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RESEARCH ETHICS POLICY

UNIVERSITY OF GHANA

Research Ethics Policy

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1. Purpose of Policy

This document accentuates the University of Ghana (UG) policy regarding ethical conduct of research involving human and non human participants. The purpose of the policy is to:

i. Have complete oversight of all UG's ethics committees.

ii. Ensure that research activities involving human and nonhuman participants are reviewed.

iii. Ensure that ethical standards for the care and protection of human and non human participants are adhered to.

iv. Ensure that research activities within UG comply with national and international regulations.

2. Aims

i. The UGwide research ethics policy is a document aimed at guiding and governing research activities involving human and nonhuman participants.

ii. For proper oversight and regulation of research, UG maintains five separate independent ethics committees namely: Noguchi Memorial Institute for Medical Research – Institutional Review Board (NMIMRIRB) and Ethical and Protocol Review Committee (EPRC) for all medical/health science related protocols; Ethics Committee for Basic and Applied Sciences (ECBAS); Ethics Committee for the Humanities (ECH) for all research within the Social and Behavioral Sciences, Arts, Business and Law; and Institutional Animal Care and Use Committee (IACUC) for all animal related protocols.

iii. All five (5) UG ethics committees will serve as administrative bodies to protect the wellbeing of human and nonhuman research subjects in research activities within UG

iv. Research activities conducted within or outside the university by a university staff or in collaboration with a university staff shall be required to conform to these guidelines.

v. The policy is to foster a culture within UG that embraces the relevant legislation to protect the rights, dignity and wellbeing of research participants.

vi. The policy aims at maintaining a review process that is subject to constant scrutiny.

3. Key Definitions

Word/Term	Definition
Benefit	The acquired right or privilege through a contract where payment of money or the giving of gifts is applied. It might also involve the impacted outcome of the research to the participants involved.
Confidentiality	The rules or promise that limits access to, or places restrictions on, types of information that have been received through an interaction with participants of a research.

Conflict of Interest	A conflict of interest is a variance between an individual's professional obligations and his or her private interests. Such a circumstance makes it possible for professional judgment or action regarding a principal interest to be overly influenced by a minor interest. This may lead to actual misconduct when consideration of personal gain or financial influence compromises an individual's judgment or action in the performance of his or her primary responsibilities.
Human Participants	Any living individual about whom an investigator conducting research obtains information or biospecimen as part of data collection and analysis. These include the use of surveys, questionnaires, interviews, focus groups or participant observation
Informed Consent	This is the voluntary choice of an individual to participate in a research based on the appreciation and understanding of the facts, implications, benefits and future consequences of the research (factors that may affect their decision to participate). In order to provide informed consent, the individual must have adequate reasoning abilities and must be in possession of all the relevant facts at the time of giving consent.
Investigator	An individual who devotes him- or herself to a systemic investigation or inquiry.
Minor	A person under the legal age of being an adult.

Research	A systemic investigation (i.e. the gathering and analysis of information) designed to develop or contribute to knowledge.
Research Protocol	A detailed plan of study; it should include the project title, project summary, project description, ethical consideration(s), gender issues and references.
Risk	The potential for a chosen action to lead to an undesirable outcome that may affect participants or researcher(s) of a study.
Social and Behavioural Research	A study conducted by researchers in disciplines across the boundaries of Behavioural and Social Science.
Special Protection	The basic principles governing the ethical conduct of research involving human participants. These include the capacity to consent, freedom from coercion and the comprehension of risk involved.
Standard Operating Procedure (SOP)	The detailed written instructions that have been put in place to achieve uniformity in the performance of a specific function by an institution.
Vulnerable Population/ Person	Person(s) without the capacity to make an informed decision as a result of their mental or emotional limitations. Vulnerable persons may include children depending on their age and some category of adults. They may be susceptible to exploitation or significant harm.

4. Scope of Policy

The term 'Investigator' in this policy, refers to UG staff and students, and to other persons involved in collaborative research at UG. Persons involved in collaborative research must agree in writing that this policy shall apply to them, whether the research is being conducted on or outside UG's premises.

5. Basic Ethical Principles

The fundamental principles that govern the operations of the UG Ethics Policy are the Declaration of Helsinki (1996); the International Conference on Harmonization, Good Clinical Practice [ICH GCP (E6)] Guidelines; Council for International Organizations of Medical Sciences (CIOMS); Belmont Report; and the Applicable Laws and Statutory Regulations of Ghana and the University.

5.1 Respect for Persons

This principle seeks to ensure that human participants have adequate information on the potential risks and benefits of the research to enable them to make informed decisions about their voluntary participation. Respect for persons encompasses two ethical principles:

i. Respect for Autonomy

This maintains that each individual is considered as an autonomous person, capable of making rational decisions about their personal choices. Thus, individuals should be treated with respect for their selfdetermination capabilities.

ii. Protection of Persons with Diminished Autonomy

This principle requires that individuals who are vulnerable or

dependent be offered security against harm. Though the principle of respect must be extended to the community in which the research is being undertaken, it is possible that its application may be difficult in certain instances.

