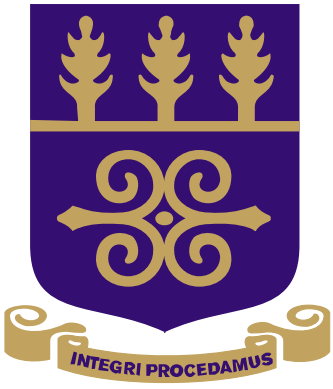
Standard Operating Procedure (SOP) for University of Ghana's Ethics Committee for the Humanities (ECH)



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1. 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 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	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	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.
Social and Behavioral Research	A study conducted by researchers in the disciplines across the boundaries of Behavioural and Social science.
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.

2. Introduction

i. Participation of human subjects within the disciplines in the humanities plays a key role in the advancement of new knowledge.

ii. Thus, research should be conducted in ways that provide protection, fairness and respect to the subject and the community in which it is undertaken.

iii. The Ethics Committee for the Humanities (ECH) shall ensure that research is conducted in a way that will protect the rights and wellbeing of human participants.

iv. The ECH shall ensure that no research subject participant is made to participate in any research without informed consent.

v. All research within the disciplines in the humanities shall be conducted in an ethical manner in compliance with the University of Ghana (UG)'s ethics policy.

3. Mission of the Ethics Committee for the Humanities

The mission of the Ethics Committee for the Humanities is to uphold all national and international guidelines and procedures that will safeguard the rights and dignity of all human subjects involved in research within the disciplines in the humanities.

4. Ethical Principles

The fundamental ethical principles that will govern the operations of the ECH are:

4.1 Respect for Persons

This principle seeks to ensure that human subjects have adequate information on the potential risks and benefits of the research that they will participate in to enable them make informed decisions and thus ensure that their participation is voluntary.

4.2 Beneficence

The ECH is committed to minimizing the potential risks and maximizing the potential benefits associated with the research.

4.3 Non-malfeasance

The principle of non-malfeasance guards against harm to research subjects. It also requires that subjects are given the opportunity to withdraw from a study at any time without penalty.

4.4 Justice

The principle of justice 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 a benefit is denied this without reasonable cause or when a burden is unduly imposed on him/ her.

5. Ethics Committee for the Humanities

The ECH is an independent committee established to review and evaluate research protocols involving human subjects.

5.1Appointment 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 the confidentiality agreement.

5.2 Composition

The Committee will have at least ten (10 members from diverse academic and cultural backgrounds. These will include:

i. Persons with a background in behavioural sciences (2)

ii. Persons with a background in social sciences (2)

iii. A person with a background in philosophy, ethics or religions (2)

iv. A person with a background in Business Studies(1)

v. A legal person (1)

vi. A member of the local community(1)

5.3 Tenure of Committee Members

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

5.4 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 five members).

v. The agenda and supporting documents for a meeting must be distributed to members at least two weeks prior to the schedule date for the meeting.

vi. Changes in meeting time, date or agenda shall be appropriately communicated to the ECH members at least two weeks in advance.

vii. In the absence of the Chairperson, the Vice-Chairperson shall chair the meeting.

viii. An ECH 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 ECH meetings to enable them to describe their proposed study and to respond to any issues raised by the ECH members.

5.5 Communicating ECH Meeting Decisions to Applicants

i. After the completion of the review of a research project application, the ECH 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.

5.6 Honorarium to the ECH Members

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

5.7 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 shall lead to the termination of membership of the Committee.

iv. A member may terminate his/her appointment voluntarily by sending a resignation letter to the Institutional Official through the chairperson.

6. Responsibilities of the ECH

The responsibilities of the ECH shall be to:

i. Ensure that research activity at UG is carried out in compliance with the UG's Ethics Policy as well as national and international regulations.

ii. Review research activities involving human subjects.

iii. Conduct an assessment of the risks and benefits of the proposed research.

iv. Approve all research protocols of approved applications before research is carried out.

v. Reject or suspend any research protocol that does not follow the ECH guidelines.

vi. Ensure the protection of the rights and wellbeing of human subjects.

vii. Ensure the security of research protocols and related materials.

