# BINGHAM UNIVERSITY KARU, NIGERIA



# RESEARCH POLICY 2019

#### Foreword

Bingham University was founded to meet the needs for high quality secular education which recognises and integrates the moral and spiritual values from the Christian faith. These as well as focus on entrepreneurship, in order to promote self-reliance among graduates of the University. But, the socio-economic needs can only be met through knowledge-based economy largely driven by research and innovation.

For these reason, the founding father envision a world class University, driven in knowledge and skills. Promoting and enhancing the much needed God-fearing manpower for the country and the world in other to ensure societal and national development. Therefore, its core values are to ensure accountability, commitment, maintain team work, speaking truthfully, ensuring mutual care, visionary, innovative and creative, due process and mentoring the next generation of leaders through effective communication. In addition, it seeks to glorify the creator of mankind by influencing lives towards excellence and distinctions in research.

This document was therefore developed to ensure that there is a framework within which research activities are to be conducted. This is with the aim of focusing research activities in relevant areas. while ensuring conformity to global best practices in the use of human and animal subjects for research. The Policy clearly articulates the management of research grants, intellectual property rights and patenting of key innovations in research.

The Bingham University is committed to conducted research from the undergraduate, through graduate studies to personal and multidisciplinary studies. The University is thus seeking to raise a learner community who are committed to the production, collation and dissemination of scientific knowledge to bring change in the society.

Being the very first version, it is expected that years of use and with the constant changing global context of research will inform necessary modifications and amendments as may be deemed necessary. It is expected that the Policy document will continue to be reviewed in line with National and International policy statements guiding research. In the meantime I am happy to present this Research Policy document to provide needed guidance in the frontiers of research by staff and students of the Bingham University.

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Forev	word	2
CHA	APTER ONE	7
1.1	BACKGROUND	7
1	1.1.1 Definition of Research	8
1	1.1.2 Bingham University Research Mandate	8
1.2	2 RESEARCH POLICY OBJECTIVES	8
1.3	3 UNIVERSITY RESEARCH BOARD (URB)	10
1	1.3.1 Vision	10
1	1.3.2 Mission	10
1	1.3.3 Research objectives of the Board	10
1	1.3.4 Members of University Research Board (URB)	11
1	1.3.5 Faculty Research Coordinator	12
1.4	ETHICAL REVIEW COMMITTEE (ERC)	12
1	1.4.1 Membership Criteria	12
1	1.4.2 Functions	12
1.5	5 INNOVATION AND PATENTING COMMITTEE (IPC)	13
1.6	6 ADMINISTRATION OF RESEARCH GRANTS	13
1.7	EXTERNAL RESEARCH ASSESSMENT (ERA)	14
1	1.7.1 Purpose of External Research Assessment (ERA)	14
1.8	B DECLARATION BY THE RESEARCHER	15
СНА	PTER TWO	16
2.1	RESEARCH PRINCIPLES	16
2.2	2 ELIGIBILITY AND CRITERIA	16
2.3	<b>GENERAL PRINCIPLES OF BINGHAM UNIVERSITY RESEARCH FUND</b>	16
2.4	GUIDELINES FOR THE RESEARCH GRANT DISBURSEMENT	17
2.5	5 OPENNESS IN RESEARCH	18
2.6	6 ACCESS TO RESEARCH DATA AND DATA BANKING	19
2.7	<b>REPORTS AND PUBLICATIONS</b>	19
СНА	PTER THREE	20
3.1	MANAGEMENT OF RESEARCH GRANT	20
3.2	DISBURSEMENT OF GRANTS	20
	3.2.1 Requirements for the release of fund	20
	3.2.3 Progress report	20
	3.2.4 Financial report	21

### Table of Contents

3.	2.5 Research grant variation	
3.	2.6 Final report	
3.3 1	ROLE OF THE PRINCIPAL INVESTIGATOR IN THE RESEARCH MA	NAGEMENT
3.	3.1 Budget for Sponsored Projects	
3.	3.2 Research Time Extension	
3.	3.3 Other Research Funds	22
3.	3.4 Awards and Incentives	22
СНАР	TER FOUR	23
4.1	INTELLECTUAL PROPERTY POLICY	
4.2	COPYRIGHT AND RELATED RIGHTS	
4.3	INDUSTRIAL PROPERTY	25
4.4	POSSESSION AND OWNERSHIP OF COPYRIGHTED WORKS	25
4.	4.1 Authorship and Permissions	27
4.	4.2 Disclosure, Licensing and Commercialization	27
4.5	PATENTABLE INVENTIONS	
4.	5.1 Ownership of Inventions	
4.	5.2 Disclosure, Assignment and Protection (appendix G)	
4.	5.3 Licensing and Commercialisation	
4.	5.4 Tangible Research Property	
4.6	SPONSORED RESEARCH AGREEMENTS	
4.7	DUTY TO DISCLOSE ON EXTERNAL GRANTS	
4.8	DISTRIBUTION OF INCOME ON OWNED INTELLECTUAL PROP	PERTY IN
THI	E UNIVERSITY	
4.9	WAIVER OF UNIVERSITY RIGHTS	
4.10	POLICY ADMINISTRATION	
4.	10.1 Intellectual Property Review Board	
4.11	DISPUTE RESOLUTION	
4.12	STUDENT RESEARCH AND SCHOLARSHIP	
4.13	INNOVATIONS & TECHNOLOGY FORESIGHT	
СНАР	TER FIVE	
5.1	ARCHIVAL POLICY	
5.2	JUSTIFICATION	
5.3	MATERIALS FOR ARCHIVING	
5.	3.1 Guidelines for printed materials	
5.	3.2 Guidelines for Tangible Collections	

5.4	MATERIAL SAMPLING AND DESTRUCTIVE ANALYSIS PROCEDURE				
CHAPTER SIX					
6.1	HUMAN SUBJECTS IN RESEARCH				
6.2	HUMAN RESEARCH PROTECTION PROGRAMME (HRPP)				
6.3	USE OF HUMAN SUBJECTS IN STUDENT PROJECTS AND PILOT STUDIES 44				
6.4	WOMEN AS SUBJECTS IN RESEARCH				
6.5 POTE	GUIDELINES FOR STUDIES INVOLVING HUMAN VOLUNTEERS RECEIVING NTIALLY ADDICTING DRUGS				
6.5.1	Informed Consent				
6.5.2	Exclusion of Subjects with a History of Addiction53				
6.5.3	Exclusion of Subjects with Direct Access to the Class of Addicting Drug under Study 54				
СНАР	TER SEVEN				
7.1	USE OF ANIMALS IN RESEARCH: PREAMBLE				
7.2	ETHICS OF ANIMAL RESEARCH				
7.3	<b>KEY PRINCIPLES FOR PROMOTING ANIMAL WELLBEING</b>				
7.4	WELLBEING, STRESS, DISTRESS AND PAIN				
7.4.1.1	Physiological and Behavioural Indicators of Wellbeing59				
7.4.3.1	Physiological and Behavioural Indicators of Distress61				
7.4.4.1	Causes of Pain				
7.5	EFFECTS OF ANIMAL WELLBEING ON SCIENTIFIC OUTCOMES				
7.6.1	Planning New Research Protocols				
7.6.3	Choosing the Right Animal67				
7.6.5	Methods Used				
7.7	THE INSTITUTIONAL ANIMAL CARE COMMITTEE (ACC)				
7.7.1	Terms of Reference for University Animal Care Committees (UACC)				
СНАР	TER EIGHT: ENVIRONMENTAL HEALTH AND SAFETY				
8.1	PREAMBLE				
8.2	PRINCIPLES, RESPONSIBILITIES AND PRACTICES				
8.2.1	Principles				
8.2.2	Responsibilities				
8.2.3	Practices				
8.3	CHEMICAL HAZARDS				
8.5	POLICY ON IONIZING RADIATION				
8.5.2	<b>Policy</b>				
8.5.3.2	Radiation Protection Advisor				

