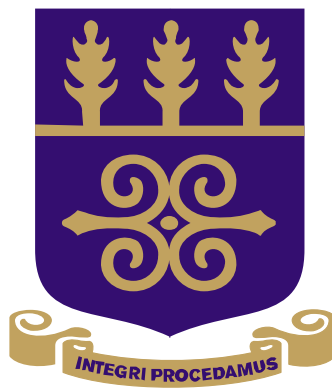


Standard Operating Procedure (SOP) for the Ethics Committee for Basic and Applied Science (ECBAS)



November, 2014

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 divergence between an individual's professional obligations and his or her private interests. Such conflicts may not be unethical and do not constitute or imply any wrong-doing. But they may lead to actual misconduct when considerations of personal gain, financial, influence or compromise an individual's judgment and actions in the performance of his or her primary responsibilities.
Institutional Official	A senior university official at the Office of Research, Innovation and Development (ORID) who is authorised to legally commit on behalf of the University. The Institutional Official in this case is the Pro-Vice Chancellor (RID).
Investigator	An individual who devotes him/herself to the systemic investigation or inquiry.
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 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	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	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.

1. Mission

The mission of the ECBAS is to ensure that research works conducted within the College of Basic and Applied Sciences are safeguarded from all risk and harm.

2. Background

- i. The Ethics Committee for Basic and Applied Sciences (ECBAS) is solely dedicated to safeguarding research works within the College of Basic and Applied Sciences.
- ii. ECBAS purpose is to review and approve research works in agricultural and veterinary sciences; engineering sciences; biological sciences; physical and mathematical sciences; and nuclear and allied sciences.
- iii. The ECBAS role is to encourage and support the scholarly ventures of students and researchers of the College regarding ethical clearance.
- iv. ECBAS will ensure that all researchers undertaking research with bio-hazardous materials that has potential threat to humans, animal and the environment are familiar with appropriate biosafety procedures.
- v. The ECBAS will ensure that research is conducted in ways that provide protection, fairness and respect to the community in which research is undertaken.
- vi. All research works within the disciplines in the College of Basic and Applied Sciences shall be conducted in an ethical manner in compliance with the University of Ghana (UG)'s ethics policy.
- vi. It should be noted that the ECBAS will review all research works (including masters and PhD research works) regardless of the level of risk.

3. Institutional Authority

The University of Ghana's Ethics policy establishes and empowers the ECBAS as an independent ethics committee with a mandate to review all research protocols within the College of Basic and Applied Sciences.

4. The Ethics Committee for Basic and Applied Science

4.1 Appointment of Committee Members

- i. The Institutional Official (IO) in consultation with the Office of Research, Innovation and Development (ORID) Management Board, shall be the appointing authority of members of the Committee.

- ii. Members shall be appointed based on their expertise, commitment and willingness to serve on the committee.
- iii. All members shall sign and abide by a confidentiality agreement.

4.2 Composition

The Committee will consist of thirteen (13) members from diverse academic and cultural backgrounds. These will include:

- i. Persons with background in the agriculture and consumer sciences
- ii. Persons with background in veterinary sciences
- iii. Persons with background in Biological Sciences
- iv. Persons with background in the physical and mathematical sciences
- v. Persons with background in the engineering sciences
- vi. Persons with background in nuclear and allied sciences
- vii. Persons with a background in research ethics
- viii. Persons with background in Health Science
- ix. A person with a background in legal issues
- x. A lay person representing the community

4.3 Tenure of Committee Members

Committee members will serve a four (4) year tenure, which may be renewed for a second term.

4.4 Meetings

- i. The Committee shall meet once every two months unless otherwise stated by the chairperson.
- ii. Members are obliged to attend all meetings.
- iii. Any member who is unable to attend a meeting must provide at least twenty-four (24) hours' notice prior to the meeting to the chairperson via email or telephone.
- iv. Major decisions and voting cannot take place unless there is a quorum (of at least seven members).

- v. The agenda and supporting documents for a meeting must be distributed to members at least two weeks prior to the scheduled date for the meeting.
- vi. Changes in meeting time, date or agenda shall be appropriately communicated to the ECBAS members at least two weeks in advance.
- vii. In the absence of the Chairperson, the Vice-Chairperson shall chair the meeting.
- viii. An ECBAS member with a conflict of interest on any research project application shall recuse him or herself from all review meetings, voting on the application, and all discussion and decision making, verbal or written, in connection with the application or research.
- ix. Where necessary investigators may be invited to ECBAS meetings to enable them to describe their proposed study and to respond to any issues raised by the ECBAS members.

4.5 Communicating ECBAS Meeting Decisions to Applicants

- i. After the completion of the review of a research project application, the Administrator shall prepare a notification letter to inform the applicant(s) or investigator(s) of the outcome of the review within three (3) working days.
- ii. The outcome of the review shall include the date the decision was reached for approved projects, the date of the next scheduled continuation review (one year from the date of approval), and the reporting requirements for the investigator.
- iii. For disapproved, suspended or terminated projects, the reasons for these decisions shall be communicated to the Investigator.

4.6 Honorarium to the ECBAS Members

An honorarium shall be paid to the Committee Members for their participation in the review process. The amount shall be determined by the ORID Management Board and reviewed periodically.

4.7 Termination of Membership

- i. Membership shall be terminated by the Institutional Official in consultation with the ORID Management Board for any form of misconduct that affects the trustworthiness of the Committee.

