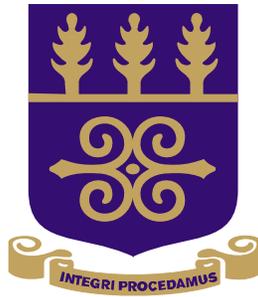


University of Ghana



Research Ethics Policy

March, 2013

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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 subjects. The purpose of the policy is to:

- i. To have complete oversight of all UG's ethics committees
- ii. Ensure that research activities involving human and non-human subjects are reviewed.
- iii. Ensure that ethical standards for the care and protection of both human and non-human subjects are adhered to.
- iv. Ensure that research activities within UG are in compliance with all national and international regulations.

2. Aims

- i. The UG-wide research ethics policy is a document aimed at guiding and governing research activities involving human and non-human participants.
- ii. For proper oversight and regulation of research, UG maintains three separate independent ethics committees namely: Noguchi Memorial Institute for Medical Research – Institutional Review Board (NMIMR-IRB) for all medical/health science related protocols; Noguchi Memorial Institute for Medical Research - Institutional Animal Care and Use Committee (NMIMR-IACUC) for all animal related protocols; and Ethics Committee for the Humanities (ECH) for all research within the Social and Behavioural Sciences, Arts, Business and Law.
- iii. All three (3) UG Ethics Committees will serve as administrative bodies to protect the wellbeing of human and non-human 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 subjects.
- vi. The policy aims at maintaining a review process that is liable 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 the access or places restrictions on types of information that has 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 circumstances create a possibility that professional judgment or actions regarding a principal interest will be overly influenced by a minor interest. This may lead to actual misconduct when consideration of personal gain or financial influence may compromise an individual's judgment and actions in the performance of his or her primary responsibilities.
Human Subjects	The use of human beings in a research process for investigation of a specific question which incorporates data collection and analysis. The process may 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 a research that may affect their person's decision to participate. In order to give informed consent the individual must have adequate reasoning abilities and is in possession of all the relevant facts at the time of giving consent.
Investigator	An individual who devotes him/herself to the 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	Research protocol is a detailed plan of a study; it should include the project title, project summary, project description, ethical consideration, gender issues and references.
Risk	The potential that a chosen action or activity will lead to an undesirable outcome that may affect participants or researcher of a study.
Special Protection	Is the basic principles governing the ethical conduct of research involving human subjects, these include the capacity to consent, freedom from coercion and the comprehension of risk involved.
Standard Operating Procedure (SOP)	This is the detailed written instructions that have been put in place to achieve uniformity of the performance of a specific function by an institution.
Vulnerable Population/Person	A person without the capacity to make informed decision based on the mental or emotional ability. A vulnerable person 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 UG’s premises or outside UG’s premises.

5. Basic Ethical Principles

The fundamental ethical 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 subjects have adequate information on the potential risks and benefits of the research to enable them to make an informed decision on 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 his personal choices. Thus, individuals who take actions based on these decisions should be treated with respect for their self-determination 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 expose participants to some level of risk which should be justified by the expected benefits to the subjects or the society. There are three categories of risk to which subjects could be exposed i.e., physical, psychological, social and economic risks.

i. Physical Harm

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

ii. Psychological Harm

Participants may experience some undesirable transformations in emotions or thought-processes. Even though some of these changes may be short-lived, intermittent or long-lasting, they have the potential of causing severe psychological harm to participants.

iii. Social or Economic Harm

Where participants participate in behavioural research that require provision of some sensitive information in relation to illegal activities, drug or use of alcohol, invasion of privacy, a breach of confidentiality could result in humiliation within one's community, loss of employment or criminal prosecution.

5.3 Non-maleficance

This principle ensures that harm is avoided to research subjects. It also requires that subjects 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 accordance with what is morally right and proper and also to give each person what is due to him or her. 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 three (3) UG Ethics Committees to perform the following mandates:

- i. To review all research projects involving human and non-human subjects.
- ii. To respect the dignity, rights and wellbeing of all research subjects.
- iii. To maximize the public benefit of research and minimize harm.
- iv. To oversee the activities in approved projects within their capacity as well as yearly scheduled continuing review and verification of compliance with approved research protocols and informed consent.