8.5.3.4 Radiation Safety Committee	
8.5.3.6 Appointed Doctor	85
8.6 BIOLOGICAL HAZARDS	85
8.6.2 Procedures	85
CHAPTER NINE	87
RESEARCH AND DEVELOPMENT	87
9.1 TRANSLATING RESEARCH FINDINGS INTO PRODUCTS	87
9.2 Translational Objectives	87
CHAPTER TEN	89
10.1 RESEARCH CLUSTERS/GROUPS, CENTRES AND INSTITUTES	89
10.1.1 Attributes of Research Clusters/Groups, Research Centres and Institutes	
10.1.2 Approval body for Research Institutes and Centres	91
APPENDIX A:	
CONTRACTUAL AGREEMENT FOR RESEARCHES	92
APPENDIX B:	
PROGRES REPORT	
APPENDIX C:	
FORMAT FOR RESEARCH PROPOSAL EVALUATION REPORT	
APPENDIX D:	
MEMBERSHIP AND TERMS OF REFERENCE OF THE RADIATION SAFETY	
COMMITTEE	
APPENDIX E:	100
DUTIES OF RADIATION PROTECTION SUPERVISORS	100
APPENDIX F:	102
FINAL RESEARCH REPORT	102
APPENDIX G:	104
RESEARCH CONTRACTS CONDITIONS	104

#### CHAPTER ONE

#### **1.1 BACKGROUND**

The core mandates of Bingham University are to advancing knowledge through teaching and learning, promote scholarly research and as well as rendering services locally, nationally and internationally. In addition the university core values are laid on principles of excellence, intellectual integrity, ethical standards and adaptability as well as academic freedom and Christ centeredness.

Research is conducted across disciplines and faculties by faculty members, undergraduate and post-graduate students and collaborators from industries, agencies and other organizations. In this era of networking and collaborative research, innovation will continue to grow with emergence of issues that were not anticipated or hitherto ignored in the past and research process is dynamic and could be complicated, if there is no policy documents that provides guidance.

This policy therefore provides the governance framework for the conduct and management of research in Bingham University. It complies with the mandate establishing the university, her vision and mission and shall become binding to all upon approval by the senate of the university.

The overall goal is to ensure a seamless, transparent and accountable disbursement and management of research in the university. The responsibilities of researchers, sponsors and research managers in the university are outlined in this policy. The university recognizes that research is conducted under acceptable best practices that are safe and protect human participants, animals, the environment, intellectual property rights administration and others, to guarantee sustainable development of the nation.

7

#### 1.1.1 Definition of Research

In this Policy, research includes those activities intended to produce one or more research outcomes, including the creation of knowledge, reorganisation, and application of knowledge.

#### **1.1.2 Bingham University Research Mandate**

The University has a mandate for Research as follows:

- 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;
- vii. Developing appropriate copyrights and trademarks for the University through patenting and branding of research products.

#### **1.2 RESEARCH POLICY OBJECTIVES**

The objectives of Bingham University Research Policy are to:

- i. Provide guidance for members of the University involved in research within and outside the University;
- ii. Encourage academic staff to conduct different types of research;
- iii. Encourage Faculties, Departments and Units in the University to develop research niche areas;
- iv. Develop and encourage multidisciplinary research culture to foster collaboration and cooperation within the University community; and
- v. Meet the requirement for qualification for national and international funding for research.

Figure 1: Organogram for the Management of Research



URB: University Research Board UERC: University Ethical Review Committee PG: Postgraduate RSC: Radiation Safety Committee UEPC: University Environmental Protection Committee PIC: Patency and Innovation Committee PDC: Product Development Committee UACC: University Animal Care Committee

#### **1.3 UNIVERSITY RESEARCH BOARD (URB)**

The University Research Board was established by the University Senate at its 101 Regular Meeting on 20th February, 2018. The purpose is to promote excellence in research, development and training that will enhance optimum performance of the University's staff and students in its bid to attain a world-class status.

#### 1.3.1 Vision

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

#### 1.3.2 Mission

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

#### **1.3.3 Research objectives of the Board**

The Committee is to:

- 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 Management;
- ii. Process research project proposals submitted to the University Research Board (URB) for evaluation;
- iii. Approve and monitor research funds 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 Bingham University 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.

#### **1.3.4** Members of University Research Board (URB)

i.	Director, University Research Board	- Chairman
ii.	University Librarian	- Member
iii.	Director, Research Centres	- Member
iv.	Director, Academic Planning Unit	- Member
v.	Director, ICT	- Member
vi.	Dean, Postgraduate School	- Member
vii.	Representative of the Registrar	- Member
viii.	Representative of the Bursar	- Member
ix.	Faculty Research Coordinators	- Member
x.	Centre Secretary	- Secretary

All research proposals for the senate grant shall be submitted, in the first instance, to the Faculty Research Coordinators, who will refer them to the University Research Board. Comments from the University Research Board shall be sent back to the Faculty Research Coordinator who shall forward them back to the initiating applicants for revision or further action. Applicants shall send revised versions of proposals through the Faculty Research Coordinator for the consideration and approval of the URB. Applications for externally funded research should be processed through the Chairman, URB with the consent of the Vice- Chancellor on behalf of the University.

#### 1.3.5 Faculty Research Coordinator

There shall be for each Faculty a Research Coordinator who shall normally be a Senior Lecturer and above, 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 Dean and represent the Faculty on the Board of URB.

#### **1.4 ETHICAL REVIEW COMMITTEE (ERC)**

Bingham University subscribes to the National Ethics and Operational Guidelines for Research on Human and Animal Subjects and the various International guidelines and Principles on researches. Therefore, an Ethical Review Committee is established for this purpose.

#### 1.4.1 Membership Criteria

Members of this Committee shall be independent and shall not be part of the University Research Board (URB) to avoid conflict of interest and bias in ethical considerations.

#### 1.4.2 Functions

i. Conduct prospective and progressive review of related research protocol involving human, animal and plant 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 noncompliance 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.

#### **1.5 INNOVATION AND PATENTING COMMITTEE (IPC)**

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)

#### 1.6 ADMINISTRATION 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 URB;
- ii. The Vice-Chancellor 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 Vice Chancellor and the Director URB shall sign on behalf of the University. Copies of the contract will thereafter be deposited in the office of the Vice-Chancellor and the Director URB;
- iv. Bingham University will charge 10% of the sum of Project Award for externally funded research. This would 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, they shall be disbursed as follows:
  - a. Research----- 90%b. University ----- 5%;
  - -----
- v. The Principal Investigator shall submit two copies of technical reports to the Director,
  URB and the University Library.

#### 1.7 EXTERNAL RESEARCH ASSESSMENT (ERA)

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

#### 1.7.1 Purpose of External Research Assessment (ERA)

i. 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.

- ii. ERA is conceived by the University itself, and therefore it is 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, while ERA will contribute to the University's own research development drive, it will also be pre-emptive of future external requirements.
- iii. 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.
- iv. ERA will be an international validation of the quality and status of Bingham University research performance.
- v. The responsibility for the implementation of ERA lies with the Chairman under the guidance of the Vice-Chancellor

#### **1.8 DECLARATION BY THE RESEARCHER**

Researchers in Bingham University will be required to be committed to the guidelines and values contained in the University Research Policy. They will be required to sign a contractual agreement form for researchers after the approval of their research proposals. (See Appendix A).

#### **CHAPTER TWO**

#### 2.1 RESEARCH PRINCIPLES

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

#### 2.2 ELIGIBILITY AND CRITERIA

Principal actors for research investigations in Bingham University are restricted to academic staff members who are holders of Ph.D. or equivalent. The Principal Investigator should be a Ph.D. holder or its equivalent and must be a permanent staff of the University. Co-Researchers without Ph.D., or its equivalent 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.