7. ECH Administration and Functions

7.1 ECH Secretariat Responsibilities

i. The ECH shall have a secretariat at the Institute of Statistical, Social and Economic Research (ISSER). The Office shall be managed by an administrator.

ii. The Secretariat shall take charge of all documentation, records and archives related to applications as well as the management and administration of the ECH.

iii. The Secretariat shall maintain a database of all ECH related documents including minutes of Board meetings, CVs of committee members, investigator periodic and final reports.

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

7.2 Responsibilities of Committee Members

i. Review research protocols to safeguard the rights and well-being of study participants.

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 training and educational programmes for newly appointed ECH members.

ii. Ensure that ECH meetings are in accordance with all regulations.

iii. Determine submissions that are exempt from review and inform the Committee and the submitting investigator of such exemptions.

iv. 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 ECH.

7.5 Responsibilities of Investigators

i. Develop research protocol(s) in line with prescribed guidelines.

ii. Provide and explain approved informed consent forms to participants.

iii. Document and report on any changes related to research participants (death, injury, or replacement of a participant) to the Committee.

iv. Conduct research in a manner that imposes minimal risks to subjects.

v. Notify the Committee of major changes to an approved protocol.

vi. Ensure that information related to research subjects will be kept confidential unless otherwise permitted by the subject/participant.

vii. 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 to subjects of a research.

9. Processes for Conducting Review

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

9.1 Exempt Review

Research work that falls under this classification includes works that represents no more than minimal risk to participants, nor involve vulnerable populations. 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. Some examples of studies exempt from review are as follows:

i. Works done in established educational settings involving regular educational practices, or research on the effectiveness of or comparison among instructional techniques such as curricula.

ii. Research involving observation of public behaviour unless the information gained could be traced to particular individuals and which could thus adversely impact them.

iii. Research data obtained through the collection or study of existing data, documents, records and specimens that cannot be traced to particular individuals.

9.2 Expedited Review

This is used where there is no more than minimal risk. Additionally, 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.

Categories of studies that may receive expedited review are as follows:

i. Where the researcher participates in activities such as surveys, interviewing et cetera or by observing the public behaviour of people.

ii. Where the researcher will be using a data recording device which has been cleared or approved for marketing and is non-invasive and routinely employed in clinical practice.

iv. Where there is time urgency to the study. For example, if the subject is leaving the jurisdiction.

9.3 Full Review

The processes for conducting full review are reserved for the entire Committee and are used when there is potential risk to human subjects. The protocol will be approved within three weeks. Below are research works subject to full review:

i. Work that might materially impact the pregnancy of a woman or the health of foetuses in the uterus.

ii. Research involving subjects with life-threatening physical conditions or one that involves physically intrusive procedures.

iii. If the researcher has cause to believe, based on previous experience, that the research has the potential of risk to subjects including significant levels of physical stress and/or psychological stress.

iv. Research that places protected populations or vulnerable groups at more than minimal risk.

v. Where the researcher's work could adversely affect the subjects, such as surveys that request information that could potentially expose the subject to criminal or civil liability or are extremely personal.

10. **Procedure for Submitting Research Protocol**

i. An Investigator, who intends to commence a research project involving human subjects shall submit an application for review to the ECH. The application shall include:

- Completion of Protocol Submission Form.
- 11 hard copies and soft copies of the research protocol.
- A submission letter.
- Consent form.
- The Principal Investigator's CV.
- A copy of the advertisement of subject recruitment that will be used (where applicable).
- 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 ECH 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 ECH Administrator shall distribute the application and documents to members two weeks prior to the meeting.

11. Informed Consent

i. The ECH shall ensure that no research involving human subjects is undertaken without the researcher obtaining the informed consent of the research subjects or a legal representative of the subjects.

ii. The process of informed consent must involve the provision of relevant information in a language that is comprehensible and understood by the research subjects.

iii. Adequate time and opportunity must be provided to research subjects to decide whether or not to participate in the research.

iv. The informed consent must be obtained by the Investigator or a key person associated with the research.

v. The elements of informed consent must include:

- An explanation of the purpose of the research, the duration of the research subject's participation in the research, the procedure to follow and the identification of possible risks and benefits to the research subject.
- Adequate measures in place in the event of potential risk to the subject.
- An outline of the benefit to society of the research.
- A statement that shows the subject that adequate confidentiality of the research subject's records and data has been assured.
- A statement of assurance to subjects that their participation is voluntary and that they are free to discontinue with the process at anytime.

vi. Informed consent is documented by the use of a written consent form which must be signed and dated by both the subject (and legally authorized representative) and the Investigator.

vii. A copy of the signed and dated form must be given to the subject (or legally authorized representative).

