study, and that this has been approved by the ACC. Painful studies requiring exemption from the use of either anesthetics or analgesia must be subject to particular scrutiny, not only prior to approval, but also during the experiment;
3. appropriate post-operative care is provided;
4. all due consideration is given to animal welfare, including environmental enrichment;

n. Ensure that policies to provide for a system of animal care that will meet the needs of the institution are established and implemented.
o. Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not; and
p. In the case of projects involving proprietary or patentable research or testing, ensure that as much information as possible is provided to the UACC in terms of what effects to expect on animal health and welfare.

**v. Meetings**

The UACC shall meet at least twice in a year and as often as necessary to fulfil their Terms of Reference.

# CHAPTER SEVEN

## 7 SAFETY IN RESEARCH

### 7.1PREAMBLE

Environmental Health and Safety matters at the University of Ilorin shall be a shared responsibility of the Environmental Protection Committee (EPC) and the Centre for Research, Development and In-House Training (CREDIT). They will set emergency procedures, deal with specific requirements to ensure bio-safety and the prevention of chemical and radiological hazards, as well as noise and environmental pollution.

### 7.2PRINCIPLES, RESPONSIBILITIES AND PRACTICES

#### 7.2.1PRINCIPLES*:*

The University of Ilorin will ensure the:

i. protection of the health and safety of members of staff and students;
ii. provision of safe research, academic and administrative workplaces for staff and students;
iii. provision of information about health and safety hazards to the University community;
iv. identification of health and safety hazards and their correction;

#### 7.2.2RESPONSIBILITIES:

Good health and safety practices are a responsibility of every member of the University community. Supervisory authority shall lie with Project Supervisors, Heads of Departments and Directors of Research Units, Deans of Faculties, Environmental Protection Committee, CREDIT and the Deputy Vice-Chancellors. Final responsibility for health and safety policy and programmes rests with the Vice-Chancellor.

i. ENVIRONMENTAL PROTECTION COMMITTEE (EPC) shall be responsible for recommending University-wide health and safety policies related to man and the University environment. EPC will ensure overall institutional compliance with relevant policies, statutes and regulations; provide central health and safety services to all areas of the University; and monitor the effectiveness of the safety programmes.

ii. DIRECTOR, CREDIT shall be responsible for:
   a. reviewing legislation, recommending policies and monitoring compliance with environmental health and safety statutes and regulations related to research activities in the University;

b. providing guidance and technical assistance in identifying, evaluating and correcting health and safety hazards in the University;
c. recommending procedures for the safe use of hazardous substances e.g. chemical, biological and radiological substances; and
d. providing training in safe and healthy workplace practices.

iii. HEADS OF DEPARTMENTS AND DIRECTORS OF RESEARCH UNITS shall be responsible for ensuring that:
a. individuals under their management implement appropriate health and safety policies, practices and programmes of the University; and
b. areas under their management have adequate safety equipment and are in compliance with University health and safety regulations.

iv.PROJECT SUPERVISORS are responsible for protecting the health and safety of employees and students under their supervision by ensuring that workplaces and equipment are safe and well maintained and that they comply with University health and safety policies.

v. EMPLOYEES AND STUDENTS are responsible for:
a. keeping themselves informed of conditions affecting their health and safety;
b. participating in training programmes recommended by their superiors or supervisors;
c. adhering to healthy and safe practices in their workplace, classroom, laboratory and campus residences; and
d. reporting hazards in the workplace, classroom or laboratory and campus residence to their superiors, supervisors or appropriate quarters.

### 7.2.3PRACTICES:

i. PROVIDING A SAFE WORKPLACE: This will be accomplished through:
a. Facility Design: The Physical Planning Unit shall ensure that facilities are designed in a manner consistent with health and safety regulations and standards of good design.
b. Ensuring the safety of the University community within the vicinity of construction sites;
c. Finding and Correcting Workplace Hazards: Periodic inspection of workplaces to identify and evaluate workplace hazards and unsafe work practices shall be done by responsible officers. The frequency of inspection shall depend on the magnitude of potential risk in the particular workplace. Inspections will be mandatory whenever new substances, processes, procedures or equipment presenting new health and safety hazards are introduced into the

workplace. Unsafe conditions which cannot be corrected by the responsible officer must be reported to the next higher level of management;

d. Shutting Down of Dangerous Activities: The University shall curtail or shut down any activity considered to constitute a clear danger to health or safety; and
e. Providing Medical Surveillance: Evaluation and monitoring, through a programme of medical surveillance, of the health of University of Ilorin members of staff and students exposed to certain hazardous materials and situations as defined by convention shall be done.