#### 2.3 GENERAL PRINCIPLES OF BINGHAM UNIVERSITY RESEARCH FUND

Bingham University Research fund will be used to undertake vibrant research that can demonstrate high level of potential to leverage external research funding. The following principles are considered in the disbursement of Research Grants. It is expected that the proposed research; is strategic, basic or applied and productive; shows evidence of solving community, regional, national, and/or global problems; is original and has potential for novel knowledge; focuses on a new research project with high level of potential that will lead to academic and research excellence; is trans-disciplinary; encourages international/ national linkage; brings development to the community; and leads to excellent research publications in reputable national and international journals and/or books.

#### 2.4 GUIDELINES FOR THE RESEARCH GRANT DISBURSEMENT

Bingham University administration is poised to promote the culture of research amongst its staff. In doing so, it has established the University Research Board (URB). The URB is to coordinate and manage submitted proposals and disbursement of funds for acceptable proposals.

The following are guidelines regulating the consideration and award of grants by the URB.

- 1. Types of Proposal to be considered
  - Individual research proposals should be submitted through the Faculty Research Coordinator, with the approval of the Dean of Faculty to the University Research Board (URB). Applicants for individual research proposals must be holders of Ph.D. degree or its equivalent. The maximum amount of award for this category is N1, 000,000.00 only.
  - Collaborative research proposals should be submitted by two or more co-principal investigators who should be holders of Ph.D. or its equivalent. The proposal should be endorsed by the Head of Department and Dean of Faculty or Provost of College of medicine before submission to the University Research Committee (URB). The maximum amount of award for this category is N1, 500,000.00 only.
  - iii. Staff-in-Training Proposal: It is the responsibility of the University to provide some financial support for staff who have been given approval and registered students of approved and recognized M.Sc. and Ph.D. programmes. Staff-intraining can submit their research proposal to the University Research Board

through the Faculty Research Coordinators for funding after endorsement by the Dean PG School. The maximum amount of award for the M.Sc. is N350, 000.00 and that for PhD is N500, 000.00.

- 2. All applications for research grants shall be submitted in soft and hard copies on the prescribed format to the Secretary, University Research Board.
- 3. Priority shall be given to research projects in order of their relationship to immediate University environment and urgent development needs of the University and the Country.
- 4. Recipients of research grants shall submit periodic progress report on the project to the University Research Board (URB) at three months interval.
- 5. All equipment, books and any other materials purchased with research grants remain the property of the University and must be accounted for on completion of any research project, and handed over to the respective Department.
- 6. Application cannot be entertained from individual of collaborative group if they already have a running grant from the URB. Application for new research grants by persons who have benefited before shall be considered only after a satisfactory report of the previous grant has been submitted to the URB.
- Award money will be disbursed in two tranches. The first tranche will be 60% of the award, and 40% will be disbursed after a satisfactory progress report by the awardee to the URB.

#### 2.5 **OPENNESS 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 Bingham University 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 policy relevant research funding categories. The University permits joint publications with project investigators in all categories of research with acknowledgements of the funding source(s).

#### 2.6 ACCESS TO RESEARCH DATA AND DATA BANKING

Research data basically include field and laboratory notebooks, questionnaires, tape recordings, specimens, samples and other records, such as, artefacts 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.

#### 2.7 REPORTS 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 URB with the knowledge of the Co-Researchers and all participants in the project. As the business manager therefore, the PI controls 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**

#### **3.1 MANAGEMENT OF RESEARCH GRANT**

This chapter covers 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.

#### 3.2 DISBURSEMENT OF GRANTS

All grants funded by Bingham University Senate research grant and/or external sponsors are offered in accordance with the deed of agreement between the sponsors and individual recipient.

#### **3.2.1** Requirements for the release of fund

The research grant recipients are required to complete the required forms and submit to the University Research Board URB after which the board will notify the Bursary for the release of funds. The amount requested must be retired before another new release of grant can be made. In the case of external grants, the release and retirement will depend on the agreement reached by the parties involved.

#### 3.2.3 Progress report

All successful applicants of must submit progress reports to through the Faculty Research Coordinator or the Secretary, University Research Board as specified in Appendix B.

#### **3.2.4 Financial report**

All recipients are required to submit financial reports to the University Research Board for each funded project on completion.

#### 3.2.5 Research grant variation

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

#### 3.2.6 Final report

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

## 3.3 ROLE 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.

#### 3.3.1 Budget 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.

#### 3.3.2 Research Time Extension

Additional time may be needed to complete a project. The Principal Investigator is obliged to request for such an extension of the duration of Research. 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.

#### 3.3.3 Other Research Funds

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

#### 3.3.4 Awards 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**

#### 4.1 INTELLECTUAL PROPERTY POLICY

Bingham University recognizes and encourages staff and students to be actively involved in the creation of valuable intellectual properties in the course of research and other activities using University resources and facilities. This policy aims at protecting the rights of the individual, the University and any sponsoring entity (as applicable), and providing reasonable and appropriate sharing of the benefits if the creation has a commercial value.

The purpose of this policy is to define the conditions of ownership, legal protection, development and licensing of intellectual properties conceived or first reduced to practice by any Staff or Student. Under this policy, intellectual properties can be managed so as to further the mission of the University, enhance the value of such properties, and properly distribute benefits to the University and the creators of the intellectual property. It is therefore important to define an author and work in the context of this policy.

A creator can be an author or an inventor. An author is the person responsible for the creation of the intellectual/artistic content of a work. A work could be a book, article, drawing, computer program, paintings, sculpture, design, invention, and the like. Intellectual property would protect such works created. An inventor is the person who is able to put technical, mechanical, electrical or other physical parts or processes together to arrive at a new transformation that is unique and useful.

This Policy is founded upon the following principles:

i. If a work is created independent of the student and official duties of the staff and without substantial University assistance, the work is owned by the creator;

23

- ii. If a work is created as part of the duties of the student and staff (contractual or tenure employment) with the University, the work is jointly owned by creator(s) and the University; and
- iii. If the work is created independent of the student and duties of the staff (contractual or tenure employment) but with substantial University assistance, the work is owned by the University.

The Policy applies to all members of Staff, Students and any person using the facilities of Bingham University, under the supervision of University personnel, including, but not limited to, visiting and adjunct members of staff. No exception to the Policy shall be valid unless agreed to in advance in writing by the Vice-Chancellor or any other officer exercising that power on his/her behalf. Intellectual property refers to the creations of the mind. These include inventions, literary and artistic works and symbols, names, images, and designs used in commerce (World Intellectual Property Organization, 2007). There are two broad categories of intellectual property:

- (i) Copyrights and Related Rights and
- (ii) Industrial Property.

#### 4.2 COPYRIGHT AND RELATED RIGHTS

Copyrights are given to creators (authors) for their literary and artistic works. Rights related to copyright are also known as neighbouring rights to copyrights. These are rights given to performers, producers and broadcasting organizations in relation to their performances, broadcasts and other copyrighted works. Neighbouring rights cover actors/actresses, script writers, directors, producers, etc.

This Policy addresses Copyright ownership, the assignment of rights associated with copyright ownership, licensing of rights and the distribution of revenues or Royalties therefore, if any. The University encourages the preparation and publication of copyrightable works that result from teaching, research, scholarly and artistic endeavours by Staff and Students. The University affirms the right of Staff and Students to retain primary control over their works. However, sharing knowledge is central to the success of the University and Copyright policies should enhance, not inhibit, productive Work.