5.2 Beneficence

It relates to the commitment to minimize the potential risks and maximize the potential benefits associated with the research. This is necessary because participating in biomedical or behavioural research exposes participants to some level of risk which should be justified by the expected benefits to the participants or the society. There are three categories of risk to which participants could be exposed i.e., physical, psychological, social and economic risks.

i. Physical Harm

Medical research may expose participants to some level of injury from medical procedures, since participants are likely to experience possible side effects of drugs.

ii. Psychological Harm

Participants may experience some undesirable transformation in their emotions or thought processes. These changes may be short lived, intermittent or long-lasting, but they all have the potential of causing severe psychological harm to participants.

iii. Social and Economic Harm

Where persons participate in behavioural research that require provision of some sensitive information in relation to illegal, activities (such as the abuse of drugs and alcohol) and to what they consider as private, a breach of confidentiality could result in humiliation within their community, loss of employment or criminal prosecution.

5.3 Nonmalfeasance

This principle ensures that harm is avoided to research participants. It also requires that participants are given the opportunity to withdraw from a study at any time without penalty.

5.4 Justice

It refers to the ethical obligation to treat each subject in a morally right manner and to give each person what is due them. An injustice therefore happens when a person who is entitled to some benefit is denied without reasonable cause or when some burden is unduly imposed on him.

6. Institutional Authority

The UG Research Ethics Policy establishes and empowers all five (5) UG Ethics Committees to perform the following mandates:

i. To review all research projects involving human and nonhuman participants.

ii. To respect the dignity, rights and wellbeing of all research participants.

iii. To maximize the benefit of research and minimize harm.

iv. To oversee the execution of approved projects within their ambit and schedule a yearly review of research projects to verify their compliance with approved research protocols and informed consent.

v. To approve new research projects after successful review.

vi. To initiate periodic auditing of approved projects.

vii. To request prompt reportage of any occurrences in the life cycle of all approved projects.

viii. To terminate or discontinue any previously approved protocol where necessary.

ix. To ensure research compliance with national and international guidelines.

7. The UG Research Ethics Coordinating Office

i. The Pro Vice-Chancellor (Research, Innovation and Development) is designated as the Institutional Official in charge of the UG Research Ethics Office. He/She shall have overall oversight of all human and nonhuman research conducted at the University.

ii. The UG Research Ethics Office shall be housed by the Office of Research, Innovation and Development (ORID).

iii. The Office shall have a Team leader who, together with the various Ethics Administrators, shall handle ethical issues from the five (5) UG Ethics Committees.

8. The UG Ethics Board

The UG Ethics Board shall comprise the Institutional Official, the Director of Research, Office of Research Innovation and Development (ORID), the Team Leads, and the Chairpersons and administrators from the five (5) Ethics Committees. The Board shall meet once per semester to discuss issues related to the activities of the Ethics Committees.

9. Responsibilities and Quality Assurance

9.1 Responsibilities of the University

The University of Ghana is guided by ethical principles that aim at protecting both human and nonhuman participants of research as enshrined in international guidelines, and the applicable laws and statutory regulations of Ghana and the University. In view of the above, the University shall ensure that:

i. No research exposes both human and nonhuman participants to any form of harm.

ii. Research participants are protected from any form of unnecessary risk.

iii. Only qualified personnel can conduct research involving human and non-human participants.

iv. All five (5) UG Ethics Committees are fully equipped with adequate resources and authorized to perform their duties without any form of interference from university authorities.

9.2 Responsibilities of the Institutional Official

The Pro Vice-Chancellor (RID), who serves as the Institutional Official shall:

i. Have complete oversight over all research activities involving both human and non human participants within the University.

ii. Review and approve recommendations made by the five (5) Ethics Committees for appointment or replacement of members.

iii. Ensure appropriate payments of honorarium to all Chairs and Board Members.

9.3 Responsibilities of Ethics Committees

i. Each Ethics Committee shall select a chair and vice-chair as stipulated the Standard Operation Procedure (SOP).

ii. Ensure institutional adherence to the UG Research Ethics Policy as well as national and international regulations.

iii. Ensure the protection of the rights and well-being of human and nonhuman participants.

iv. Ensure equitable selection of research participants and respect the autonomy of participants; and must understand the local research context regarding the choice of participants.

v. Have the responsibility to review, and the authority to approve, disapprove, demand modification, and suspend research activities.

vi. Ensure that informed consent forms are documented appropriately.

vii. Put in place procedures to ensure participants' privacy, maintenance of confidential data, and to adequately protect vulnerable participants.

viii. Undertake periodic monitoring of approved research.

ix. Contribute to the effectiveness of the UG Ethics Board by implementing recommendations put forth by the board.

x. Submit annual report to the Office of Research, Innovation and De velopment through the Ethics Team Leader.

9.4 Responsibilities of Investigators

An Investigator shall:

i. Design a scientifically and ethically sound research.
ii. Ensure that adequate logistics are obtained for the proposed research.
iii. Seek ethics approval before the commencement of the research.
iv. Follow Informed Consent processes
. v. Report serious and unexpected adverse events in the course of the research to the ethics committee.
vi. Submit interim and final reports to the ethics committee.

9.5 Quality Assurance

i. There shall be monitoring of the activities of the committees to ensure full compliance with the UG Research Ethics Policy and other related policies.

ii. ORID shall ensure continuous education of all the Chairs and Members of the various UG Ethics Committees on this Policy.

10. Version Control and Change History

Version Control	Date Effective	Approved By	Amendment
1	December 5, 2013	Council of the University of Ghana	June 17, 2022
2	March 30, 2023	Council of the University of Ghana	