12. Vulnerable Population and Special Protections

i. The ECH will consider certain groups of human participants to require special protections because they may be particularly vulnerable to coercion, undue influence, or risk in a research setting; these include, but are not necessarily limited to:

- Children and infants (minors)
- Fetuses and human in vitro fertilization
- Pregnant and lactating women
- The mentally ill
- The intellectually disabled
- Prisoners

ii. In reviewing research projects, the ECH will exercise special rigour in the review of research protocols involving such vulnerable groups, to ascertain that their participation is adequately justified, and additional safeguards are implemented to minimize risks to them.

13. The ECH Records

i. All documents and communication of the ECH 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 ECH.
- Recent curriculum vitae of members of the ECH.
- Minutes of all meetings of the ECH.
- Copies of all protocols and other documents submitted for review.
- Correspondence between the ECH 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 ECH.

Appendix

Guidelines for determining the Need for Committee Review

The Committee may decide on when a study needs to be reviewed or not. This will be based on the risk that is posed to the subjects involved and this may be expedited review (i.e., when review is conducted outside the scheduled meeting time of the committee) or by the full committee. Not all research that requires human subjects will require review. The following are some of the types of research that may or may not require a review.

a. General survey and interview research: this involves a research where the participants' behavior are not manipulated or deceived.

May require review, either expedited or full	May be exempt from committee review
Where research participants are minor, or adults not capable of giving consent or patients	Where research participants are capable adults
Where the research deals with sensitive topics	The topic is not sensitive.
Where identifiers are recorded or linked to data	No identifiers are recorded with or linked to data
Where participants are recorded on audio or video tape with their knowledge and consent.	Where any information that becomes known outside the research may not potentially harm the participants' reputation, legal or social standing or

b. Survey or interviews with elites or government officials: this is a written or oral questionnaires or interviews conducted with public officials (corporate, government, social or religious officials etc.)

May require review, either expedited or full	May be exempt from committee review
The research deals with sensitive topics relating to participants own behavior	The survey or interviews involves elected or appointed public officials or candidates for public office
Participants are recorded on audio or video tape with their knowledge or consent.	Where the survey or interview involves a public official but does not deal with sensitive topics relating to the participants own behavior.

c. Observation Research: this is a research where the investigator observes, and perhaps records public or private behaviour. It may include interaction with the participants and they may or may not be recoded.

May require review, either expedited or full	May be exempt from committee review
Investigator interacts with participants and/ or manipulates participant's behavior.	Where the investigator does not interact with participants
Where observation takes place in a private location, or where the participants have reason to believe that they are not observed.	Where the participants behaviour are not manipulated
Where participants behaviour are recorded on audio or video tape	Where the observation takes place in a public location
Where the research involves participants observation or anthropological fieldwork.	Where participants identities are not linked to data or recorded

d. Research of existing records: studying, re-analyzing or using an already existing data collected by another investigator or agency for research or other purposes. The Committee would have to assess under what circumstances the data were originally collected and if participants were aware of the future use of their information.

May require review, either expedited or full	May be exempt from committee review
Analysis of existing records or data with identifiers attached.	Reviews or reanalysis of previously collected data from which no participants are identified.
Follow ups studies, where participants are re-contacted and new data are collected or correlated with existing data	Review of publicly available records such as census data.

e. Case studies: research where in-depth data are collected on one or more subjects for the purpose of analysis to yield generalizable knowledge data. Participants may or may not be identified in the report

May require review, either expedited or full	May be exempt from committee review
Research involves sensitive data.	Research in which no sensitive data are collected.
This will be reviewed if the participants' identities may be determined from the information in the research report.	Where participants identities are not incomprehensible in any research report.