#### 4.3 INDUSTRIAL PROPERTY

Industrial property refers to a collection of intellectual properties covering a wide range of creations of the mind, including patents, trademarks, industrial designs, geographic indications and trade secrets (WIPO, 2007). Patents are exclusive rights granted to inventors for their inventions. A trademark is a distinctive sign which identifies certain goods and services. Industrial design is the ornamental or aesthetic (shape) of an article. A geographic indication is a sign used on goods that have a specific geographic origin and possess qualities or a reputation that is due to the place of origin (source of the product). Trade secrets are internal confidential information of an organization, which if it is released to its competitors, would put the organization at a disadvantage.

#### 4.4 POSSESSION AND OWNERSHIP OF COPYRIGHTED WORKS

i. In keeping with academic tradition, except to the extent required by the terms of any contract or as otherwise expressly provided in this policy, works that are created as part of independent research or scholarship of members of staff and students are not owned by the University. The University does not claim ownership to pedagogical, scholarly or artistic works, regardless of their form of expression. These copyrighted works include, but are not limited to, textbooks, course materials, refereed literature, and works created by students in the course of their education, such as dissertations, theses, papers and journal articles. Furthermore, the University claims no ownership

in popular non-fiction, novels, poems, musical compositions, or other works of artistic imagination. Authors of course materials shall grant the University a non-exclusive, royalty-free, perpetual license to use, display, copy, distribute, and prepare derivative works for the use of such materials by the University.

- ii. The University is the owner of all copyrighted works, including software, electronic courses, course materials and any other electronic media, course modules or course design products that are created for an institutional purpose in the course of employees' prescribed duties or as contracted by the University. These include works on which there have been simultaneous or sequential contributions over time by numerous employees or students.
- iii. The growth of the World Wide Web and information technology has led to the emergence of electronic courses. The creation of electronic courses may require the provision and contribution of substantial resources of the University. Thus, where the University has provided and/ or contributed substantial resources to authors, they shall assign their rights in such works to the University in exchange for the royalties described below. The University's title shall include all rights provided by the Copyright Laws of Nigeria. Such title is necessary to guarantee the exclusive right of the University to control the method and manner in which its educational programmes and courses are offered to the public and to secure new revenues from which to replenish and enhance University technology resources.
- iv. Whenever the University commissions a new work, copyright issues are to be clarified and fixed in a written agreement prior to the start of the project.
- v. In determining the ownership of any copyrighted work not covered by this policy or by a written agreement, three factors are to be considered:
  - a. The creative initiative for the work,

- b. Control over the content and final approval, and
- c. Resources or compensation, if any, provided by the University.

#### 4.4.1 Authorship and Permissions

- i. Collaborators on a single work are joint authors, as that term is defined under
- ii. Copyright Act Cap C.28 Laws of the Federation 2004. However, because joint ownership creates complex management problems, it is recommended that faculties have agreements that define the interrelated rights and duties among the parties prior to beginning work on the project.
- iii. All copyrighted works owned by the University shall prominently bear the legend "© Bingham University. All rights reserved." The University shall also reflect by appropriate copyright notice, the Copyright of authors on works owned by authors other than the University, but contained in a work owned by the University.
- iv. It is the responsibility of all users of copyrighted works to secure permission from owners before reproducing, distributing, making a derivative work, or displaying copyrighted works.
- v. The use of University trademarks or logos requires permission of the University. Requests for permission should be directed to the Director of Academic Planning

#### 4.4.2 Disclosure, Licensing and Commercialization

i. The Office of the Director of Legal services shall draft agreements for the University to enter into with faculty members and others in order to clarify ownership of copyrights and the allocation of rights associated with specific projects.

- Agreements that grant to third parties the rights to commercially developed works owned by the University are encouraged. The Office of the Director of Legal services is responsible for negotiating such agreements.
- iii. Licenses, sales, or other transfers of copyrighted Works must be approved by theOffice of the Director of Legal services.
- iv. Authors shall, whenever practicable, be advised and consulted on the progress of license negotiations.

#### 4.5 PATENTABLE INVENTIONS

#### 4.5.1 Ownership of Inventions

- i. Any Invention shall be assigned to and owned by the University.
- ii. Inventions (other than those of the University), shall be owned by the Inventor or as determined in accordance with the terms of any applicable grant or contract.

#### 4.5.2 Disclosure, Assignment and Protection (appendix G)

- i. All persons subject to this policy shall promptly disclose University inventions.
- ii. To protect and preserve the intellectual property rights defined in this policy and to comply with all laws in that connection, Inventors shall execute assignments and other appropriate documents as may be requested by the University to perfect its ownership and rights to University inventions.
- iii. No inventor shall have an Invention patented without the knowledge of the University.
- iv. The University acknowledges the rights of Inventors to protect their Inventions.
- v. Thus, inventors may take reasonable precautions to assure the confidentiality and physical security of formulas, methods, processes, patterns, computer codes, devices, compositions of matter, or other tangible research property. In such cases, inventors

shall ensure that students are not deprived of the opportunity to publish and otherwise fully participate in, and benefit from, the research.

#### 4.5.3 Licensing and Commercialisation

The following shall apply on this issue:

- i. Agreements that grant to others the rights to commercially develop University inventions are encouraged.
- ii. The Office of the Director of Legal services is responsible for negotiating such agreements on behalf of the University.
- iii. Inventors shall, whenever practicable, be advised and consulted on the progress of license negotiations related to inventions from the University.

#### 4.5.4 Tangible Research Property

- i. Ownership of Tangible Research Property (TRP) resides with the University unless the TRP arises as a result of a grant or Sponsored Research Agreement (SRA), in which case, the terms and conditions of the grant or SRA will apply. Where the grant or SRA is silent, TRP is owned by the University.
- ii. Principal investigators and laboratory directors are primarily responsible for the custody, care, and control of TRP, including its storage, use, and distribution.
- iii. Principal investigators may wish to make TRP broadly available for other scientific use. Scientific exchanges should not be inhibited due to potential commercial considerations.
- All questions regarding Intellectual Property rights in TRP should be referred to the Office of the Director of Legal Services.

#### 4.6 SPONSORED 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 non-grant-making entities that wish to sponsor faculty research, clinical or training projects.
- ii. 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.
- iii. To retain maximum flexibility and achieve the desired goals of this Policy, the Chairman (URB) 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.
- iv. An SRA and an intellectual property license may be negotiated simultaneously.

#### 4.7 DUTY 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 Chairman URP who will notify the sponsoring agency; and  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.

### 4.8 DISTRIBUTION OF INCOME ON OWNED INTELLECTUAL PROPERTY IN THE UNIVERSITY

The University assumes financial responsibility for the intellectual property it owns. The University is not, however, obliged to protect or commercialize any intellectual property unless it has made an explicit contractual commitment to do so. Activities relating to the protection and marketing of University intellectual properties are intended to be self-supporting. Income earned from the sale, licensing or other transfer of Intellectual Property of the University shall be received solely by the University and shall, except where a grant or SRA specifies otherwise, be distributed successively as follows:

a. Reimbursement of all direct expenses related to prosecuting and maintaining
 Intellectual property protection and securing licenses, such as fees for outside legal
 Counsel and other experts, if required; and

b. The remaining shall be equally shared between the Creator and the University. Where there is more than one creator, distribution shall be prorated according to the contribution of each as may be agreed in writing between the parties, or, if an agreement cannot be reached, then according to the provisions of the Dispute Resolution mechanism in this policy. The University shall be entitled to 50% of the balance while the creator(s) will share the other half.

In rare and exceptional circumstances, a student may make an important inventive contribution to the development of an intellectual property. In such cases, of a project

31

may share a portion of their royalties with the student(s). Student rights under this policy are more particularly provided. Royalties are payable to creators only upon actual receipt by the University. In the case of the death of a creator, all royalty distributions which would have been due to such person shall be paid to his or her estate.