ii. EMERGENCY RESPONSE AND PREPAREDNESS: The Centre for Research, Development and In-house Training (CREDIT) shall provide guidelines for emergency response plans. Every building shall have individual emergency response plans to include evacuation and assembly procedures, posted evacuation maps, reporting and communication lines, training and drills. Exits shall remain free of obstructions and materials that could render the exit hazardous.

iii. COMMUNICATION AND TRAINING: Members of staff and students who may come in contact with hazardous substances or practices either in the workplace or in the laboratory shall be provided information concerning the particular potential hazards, and the methods to deal with such hazards in a manner that is safe and healthful. In areas where hazardous chemicals are used, handled or stored, communication about these hazards shall be displayed. Training shall be provided for responsible officers in the safety and health hazards to which employees and students under their direction and control may be exposed. They shall, in turn, train employees and students in the recognition and assessment of health and safety risks; and how to minimize risks through sound safety practices and the use of protective equipment.

iv. DOCUMENTATION AND RECORD KEEPING: To show compliance with statutes, regulations and standards, records and documentation shall be kept including:

a. Records of training showing who was trained, who provided the training, what the training covered, where and when the training took place;
b. Records of workplace inspection and hazard correction showing who conducted the inspection, the date, any unsafe conditions or practices found and the corrective measures taken; and
c. Records of disciplinary action taken for failure to comply with health and safety policies.

## 7.3CHEMICAL HAZARDS

The Centre for Research, Development and In-House Training (CREDIT) shall work with academic departments to develop local programmes for the safe use of chemicals, to include:

i.control of exposures to hazardous chemicals in laboratories; ii.information dissemination and training of employees and students on chemical hazards when they start work, when their work change or when a new hazard is introduced into the laboratory;

iii. a programme of medical surveillance for members of staff and students who are exposed to certain hazardous chemicals, as defined by convention; and
iv. chemical waste management reference guide and laboratory clean-out guidelines for chemical reagents.

## 7.4RADIOLOGICAL HAZARDS

i.The Centre for Research, Development and In-House Training (CREDIT) shall be responsible for the registration of all machines which produce ionizing radiations for which national registration is required. They are also to authorize the possession and use of radioisotopes under a radioactive materials license from the Ministry of Science and Technology or any other relevant government agency. ii.CREDIT shall review and approve uses of radioactive materials and radiationproducing machines, and is to recommend radiation policies to the ViceChancellor.

iii. All regulated radiation activities at the University of Ilorin will be open to inspection by CREDIT to enable the monitoring of compliance with regulations, license conditions and policies related to the utilization of radiation.
iv. Concerned research units are to maintain personnel dose measurement devices and records of radiation exposures to users, keep account of the use of machines and materials, provide for the inspection of new shipments of radiation sources and safe disposal of materials and devices, and train personnel on radiation safety. The units will also provide advice and safety support to staff utilizing lasers, ultraviolet light, radio-wave and microwave sources.

## 7.5POLICY ON IONIZING RADIATION

### 7.5.1DEFINITIONS:

Ionizing Radiation: (IR) Ionizing Radiation is a form of radiation that has sufficient energy to cause ionization of matter. Examples of Ionizing Radiation include x-rays, gamma rays, alpha particles, beta particles, and neutrons. Exposure of biological

tissues to this ionizing radiation in sufficient energy can result in damage to either the cells or the DNA.

The purpose of this document is to lay down the policy of University of Ilorin to ensure the safety of staff, students and visitors who might be exposed to sources of ionizing radiation. This policy seeks to explain how the Ionizing Radiation is being managed within the University.

University of Ilorin is committed through protocols contained in this policy to maintain an environment where all statutory duties relating to Ionizing Radiation are guided by best practices to ensure that radiation to classified personnel are as low as reasonably practicable.

Staff, students, visitors and contractors of the University are required to comply with all aspects of the policy as relevant and appropriate.