- v. Providing approval for the initiation of a new research project after successful review.
- vi. To initiate periodic auditing on approved projects.
- vii. To request prompt reportage of any occurrences throughout the approved project life cycle.
- viii. To terminate or discontinue any previously approved protocol where necessary.
- ix. To ensure research compliance with national and international guidelines.

7. UG Research Ethics Office

- i. The Pro-Vice Chancellor (Research, Innovation and Development) is designated as the Institutional Official (IO) in charge of the UG Research Ethics Office. He/she shall have overall oversight of all human and non-human research conducted at the University.
- ii. The UG Research Ethics Office shall be housed at the Office of Research, Innovation and Development (ORID) and shall coordinate the activities of the various ethics committees in the University.
- iii. The Office shall have an administrator who will handle issues relating to ethics from the three (3) UG Ethics Committees.

8. The UG Ethics Board

The UG Ethics Board shall comprise the Institutional Official (IO), the chairpersons and administrators from the three (3) Ethics Committees. The Board shall meet twice yearly to discuss issues relating to the activities of the three 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 non-human subject participants 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 non-human subjects to any form of harm.

- ii. Research subjects are protected from any form of unnecessary risk.
- iii. Only qualified personnel are allowed to conduct research involving human and non-human subjects.
- iv. All three (3) UG Ethics Committees are fully equipped with adequate resources and authorised to perform their duties independently without any form of interference from the University authorities.

9.2 Responsibilities of the Institutional Official

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

- i. Have complete oversight over all research activities involving both human and non-human subjects within the University.
- ii. Chair semi-annual meetings involving Chairpersons from the three (3) Ethics Committees and their Administrators.
- iii. Be involved in the selection of board members for the three (3) Ethics Committees.
- iv. Ensure the protection of research participants at all times.
- v. Review the qualifications and expertise of Chairs, Board Members and Administrators periodically.
- vi. Ensure that appropriate payments of honorarium to all Chairs and Board Members are made.

9.3 Responsibilities of Board Members

- i. Ensure that research activity is carried out in compliance with the UG Research Ethics Policy as well as national and international regulations.
- ii. Ensure the protection of the rights and wellbeing of human and non-human subjects.
- iii. Undertake periodic audits of research work.
- iv. Ensure the safety of research protocols and related materials.

9.4 Responsibilities of the Chairpersons of Ethics Committees

- i. The Chairperson must understand and apply the ethical principles that regulate human and non-human subject participants in research.
- ii. The Chairperson must ensure equitable selection of research participants, respect the autonomy of the participants and must understand the local research context regarding the choice of participants.
- iii. Have the responsibility to review, and the authority to approve, disapprove, or require modification, and suspend research activities.
- iv. Ensure that informed consent forms are documented appropriately.
- v. Put in place procedures to ensure participants privacy, maintenance of confidential data, and adequate protection of vulnerable participants.

9.5 Responsibilities of the Investigator

- i. The Investigator shall bear primary responsibility for the protection of human and non-human subjects in research.
- ii. To adequately explain to research subjects, prior to their participation, why they are conducting the research, what procedures research subjects should follow and the potential risks and benefits to the research subjects and the society.
- iii. The Investigator shall not coerce any individual to participate in any research unless they consent and thereby fill the informed consent forms knowing vividly the consequence of their actions.
- iv. The Investigator shall at all times respect the privacy of research subjects as well as protecting confidential information of research subjects.
- v. The Investigator must make it clear to research participants that they are free to withdraw from the research without any form of prejudice or witch-hunting.
- vi. Must ensure adequate participation and cooperation with all research quality assurance reviews.

9.6 Quality Assurance

- i. There shall be monitoring of the activities of the committees to ensure full compliance to 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.

10. Version Control and Change History

Version Control	Date Effective	Approved By	Amendment