#### 4.9 WAIVER 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.

#### 4.10 POLICY ADMINISTRATION

#### 4.10.1 Intellectual Property Review Board

The Intellectual Property Review Committee shall be created by the University to review and rule on all disputes regarding copyright ownership.

- i. The Intellectual Property Review Committee ("Committee") is an advisory body reporting to the Vice-Chancellor.
- ii. Committee members shall be appointed by the Vice-Chancellor, Director (URB) asChairman. A majority of the members shall constitute a quorum and
- iii. The Committee shall advise the Vice-Chancellor by:
  - a. Interpreting the terms of this Policy; and
  - b. Recommending changes or exceptions.

#### 4.11 DISPUTE RESOLUTION

i. The Vice-Chancellor shall resolve any claim, dispute or controversy involving the rights to intellectual property.

ii. Should the parties not reach an agreement, then any party to the dispute may appeal in writing to the Intellectual Property Review Committee. The Committee findings shall be made in the form of recommendations to the Vice-Chancellor whose decision shall be final.

#### 4.12 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.

33

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.

#### 4.13 INNOVATIONS & 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**

#### 5.1 ARCHIVAL POLICY

Bingham University Archives and Documentation Centre of the Library shall be the Institutional Repository for the collection, organization, access, annotation and preservation of research outputs of members of the University in digital formats.

#### 5.2 JUSTIFICATION

- i. Research outputs of members of the University will be housed in a place where they could be located by other researchers.
- ii. Researchers will be able to locate other research works and be able to build up on such works rather than wasting time to reinvent the wheel.
- iii. Existence of the Centre will increase the exposure of the research activities of the University, which will:
  - a. Enhance the reputation of the University;
  - b. Make the research works more widely accessible;
  - c. Lead to increased citation of research works from the University; and
  - d. Boost the impact of the research works on scientific advancement and global developments.

#### 5.3 MATERIALS FOR ARCHIVING

A collection is a grouping of items that are similar in one or more respects. For example, articles and conferences emanating from a department may represent a collection. An item is the basic archival element of the University Research Archive. Each item belongs to one

collection but may appear in other collections. It is the actual document. The materials for inclusion in the Centre of the University include:

- i. Journal articles (pre-printed or post printed);
- ii. Books;
- iii. Academic forum discussion papers;
- iv. Research Reports of sponsored works;
- v. Conference papers;
- vi. Theses;
- vii. Data sets;
- viii. Audio or video files of performed research works;
  - ix. Geological specimens;
  - x. Anthropological specimens;
  - xi. Paleontological products;
- xii. Historical materials; and
- xiii. Software.

#### 5.3.1 Guidelines for printed materials

Any of the aforementioned documents will be accepted on the following conditions:

- a. The work done is scholarly in nature.
- b. The work is a production of an academic staff of the University or is sponsored by a department, faculty or unit of the University.
- c. The work is completed and ready for distribution.
- d. It is a previously published item that is supported by clearance from the copyright owner.
Bingham University Archive shall be an open access repository. Any individual that can access the internet shall be able to access, view and download contents of the archive, except when an item is restricted to authorized users only.

To deposit a research item into the archive, an individual must register with the University Research Archive by providing an e-mail address and assigning a password for further communication.

A contributor will then be informed when to submit items for the archive. Submissions will then be validated and approved by library staff or curator of archival specimens before being made available. Each collection may have guidelines describing the type of materials that are acceptable such as, a Thesis collection is intended just for Thesis. The system will be in a position to accept any file format stored in the PC of a depositor. Files deposited into the University Research Archive may be removed only by the University Research Archive staff on the advice of a depositor.

A depositor retains any rights in existence prior to deposits of an item. In the case of a published article where the publisher has granted special permission in order to deposit a paper, the depositor continues to retain those rights. When an individual deposit a work, he/she grants the Bingham University the nonexclusive right to:

- a. *Reproduce*, translate and/ or distribute such submission (including the metadata and abstract) globally, in any format or medium for non-commercial, academic purposes only.
- b. *Translate* the submission without changing the content to any medium or format, and keep more than one copy of the work for purposes of scrutiny, backup and preservation.

37

#### 5.3.2 Guidelines for Tangible Collections

Bingham University shall provide a platform for the collection, organization, access and preservation of materials that are products of geological, anthropological, paleontological research in nature as well as historical and cultural products of research.

The University shall retain a curator who will be in charge of accessing and preserving these items. Each collection will be registered, accessed and preserved according to the University Guidelines on archiving of tangible scientific collections. Each material will be identified by stamps and pertinent written documentation. Photographing, casting, or copying materials by any method is only permitted with the consent of the collection curator. Such copies or derivatives thereof may not be transferred to another individual or institution or reduplicated without the permission of the University curator of archives material.

# 5.4 MATERIAL SAMPLING AND DESTRUCTIVE ANALYSIS PROCEDURE

Material sampling or destructive analysis of any object or specimen requires special circumstance. Request for samples are evaluated due to the fact that such uses inherently lead to reduced quality of the original specimen. Researchers must request permission for destructive analysis or sampling of specimens by submitting a detailed written proposal to the appropriate responsible officer designated for that purpose. The officer will evaluate such proposals according to scientific value, the researchers experience, the type of sample requested and the type of specimen required. Accessioned typed material in any form are prohibited from destructive analysis or sampling. Destructive analysis will not be permitted if specimen will lose its overall original integrity.

38

#### **CHAPTER SIX**

#### 6.1 HUMAN SUBJECTS IN RESEARCH

This section provides comprehensive information about the organization, scope, authority and responsibilities associated with Bingham University's programme for the protection of human research subjects. In this regard Bingham University subscribes to the National Ethics and Operational Guidelines for Research on Human Subjects and the various International guidelines and Principles on researches involving human subjects 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.

# 6.2 HUMAN RESEARCH PROTECTION PROGRAMME (HRPP)

#### 6.2.1 Background

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 (HRPP) to the members of the research community at Bingham University and affiliated organizations. The HRPP will be conducted by the UERC 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.

## 6.2.2 Authority and Responsibility

The Chairman UERC have been given the authority and responsibility to establish, maintain, and oversee the HRPP by the Vice-Chancellor Bingham University, and will also have the primary administrative responsibility for the day-to-day operation of the HRPP.

## 6.2.3 Participating Organizations

The HRPP applies to the human subject research done at Bingham University 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: Bingham University and Bingham University Teaching Hospital. This coverage includes any subsidiary entities listed by these organizations.

# 6.2.4 HRPP 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.

#### 6.2.5 Compliance and Monitoring

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

### 6.2.6 Role of the University Ethical Review Committee (UERC)

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

- i. Prospective and continuing review of each research protocol involving human subjects, including an evaluation of its risks and benefits to the human subjects,
- ii. Reviewing the adequacy of the informed consent document, particularly as to its description of the risks and benefits,

iii. 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.

### 6.2.7 Registration and Certification of the UERC

In conformity with global standards, the UERC shall ensure its accreditation by appropriate National and International accrediting bodies such as the National Ethics Committee are current.

## 6.2.8 Composition of the UERC

- i. The UERC shall be a multidisciplinary Committee, comprising 10-15 members with at least 2 members who are not directly affiliated to the University representing the community. Membership shall be drawn from health sciences, social sciences, humanities and administration.
- 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 UERC shall be 2 (two) years and renewable once

## 6.2.9 UERC 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 (for example, Bingham University Teaching Hospital) is required.

#### 6.2.10 General 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 institution or its agents from liability for negligence.

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, reasonably 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.

42

#### 6.2.11 Training Concerning the HRPP

Bingham University and its affiliates will train and require documentation of training for all investigators, research staff, students, UERC 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 Bingham University organized training. Refresher training is required once in every three years.

### **6.2.12** 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 UERC 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.

#### 6.2.13 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 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 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.

#### 6.2.14 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 should be contacted. Contacting the UERC may be done anonymously.