### 7.5.2POLICY

University of Ilorin seeks to ensure the well-being of staff, students and visitors is protected from the potentially harmful effects of Ionizing Radiation. Procedures performed on the University campuses involving the use of Ionizing Radiation must comply with the prevailing Ionizing Radiation regulations of Nigeria as contained in the Federal Republic of Nigeria Gazette No 123 Vol. 90 and enforced by Nigerian Nuclear Regulatory Authority (NNRA). These regulations require that the University should establish a suitable management structure for the purpose of maintaining radiation safety by establishing the following:

i. Radiation Safety Committee headed by the Chief Executive who is the ViceChancellor as the license holder.
ii. The Vice-Chancellor may wish to nominate an officer who is a member of the standing Radiation Safety Committee as Chairman in his place.
iii. Radiation Safety Supervisor iv. Radiation Safety Officer (s)
v.University local rules to enable it perform its statutory obligation concerning radiation protection.

Possession and disposal of Ionizing Radiation material is controlled by Nuclear Safety & Radiation Protection Act 1995, Nigeria Basic Ionizing Radiation 2003 and all related activities performed at University of Ilorin must comply with this Act.

All exposure involving the use of medical X-rays shall comply with Nigerian Basic Ionizing Radiation Act 2003 implemented and enforced by Nigerian Nuclear Regulatory Authority. The University of Ilorin Ethical Advisory Committee shall scrutinize risk assessment and make judgments on exposures (medical exposures) in this category. The University of Ilorin through the Radiation Safety Committee shall regulate:

a. Use of electrical equipment to produce X-rays for the purpose of research and radiography.
b. Use of accelerators (except electron microscope).
c. Use radioactive sources and nuclear materials.

At the University of Ilorin, justification for use of Ionizing Radiation shall be based on prior Risk Assessment made on a procedure and balanced against the need for academic freedom and shall be jointly monitored by the University Ethical Advisory Committee and University Radiation Safety Committee. At all times the University Policy shall optimize practices to make ionizing radiation as low as practicable.

The appropriate legislation relevant to this subject are:

1. Nigerian Safety and Radiation Protection Act 1995
2. Nigerian Nuclear Regulatory Authority Act 2001
3. Nigerian Basic Ionizing Radiation Regulations (NIBIRR) 2003

## 7.5.3PROCEDURES / GUIDANCE

### *7.5.3.1Responsibilities of the Radiation Safety Committee*

Implementation of the University policy on Ionizing Radiation and The Local Rules of the University. The Radiation Safety Committee shall be satisfied that all relevant staff within the University are aware of the University requirements. The University must nominate a suitably qualified and trained member of Faculty staff to manage radiation safety on a daily basis (Radiation Protection Officer).

### *7.5.3.2Radiation Protection Advisor*

University of Ilorin shall appoint a Radiation Protection Advisor (RPA)under the terms of the Ionizing Radiations Regulations. The RPA, who is an external consultant, shall advise the University on all aspects of the use of ionizing radiations and radioactive substances relating to the health and safety of workers, including the designation of workers and the classification of controlled areas.

### *7.5.3.3Radiation Protection Officer*

The Radiation Protection Officer is a member of University staff, and shall be a member of the Radiation Safety Committee; is responsible for the overall management of ionizing radiation health and safety. The officer shall perform routine work of the Radiological Safety Committee and shall be present at its meetings. The officer shall be responsible for liaison with related external bodies such as NNRA, Federal Environmental Protection Agency (FEPA).

#### *7.5.3.4Radiation Safety Committee*

The Radiation Safety Committee shall be a standing Committee of University of Ilorin established to provide specialist advice on health and safety matters in the radiological field to ensure compliance with legislative requirements.Terms of reference of the Radiation Safety Committee are outlined inAppendix C

#### *7.5.3.5Radiation Protection Supervisors*

Faculties in the University of Ilorin whose staff are engaged in work involving the use of Ionizing Radiation are expected to nominate a Radiation Protection Supervisor to manage radiation safety within the faculty. Persons appointed to the role of RPS should be sufficiently competent through experience and/or qualification to carry out the role. Radiation Protection Supervisors will be appointed in writing by the Registrar and attend the meetings of the Radiological Safety Committee.

The duties and responsibilities of Radiation Safety Supervisors are outlined in Appendix D

#### *7.5.3.6Appointed Doctor*

The University will appoint a suitably qualified medical doctor as an "Appointed Doctor" under the requirements of The Ionizing Radiations Regulation 1999. The NNRA will be notified of the appointment.

## 7.6BIOLOGICAL HAZARDS

The use of hazardous biological agents in Research or Instruction at the University of Ilorin shall be governed by the following policies and procedures:

### 7.6.1SCOPE:

The bio-safety policy shall apply to research projects and teaching programmes in the University which employ:

i.recombinant DNA which may be hazardous to humans or other life forms; ii.potentially oncogenic biological materials; iii.infectious biological materials; iv.human and simian cell cultures and body fluids; v.biological toxins and venoms; and vi.transgenic materials which may be hazardous to humans, animals and plants.