- ii. A member convicted by a court of law for a criminal offence shall have his/her membership terminated.
- iii. Absence from at least four consecutive meetings (without apologies) shall lead to the termination of membership from the Committee.
- iv. A member may terminate his/her appointment voluntarily by sending a resignation letter to the Institutional Official through the chairperson.

5. Responsibilities of the ECBAS

The responsibilities of the ECBAS shall be to:

- i. Ensure that research activities at the College of Basic and Applied Sciences are carried out in compliance with UG's Ethics Policy as well as national and international regulations.
- ii. Review research protocols from the College of Basic and Applied Sciences.
- iii. Conduct an assessment of the risks and benefits of the proposed research.
- iv. Ensure that all research protocols are approved before research is carried out.
- v. Monitor approved protocols to ensure their ethical conduct
- vi. Reject or suspend any research protocol that does not follow the ECBAS guidelines.
- vii. Ensure the security of research protocols and related materials.

7. ECBAS Administration and Functions

7.1 ECBAS Secretariat Responsibilities

- i. The ECBAS shall have a secretariat at the College of Basic and Applied Sciences. The Office shall be managed by an administrator (a Research Development Officer)
- ii. The Secretariat shall take charge of all documentation, records and archives related to applications as well as the management and administration of the ECBAS.
- iii. The Secretariat shall maintain a database of all ECBAS related documents including minutes of Board meetings, CVs of committee members, investigator periodic and final reports.

The Secretariat shall advise Investigators on the preparation and submission of protocols for review.

7.2 Responsibilities of Committee Members

- i. Reviewing research protocols.
- ii. Support the secretariat in the discharge of their duties when called upon.
- iii. Undertake duties assigned to them by the Chairperson.
- iv. Study documents submitted to them before meetings.
- v. Members are obliged to keep Ethics Committee documents given to them in a secure, private and confidential manner.
- vi. Attend meetings regularly and participate actively during deliberations.

7.3 Responsibilities of the Chairperson

- i. Ensure that ECBAS meetings are in accordance with all regulations.
- ii. Determine submissions that are exempt from review and inform the Committee and the submitting investigator of such exemptions.
- iii. Assign responsibilities to the Vice-Chairperson.

7.4 Responsibilities of the Vice-Chairperson

- i. In the absence of the Chairperson, the Vice-Chairperson shall perform the responsibilities of the Chairperson.
- ii. He/She shall be required to perform responsibilities assigned by the Chairperson and the ECBAS.

7.5 Responsibilities of Investigators

- i. Develop research protocol(s) in line with prescribed guidelines.
- ii. Conduct research in a manner that imposes minimal risks.

- iii. Notify the Committee of major changes to an approved protocol.
- iv. Ensure that information related to the research process will be kept confidential.
- v. Inform the Committee of the completion of a project.

8. Compliance/Non-Compliance

Non-compliance may include:

- i. Conducting research when the research protocol has not been approved;
- ii. When a research protocol violates ethical standards as a result of deviation from the initially approved protocol;
- iii. Failure to report to the Committee any harm caused.

9. Processes for Conducting Review

The ECBAS will review research protocols in one of three ways: Exempt; Expedited or Full Board Review.

9.1 Exempt Review

Research works that fall under this classification include works that represents no more than minimal risk or impact on the physical, biological and spatial environment. The Chair of the Committee and some selected committee members may review the study. The protocol will be approved within one week of receipt/after deadline.

9.2 Expedited Review

The Committee could use the expedited review process when minor changes have been made to an already approved research project within the same year. For expedited review, the Committee Chair and some selected committee members may review the study. The protocol will be approved within two weeks.

9.3 Full Review

The processes for conducting full review are reserved for the entire Committee and are used when there is a potential risk to the physical, biological and spatial environment. The

protocol will be approved within three weeks. Below are research works subject to full review:

- i. Research works with bio-hazardous materials that could potentially cause harm to humans, animals or the environment.
- ii. Research involving genetically modified organisms or crops.
- iii. Research involving organism that is pathogenic to humans and/or animals.
- iv. Research involving radiation
- v. Research works which may cause potential harm to the natural environment
- vi. Any other research that may be determined by the Chairman to require a full committee review

10. Procedure for Submitting Research Protocol

- i. An Investigator, who intends to commence a research project, shall submit an application for review to the ECBAS. The application shall include:
 - The completion of an Initial Protocol Submission Form (IPSF).
 - Submission of 13 hard copies and a soft copy of the research protocol.
 - A submission letter.
 - The Principal Investigator's CV.
 - Copies of all questionnaires, interviews guides and other data collection instruments that will be used.
 - Insurance Policies (If applicable).
 - Any other relevant documentation.
- ii. The ECBAS Secretariat shall check the application to ensure that all the necessary documents are submitted and completed. Each application shall then be assigned an individual number.
- iii. The protocol shall be stamped and entered into a database.
- iv. The ECBAS Administrator (Research Development Officer) shall distribute the application and documents to members two weeks prior to the meeting.

13. The ECBAS Records

- i. All documents and communication of the ECBAS must be dated, filed and stored in line with written procedures.
- ii. Records must be maintained for a minimum period of three years following the completion or termination of a study.
- iii. The following records among others should be maintained indefinitely.
 - The Standard Operating Procedures (SOP) of the ECBAS.
 - Recent curriculum vitae of members of the ECBAS.
 - Minutes of all meetings of the ECBAS.
 - Copies of all protocols and other documents submitted for review.
 - Correspondence between the ECBAS and Investigators pertaining to application decisions and follow-up.
 - Record of notices issued in the event of an untimely termination of a study stating reasons for the termination.
 - Progress and final reports of the study.
 - An account of income and expenses of the ECBAS.