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

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

#### 6.3.1 Human Subject Research

## 6.3.1.1 Student Projects

Bingham University 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.

## 6.3.1.2 Pilot 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, for example, "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.

# 6.3.1.3 Other 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 for review.

## 6.4 WOMEN AS SUBJECTS IN RESEARCH

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

## 6.4.1 Introduction

Historically, there have been concerns about the participation of women with childbearing potential in research trials due to potential risks of foetal harm should a woman become pregnant. Such apprehension has resulted in guidelines or policies. In 1977, for example, USA 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 foetal 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 childbearing 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. Bingham University endorses these changes and has adopted the following policy regarding the inclusion of women as subjects in human research as a guideline to researchers. These is due to the fact that, so far in Nigeria we do not have a comprehensive guideline regarding involvement of women as a subject for research.

# 6.4.2 Pregnant Women as Human Research Subjects

Drug research using pregnant women as subjects is governed by regulations. Bingham University 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 foetus will be

placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the foetus 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 foetus, 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."

### 6.4.3 Women 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.

# 6.4.3.1 Risk 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."

# 6.4.3.2 Risk to Fetus and/or Infant

i. General Guidelines: "Appropriate precautions should be taken in research studies to guard against inadvertent exposure of fetus 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 counsellor 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 fetus. 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.

# 6.4.3.3 Active Recruitment of Women

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

#### 6.4.4 Sample Informed Consent for a Potentially Toxic Drug Study

The following language is recommended when women of child-bearing potential (nonpregnant) 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.

#### 6.4.5 Protocol 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.

# 6.5 GUIDELINES 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.

# 6.5.1 Informed 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.

## 6.5.2 Exclusion 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 ethology of the disorder.) The justification for experimental ingestion or intoxication must be included in the application.

# 6.5.3 Exclusion 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 SEVEN**

### 7.1 USE OF ANIMALS IN RESEARCH: PREAMBLE

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.

# 7.2 ETHICS 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.

### 6.3.3 Principles

 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.

- 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.

# 7.3 KEY 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.

## 7.4 WELLBEING, STRESS, DISTRESS AND PAIN

## 7.4.1 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.

# 7.4.1.1 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.

## 7.4.2 Stress

Stress is the response of the animal to a  $\Box$ 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 pre pathological 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.

## 7.4.3 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.

## 7.4.3.1 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 orb 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 defence. 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 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.

#### 7.4.4 Pain

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.

### 7.4.4.1 Causes 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.

# 7.4.4.2 Physiological 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. Pain related 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.

# 7.5 EFFECTS 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.

# 7.6 PLANNING, CONDUCTING AND REVIEWING RESEARCH PROTOCOLS

#### 7.6.1 Planning 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.

#### 7.6.2 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

## 7.6.3 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.

### 7.6.4 Experimental 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.

#### 7.6.5 Methods 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 (for example, bodyweight, age, sex)

## 7.6.6 Data Management

When designing the experiment, the final stages (for example, 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 (for example, 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.

### 7.7 THE INSTITUTIONAL ANIMAL CARE COMMITTEE (ACC)

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.

## 7.7.1 Terms of Reference for University Animal Care Committees (UACC)

# i. Membership

The UACC should comprise between 10-15 members. The complements should include:

- Scientists and/or teachers experienced in animal care and use, who may or may not be actively using animals during their term on the UACC. There should be a minimum of two such members, and representation of all the major animal-using divisions of the institution must be ensured;
- A veterinarian, normally experienced in experimental animal care and use;
- An institutional member whose normal activities, past or present, do not depend on or involve animal use for research, teaching or testing;
- At least one, and preferably two or more, person(s) representing the University;
- 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;
- Student representation (graduate and/or undergraduate), in the case of institutions that have programmes where students use animals; and
- The UACC Secretary (the institutional employee who provides support to the UACC).

- The UACC Chair shall be appointed by the Vice Chancellor.
- 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 UACC members who must be part of the UACC because of their role within the institution

(Ex officio members): the UACC Secretary, the veterinarian(s) and the animal facility manager.

## iii. Authority

The UACC will have the authority, on behalf of the Vice Chancellor 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 nonproved procedure, or any procedure causing unforeseen pain or distress to animals.
- 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 UACC 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 UACC Chair, but the veterinarian must have the authority to proceed with any necessary emergency measures, whether or not the animal user and UACC Chair are available. A written report should be sent by the veterinarian to the animal user and to the UACC following any such event.

## iv. Responsibility

It is the responsibility of the UACC to:

- a. Ensure that no research or testing project or teaching programme (including field studies) involving animals be commenced without prior UACC approval of a written use protocol. Further to this, that no animals 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 UACC approval of a written animal use protocol, except where current guidelines provide for exemptions. The UACC 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 UACC can readily understand. To facilitate the work of both protocol
authors and UACC members, appropriate Standard Operating Procedure (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 (for example. 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 UACC or a delegate. For any major changes to a protocol, it requires that a new one be submitted. UACCs 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 UACC;
- 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 UACC 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;
- 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:
  - unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;
  - anaesthesia 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 anaesthetics or analgesia

must be subject to particular scrutiny, not only prior to approval, but also during the experiment;

- appropriate post-operative care is provided;
- 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 EIGHT:**

### ENVIRONMENTAL HEALTH AND SAFETY

#### 8.1 **PREAMBLE**

Environmental Health and Safety matters at the Bingham University shall be a shared responsibility of the Environmental Protection Committee (EPC) and the Bingham University Medical Centre. 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.

### 8.2 PRINCIPLES, RESPONSIBILITIES AND PRACTICES

## 8.2.1 Principles

Bingham University shall 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;
- v. Encouragement of faculty, students and other members of staff to report hazards; and
- vi. Provision of information and safeguards on environmental hazards arising from activities at Bingham University to the campus and the surrounding communities.

#### 8.2.2 Responsibilities

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, Heads of Units and Directors, Deans of Faculties, Environmental Protection Committee, and the Deputy Vice-Chancellors. Final responsibility for health and safety policy and programmes rests with the Vice-Chancellor.

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.

Chairman, EPC shall be responsible for:

- i. Reviewing legislation, recommending policies and monitoring compliance with environmental health and safety statutes and regulations;
- ii. Providing guidance and technical assistance in identifying, evaluating and correcting health and safety hazards in the University;
- iii. Recommending procedures for the safe use of hazardous substances for example chemical, biological and radiological substances; and
- iv. Providing training in safe and healthy workplace practices.

## HEADS OF DEPARTMENTS AND DIRECTORS shall be responsible for ensuring that:

- i. Individuals under their management implement appropriate health and safety policies, practices and programmes of the University; and
- ii. Areas under their management have adequate safety equipment and are in compliance with University health and safety regulations.

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.

EMPLOYEES AND STUDENTS are responsible for:

- i. Keeping themselves informed of conditions affecting their health and safety;
- Participating in training programmes recommended by their superiors or supervisors;
- iii. Adhering to healthy and safe practices in their workplace, classroom, laboratory and campus residences; and
- iv. Reporting hazards in the workplace, classroom or laboratory and campus residence to their superiors, supervisors or appropriate authorities.

# 8.2.3 Practices

- i. PROVIDING A SAFE WORKPLACE: This will be accomplished through:
  - 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.
  - Ensuring the safety of the University community within the vicinity of construction sites;
  - 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;

- 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
- Providing Medical Surveillance: Evaluation and monitoring, through a programme of medical surveillance, of the health of Bingham University 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 Chairman EPC 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:

79

- Records of training showing who was trained, who provided the training, what the training covered, where and when the training took place;
- 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
- Records of disciplinary action taken for failure to comply with health and safety policies.

### 8.3 CHEMICAL HAZARDS

The Chairman EPC 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;
- 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;
- 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.