### 7.6.2 PROCEDURES:

i. All research involving biological materials listed under 5.4a. should be registered with CREDIT after approval by Faculty Research and Ethics Committee;
ii. When activities involving genetically modified organisms (GMOs) become relevant, they will be done in confined areas such as a laboratory, plant or animal facility or production plant approved for the purpose based on the bio-safety level required for the particular genetically modified organism; and

iii. All deliberate releases into the environment of genetically modified plants and/or micro-organisms for agricultural purposes shall be consequent on approval by the national competent authority.

# CHAPTER EIGHT

## 8RESEARCH SUPPORT AND CAPACITY DEVELOPMENT

The University shall, as much as it is practicable, sponsor research adjudged feasible and innovative by Committees and bodies charged with the responsibility. A policy of open competition for funding of research shall be promoted to boost opportunities for collaborative research. Fresh and stale academic staff shall be encouraged to be familiar with the current issues of research in their field of specialization and adopt a progressive growth pattern.

It shall be the objective of research units and groups to plan capacity building for young academics in various research activities. The Faculties, Departments and other research units shall make concerted efforts to equip academics to attract internal and external funding for their research. In connection with this, a list of funding agencies and their proposal submission deadlines shall be updated and brought to the notice of staff members while procedures for internal review of proposals shall be instituted.

Grants attracted shall be acknowledged and procedures for ensuring delivery specified in this policy shall be strictly implemented. Funds shall be provided for academic staff to plan and execute specific workshops, seminars, trainings and meetings for the dissemination of research results. Academic staff of the university shall be required to make an annual submission on current state of knowledge in their area of research interest and their contributions to discourse in their field.

Visiting scholars will not only be welcomed from other institutions across the globe, the university shall sponsor its academic staff as Visiting scholars to other institutions to engage in research, obtain data to further their research or share knowledge.

The University shall canvass for sponsors that will endow chairs in specific areas of interest to the University. The procedures for occupying such chairs shall be stipulated by the University.

# CHAPTER NINE

## 9PRODUCT DEVELOPMENT FROM RESEARCH OUTPUT

### 9.1TRANSLATING RESEARCH FINDINGS INTO PRODUCTS

CREDIT shall translate research findings into usable products that can solve societal problems and generate growth and development opportunities.

#### 9.1.1TRANSLATIONAL OBJECTIVES

CREDIT shall seek to achieve this product development mandate through the following:

i. Formulation of policies and procedures for engaging with the local community and the society in general by;
   a. establishing a Central Collaboration Committee;
   b. establishing a Unit under CREDIT for Research Extension Services;
   c. signing and executing Memoranda of Understanding with Research Centres within and outside Nigeria; and
   d. organizing joint conferences with other establishments and other countries through Departments, Faculties, etc.

ii. Encouragement of individual staff, departments, units, centres, faculties and College to develop and implement strategies for community engagement;

iii. Keeping of records and information on all relationships established between members of the university community and the host and larger societies.

iv. Engaging students to apply knowledge and research in solving societal problems through:

   a. interacting with schools, industries, and other establishments in their host communities and beyond;
   b. focusing research activities on problems in the host community; and
   c. applying research outcomes to solve the problems of the community;

v. Partnering with others within the education sub-sector to enhance the quality of education nationally and globally by;
   a. establishing official relationships for research purposes;
   b. encouraging the host community to fund research activities; and
   c. participating in community activities through its research and education;

vi. Disseminating information on the University's community engagement activities to the local community;

vii. Mounting relevant short courses to the community based on identified needs and supporting identified economic opportunities;

viii. Involving qualified experts in the host community in reviewing research proposals;
   a. inviting relevant neighbouring research centres and Institutes to its annual research review sessions;
   b. Engaging experts in indigenous knowledge in the creation and expansion of the frontiers of knowledge.

ix. Extending the use of the University facilities (where possible) to the local community in support of community and socio-economic development activities.

The University is at liberty to review this policy.

# APPENDIX

## APPENDIX A

### DECLARATION BY THE RESEARCHER

I,……UIL/PF/SSE/……
…,

Phone No……, e-mail address ……., of the Department of ……., Faculty of ……, declare that I have read the University of Ilorin Research Policy and understood its content and meaning. I hereby undertake to abide by it.