#### 8.4 RADIOLOGICAL HAZARDS

i. The Chairman EPC 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. URB shall review and approve uses of radioactive materials and radiation producing machines, and is to recommend radiation policies to the Vice-Chancellor.
- iii. All regulated radiation activities at the Bingham University will be open to inspection by URB 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.

## 8.5 POLICY ON IONIZING RADIATION

#### 8.5.1 Definitions

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 Bingham University 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.

Bingham University 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.

### 8.5.2 Policy

Bingham University 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:

- Radiation Safety Committee headed by the Vice- Chancellor as the license holder.
- The Vice-Chancellor may wish to nominate an officer who is a member of the standing Radiation Safety Committee as Chairman in his place.
- Radiation Safety Supervisor

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 Bingham University 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 Bingham University Ethical Advisory Committee shall scrutinize risk assessment and make judgments on exposures (medical exposures) in this category. The Bingham University through the Radiation Safety Committee shall regulate:

• Use of electrical equipment to produce X-rays for the purpose of research and radiography.

- Use of accelerators (except electron microscope).
- Use radioactive sources and nuclear materials.

At the Bingham University, 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:

- Nigerian Safety and Radiation Protection Act 1995
- Nigerian Nuclear Regulatory Authority Act 2001
- Nigerian Basic Ionizing Radiation Regulations (NIBIRR) 2003

## 8.5.3 Procedures / Guidance

# 8.5.3.1 Responsibilities 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).

## 8.5.3.2 Radiation Protection Advisor

Bingham University 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.

## 8.5.3.3 Radiation Protection Officer

The Radiation Protection Officer is a member of University staff, and shall be a member of the Radiation Safety Committee; he/she 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).

## 8.5.3.4 Radiation Safety Committee

The Radiation Safety Committee shall be a standing Committee of Bingham University 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 in Appendix E.

### 8.5.3.5 Radiation Protection Supervisors

Faculties in the Bingham University 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.

### 8.5.3.6 Appointed 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.

### 8.6 BIOLOGICAL HAZARDS

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

## 8.6.1 Scope

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.

## 8.6.2 Procedures

- i. All research involving biological materials listed under 5.4a. Should be registered with URB after approval by 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

 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 NINE

## **RESEARCH AND DEVELOPMENT**

### 9.1 TRANSLATING RESEARCH FINDINGS INTO PRODUCTS

Product Development Committee (PDC) shall translate research findings into usable products that can solve societal problems and generate growth and development opportunities.

### 9.2 Translational Objectives

PDC 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;
  - establishing a Central Collaboration Committee;
  - establishing a Unit under PDC for Research Extension Services;
  - signing and executing Memoranda of Understanding with Research Centres within and outside Nigeria; and
  - 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:
  - interacting with schools, industries, and other establishments in their host communities and beyond;
  - focusing research activities on problems in the host community; and

- applying research outcomes to solve the problems of the community;
- v. Partnering with others within the education sub-sector to enhance the quality education nationally and globally by;
  - establishing official relationships for research purposes;
  - encouraging the host community to fund research activities; and
  - 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;
  - Inviting relevant neighbouring research centres and Institutes to its annual research review sessions;
  - 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.

#### **CHAPTER TEN**

### 10.1 RESEARCH CLUSTERS/GROUPS, CENTRES AND INSTITUTES

Research Clusters/Groups, Centres and Institutes shall be established to provide platforms to undertake interdisciplinary and multidisciplinary research to profoundly address research questions in a broader way. These platforms shall be managed using the guideline for the establishment of Research Groups/ Clusters, Centres and Institutes that will be setup by the University Senate.

#### 10.1.1 Attributes of Research Clusters/Groups, Research Centres and Institutes

- i. Research Clusters/Groups: Research Groups shall be established and consist of researchers undertaking interdisciplinary and multidisciplinary research as an emerging group with a defined research scope. The Research Cluster/Group shall consist of 5 10 research members, with a Principal Investigator or Team Lead and a Deputy (Co-Principal Investigator). The Research Clusters/Groups are important platforms that will collaborate with other research groups to provide a multidisciplinary outlook in addressing research queries and also form the primordial unit for the establishment of Research Centres as they grow over time. The Research Cluster/groups shall:
  - a. Develop research proposal within their scope
  - b. Provide specialized services to the community based on their skills and special capabilities
  - c. Contribute to the development of policies or policy review related to their area of competence
  - d. Collaborate with stakeholders/institutes/organizations to advance their core area of interest.

- The URB shall midwife the formation of Research Clusters and guide members of the Research Clusters/Groups.
- iii. Research Institutes and Centres: Research Institutes and Centres shall be established to address competitive and impactful research. Research Centres shall position, promote and project the University's areas of research excellence and develop and strengthen the University's research reputation. The research centres shall also serve as a platform for interfacing with other research institutions, industries, public or private organizations; and a medium for facilitating interdisciplinary and multidisciplinary collaborations. Similarly, the research centres, which are made up of several Research Clusters/Groups, shall be able to make substantial impact to solving local community, state, national, continental and global challenges in diverse areas in unique ways and approaches.

Research Institutes and Centres shall:

- a. Absolutely align with the strategic interests of the University
- b. Demonstrate convergence with the University's Research Strategy
- c. Strategically align with the priorities of research funders and compete and bid for Research or implementation funding.
- d. Compete for research funding and implementation of grants.
- e. Be of high quality with demonstrable evidence of international best practices.
- f. Translate knowledge to solutions for real world problems.
- g. Organize colloquia, workshops and capacity building and research/ programmes, Implementation of projects, in collaboration with statutory bodies of the University.
- h. Demonstrate the highest level of financial management and capacity for research.

- i. Provide quarterly and annual reports as and when due on the activities of the Institutes or Centres.
- j. Function in accordance with the laws of the University and the governance framework for the operationalization of Institutes and Centres.

## **10.1.2** Approval body for Research Institutes and Centres

Senate shall approve Research Institutes and Centres upon recommendation by either the URB or the Academic Planning Unit. The title "centre" or "institute" shall only be used after approval. Other research groups not approved shall use other general identifiers such as "project" or "group".

# **APPENDIX A:**

# CONTRACTUAL AGREEMENT FOR RESEARCHES

Please refer to the conditions of the research contract (overleaf) before filling out this form

# 1.Title of project

.....

# 2. Full details of PI and the collaborators

Name(s)	Institutional Address	Mobile No &	Role in the project	Signature
		Email address		
a.				
b.				
с.				
d.				
е.				
f.				
g.				

(Attach on separate page in case of extra collaborators)

- 3. Funding agency:-----
- 4. Sponsor's Code Number (If External):-----
- 5. Bingham University code Number-----

**6**. **Compliance with Project Proposal:** The project shall be implemented as per the details contained in the approved project proposal, which is attached hereto. Any changes in project plans shall be undertaken only if approved by the University and or the project sponsor.

7. Duration of Engagement: The project shall be undertaken for a period of ------ months/years plus any additional extension approved by the parties, and I undertake to avail my professional services for the full life of the project.

**8. Funding:** The University, or the external sponsor through the University, undertakes to provide funding for the proposed project for the total amount of ------ Funds will be disbursed annually at a maximum------ per year for a maximum of three year(s). The first instalment shall be released on satisfactory completion of this agreement and dully filled forms of Key Performance Indicators(KPI), Intellectual Property (IP) audit forms and Grants charts. Annual disbursements of subsequent instalments shall be subject to satisfactory technical/financial reports and Monitoring & Evaluation report.

9. Planned reporting schedule: Quarterly:----- Semi-annually:----- Annually:-----

Report No.	Period Covered	Date report expected
1 <sup>st</sup>		
2 <sup>nd</sup>		
3 <sup>rd</sup>		
4 <sup>th</sup>		

## **10. Planned disbursement schedule**

Instalment No.	Date	Amount
1 year		
2 year		
3 year		
Total		

**11.** Adherence to Bingham University employment policy: All supporting staff, e.g. secretarial, technical and auxiliary will be from among the Bingham University staff/students. Permission to employ staff outside Bingham University.

# 12. In case of unsatisfactory technical and /or financial performance:

- i. Bingham University reserves the right to withhold disbursements, partially of fully, if it is not satisfied with the progress of the project.
- ii. If poor performance is detected over two consecutive progress evaluations, Bingham University shall have the right to terminate the forthwith, in accordance with policy on premature project
- iii. In case a project does not commence six months after the award, Bingham University reserves the right to rescind the decision.
- iv. In case the principal investigators leaves/ resigns or abandons the project, the research team reserves the right to appoint a new PI. This is subject to submission of satisfactory technician and financial reports.

**13. Intellectual property rights:** Copyright ownership shall be determined in accordance with the Bingham University policy currently in force.

# 14. Declaration:

I, -----, being the principal Researcher in the project named above, undertake to implement the project under the terms and conditions stated herein.

\_\_\_\_\_

-----

-----

**Principal Investigator** 

**Director**, URB

-----

**Vice Chancellor** 

Date

# **APPENDIX B:**

## **PROGRES REPORT**

- 1. Use Gantt charts with elaborate footnotes for each activity ( Planned and achieved)
- 2. Financial Statement of Income and Expenditure during reporting period

Project TitleBHU Ref:										
Report No: Period Covered: to to										
	Amount Funds Funds Bala									
		brought	Received	Expended						
		forward								
1.	Consumables									
2.	Personnel									
3.	Equipment									
4.	Travel costs									
5.	. Students stipends and fees									
6.	Student bench									
7.	Equipment's costs									
8.	Laboratory costs									
9.	Field work costs									
10.	Consultants									
11.	Printing and publishing costs									
12.	Workshops/Conference									
13.	Unforeseen costs									
14.	Co-ordination costs									
15.	Overhead charges									
	GRAND TOTAL (N)									
	GRAND TOTAL (other									
	currency)									

Note: Currency conversion rate @ N

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- 1. Amount should be shown in Nigerian currency but may be converted to any other desired
- 2. The breakdown should be as shown in the budget approved for the reporting period
- 3. Include as funds expended those for which commitments have been made
- 4. This amount is the sum of amounts in the first two columns, less the amount in the third
- 5. The balance should be reconciled with approved budget indicated in Annex V

# **APPENDIX C:**

# FORMAT FOR RESEARCH PROPOSAL EVALUATION REPORT

Project Title:	•••	•••	••••	••••		••••	
Evaluation Report:							
EXECUTIVE SUMMARY	YES					NC	)
Is clear and concise		[	]			[	]
Comments:							
BACKGROUND INFORMATION							
Introduction clearly shows need for this project		[	]			[	]
Literature Review is comprehensive, relevant							
and up to date [ ]				[	]		
Hypothesis is logical and clearly stated		[	]			[	]
Comments:							
GOALS AND OBJECTIVES [ ]				[	]		
Both are clearly stated							
Priority is clear		[	]			[	]
Objectives are achievable	l	[	]			[	]
Comments:							
METHODOLOGY AND ACTIVITIES							
Methodologies are scientifically acceptable	l	[	]			[	]
Activities are proper, well designed and related							
to all objectives stated	l	[	]			[	]
Time plan suits planned activities	l	[	]			[	]
Monitoring and evaluation plans are suitable		[	]			[	]

Comments:

PERSONNEL AND FACILITIES									
Project personnel are scientifically and									
technically capable	[	]			[	]			
Research facilities are adequate for									
implementation of the project [	]		[	]					
Comments:									
BUDGET									
All planned activities are represented in budget	[	]			[	]			
Cost estimates and total budget are realistic	[	]			[	]			
Comments:									
RATIONALE AND JUSTIFICATION									
Problem is clearly stated			[	]			[	]	
Project is technically feasible	[	]			[	]			
Cost-benefit is well reasoned out			[	]			[	]	
Comments:									
CONCLUSION: Do you recommend approv	val of	this	pro	pos	al?				
Yes, as presented			[	]			[	]	
Yes, subject to minor revisions			[	]			[	]	
No, do not			[	]			[	]	
Comments:									
ANY OTHER COMMENTS?			[	]			[	]	
(Attach additional sheets of paper for detailed con	mmen	ts)							

#### **APPENDIX D:**

# 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 of 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 quadrennials 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 Radiation Protection Officer to the University.

#### **APPENDIX E:**

#### **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.

# **APPENDIX F:**

## FINAL RESEARCH REPORT

Investigators:	•••••	 	

Project Sponsor:....

Report Date:....

## Table of Contents

A research report should include the following headings:

- a) Abstract/Executive summary
- b) Acknowledgements
- c) Table of contents
- d) List of figures
- e) List of symbols
- f) Introduction
- g) Objectives
- h) Literature review
- i) Methodology
- j) Experimental /Activity details
- k) Results
- l) Analysis and Discussion of the results (Activity of planned objectives, constraints,

Conclusion and Recommendations)

- m) Comments on expenditure accounts
- n) Reference / Bibliography
- o) Tables
- p) Plates
- q) Figures

r) Appendices (e.g. original work schedule, original project budget, expenditure accounts, etc.)

Report Format

- All headings should be left justified
- Line spacing should be single and fonts should be 12.
- Margins should be 1.5 inches on the left and 1 inch on all other sides
- Typing should be on one side of the A4 page
- Format for quoting reference numbers in the text and reference should be standard.
- British Citation Standard BS 5605:1990 is recommended. Any other standard that is recommended for certain professions could also be used
- Report cover shall be as shown in the attached format

#### **APPENDIX G:**

#### **RESEARCH CONTRACTS CONDITIONS**

#### EMPLOYEE PATENT, RESEARCH AND PROPRIETARY RIGHTS AGREEMENT

I understand that my duties as an employee of Bingham University may include some form of research and access to proprietary data.

I agree that the facilities, equipment's, funds, and/or stimulation provided to me by or through the University has greatly contributed to my effort and the conception and/or reduction to practice of discoveries, invention, development of apparatus, or software and/or the creation of related documentation, data, reports (hereinafter referred to as proprietary information).

Consideration of my employment with and/or studies in the University; and in order to settle in advance any question regarding the ownership of any patent or copyright which may be granted to me, or the rights in any propriety information which may be developed by me.

I agree that the University shall own any proprietary information that is conceived by me, either solely or jointly with others, during the course of my employment and/or through the use of facilities and/or equipment of the University, whether made during my usual working hours or otherwise, and the University also shall own any patents or copyrights relating to such proprietary information.

I further agree that I will promptly and fully disclose such proprietary information to the URB/PDC. I will co-operate with the University in making application for Nigeria and foreign patents or copyright at the request of and at the expense of the University should it determine, in its sole discretion, that an application is warranted. I will do all acts required to assist the University in obtaining, maintaining, and enforcing patents and copyrights or other

protecting proprietary information in any and all countries, all to be done without further compensation to me as spelt out in the policy.

Upon request of the University, I will assign to its Management Board all proprietary information and/or application for patents and/or copyrights issued on such proprietary information based on my disclosure, with full rights, powers and privileges of ownership.

The University may: Determine in its sole discretion that the ownership of the proprietary information will not be retained by the University and it will notify me of the relinquishment of its rights to me.

Notify me that the proprietary information will be accepted on a provisional basis.

Accept the proprietary information. The URB may assign the ownership of the proprietary information and/or application, patent, or copyright on such proprietary information back to me should it determine, in its discretion, that further expenses for development is unwarranted.

**Principal Investigator** 

**Director URB/PDC** 

**Vice-Chancellor** 

Date

For Enquiries contact:

University Research Board

Bingham University