……

Name of Researcher Signature Date

……

Name of Head of Department Signature Date

……

Name of Dean of Faculty Signature Date

……

Name of Director, CREDIT Signature Date

## APPENDIX B
## MANAGEMENT GUIDANCE

The following University Guidance forms part of the management policy for sources of IR:

- **Radioactive material or instruments capable of generating ionizing radiation must not be brought to the University campus without the prior approval of the RPO.**
- **Radioactive material must not be purchased without the written authorization of the RPO.**
- **The University Local Rules for the Protection of Persons Exposed to Ionizing Radiation must be adhered to and shall be enforced at all times.**

- Justification for the use of radioactive material must show an overall benefit.
- Risk assessments for the use of an ionizing radiation must be prepared and made by a competent person. It shall be suitable and sufficient and reviewed as necessary and recorded.
- Occupational exposures to IR must be kept as low as reasonably practicable (ALARP) and must be within the statutory limits.
- Any staff engaged in work involving the use of Ionizing radiation must be 18 years and above.
- Before commencement of work with IR every worker must fill a radiation worker form and undergo suitable training.
- A female worker of reproductive capacity must consider the possible hazard arising from IR to the foetus in early pregnancy and inform the RPO as soon as pregnancy is suspected or confirmed.
- Controlled and Supervised areas will be designated by the Radiation Safety Committee for areas where sealed and unsealed sources and X-rays will be used.
- Appropriate operational safety measures such as administrative controls must be implemented as appropriate.
- Appropriate personal protective equipment must be worn where control of exposure cannot be achieved by any other means.

## APPENDIX C
## MEMBERSHIP AND TERMS OF REFERENCE OF THE RADIATION SAFETY COMMITTEE

The members of the committee shall consist of:

- The Radiation Protection Officer
- Faculty Radiation Protection Supervisors who shall be members of staff in Faculties working with ionizing radiations, nominated by their Deans and appointed by the Vice-Chancellor.
- The Appointed Doctor or his/her representative.
- The University Director of Health Services or his / her representative.
- The Director of Works or his/her representative.
- A Secretary who shall be a member of the administrative staff of the University
- The Chairman of the committee shall be appointed by the Vice-Chancellor quadriennially or on the resignation of the Chairman.

**Terms of Reference**

- The Radiation Safety Committee shall monitor health aspects and control of ionizing radiation and radioactive materials within the University.
- The Committee shall be responsible for establishing protocols and procedures for the management of radioactive materials and wastes under the terms of the University's Authorization from the Federal Ministry of Environment.
- It shall be responsible for drafting local rules for approval by University Administration and for ensuring that these regulations are enforced.
- The Committee shall report its yearly activities through the Radiation Protection Officer to the University.

## APPENDIX D

## DUTIES OF RADIATION PROTECTION SUPERVISORS

The Faculty Radiation Protection Supervisors will be responsible, in close collaboration with the Radiation Protection Officer, for day-to-day matters of safety and close supervision of radiation work within their own faculties. These include:

- Keeping a weekly register of all sealed radioactive sources that are permanently in the Faculty together with a record of periodic leakage tests, which must be carried out at regular intervals not exceeding 24 months. Records relating to the whereabouts of each sealed source must be kept up-to-date regularly and on a daily basis.
- Keeping an up-to-date register of unsealed sources, their usage and ultimate disposal when no longer needed.
- Sending at intervals of not more than three months, a copy of the current sealed source records as contained in the register(s); and at intervals of not more than 1 month a copy of the unsealed source registers and waste disposal records shall be sent to the Radiation Protection Officer.
- Conduct and record regular surveys for contamination where unsealed radioactive materials have been used.
- To conduct and record regular leakage surveys on equipment emitting ionizing radiations at intervals of not less than 6 months.
- In consultation with the Radiation Protection Officer, carry out duties relating to the registration of radiation workers, administration of Thermo Luminescent Dosimeter (TLD) or film badges as well as notification of termination of work, together with other general measures controlling safety as laid down in the Local Rules. In Exceptional circumstances, and in order to ensure the necessary close supervision, it may be necessary to appoint more than one Radiation Protection Supervisor within a Faculty.
- To ensuring that suitable risk assessments are carried out on all new work involving the use of Ionizing radiation.

For Enquiries contact:
Director Centre for Research Development and In-House Training University of Ilorin, Ilorin
www.unilorin.edu.ng
dcredit@unilorin.edu.ng