Submission Checklist

What do I need to include in the application? Which documents do I need to submit?

The following is a list of documents that should be provided with an ethics application to guarantee a complete and timely evaluation. Please note that **NOT ALL** documents should be attached – this is depending on the nature/objective of the research study.

Please use the checklist on **Page 4** to check whether the required documents applicable to your study have been developed and attached. This serves as a guide to check that the applications are complete for ethics review.

1. * **Research proposal**

A complete and detailed research proposal is required (see page 5 what information to include).

2. * **Executive summary or synopsis of the project** (minimum 2 pages)

This is an abstract that comprises all central elements like populations, objectives, rationale, methods, time frames and expected outcome. The outline of the executive summary: Name of researcher/student, Staff/Student Number, Title of project, Introduction, Motivation and Literature (1 Paragraph), Research questions (1 Paragraph), Study Objectives/Aims (4 lines), Research Methodology (clear, concise and to the point (5 lines), Ethical Considerations (State clearly and how this fit the research context (4 lines).

3. **Research tool or data collection instruments i.e. questionnaire or interview questions** (where applicable)

The instruments to be used for data collection should be attached to your ethics application. This includes, but is not limited to, interview questions, questionnaires, observation schedules, film and or visual/audio instruments. If these instruments are not in the public domain (i.e. you do not own the copyright or you need to obtain permission to use the instruments), please include the letter from the copyright-holder, granting you permission to use the instrument.

4. * **CVs of researchers/investigators**

5. **Consent form** (where applicable)

It is a document with details that indicates that the participants have freely decided to join the study. An informed consent form should be prepared for all participant groups. If these forms require translation into other languages, proof of translation should be attached to the

application to certify that it is an accurate representation of the original document.

6. Assent form (where applicable)

It is a document with details that indicates that minors have freely decided to join the study; in the case, adults have to give consent on their behalf). Assent forms should be prepared when obtaining assent from minors (children under the age of 18 years). If these forms require translation into other languages, proof of translation should be attached tothe application to certify that it is an accurate representation of the original document. Please note that assent forms should be prepared for the parents/ legal guardians of participating minors for their permission to allow the child to participate in the research study.

7. Information sheet (where applicable)

Document with details of the study that are shared with the participants before deciding to participate in the study. An information sheet may be a copy of the informed consent form that is given to participants which they can take home and read in their own time. An information sheet also refers to the written script thatwill be used when obtaining verbal consent from participants. Applicants need to indicate whether they will disclose the purpose(s) of the research to participants fully, partially or not at all in the application. Intended *partial disclosure* should be fully motivated in the Research Proposal or in a separate, detailed statement which indicates why partial disclosure is suitable for data collection. Contingencies, conditions, possible interpersonal, social, and other consequences and their mitigation should be fully elaborated, including participant debriefing where necessary. The statement should be signed and dated by the Principal Investigator and the Main Supervisor (in the case of postgraduate studies).

8. Permission letters (where applicable)

The applicant need to obtain permission from relevant authorities, organisations or institutions to access their data/information **OR** to collect data from communities that is not in the public domain. Such authorities, organisations or institutions may include traditional authorities, Governors or Regional Counsellors, the National Council on Research, Science and Technology (NCRST), Ministry of Environment, Forestry and Tourism (MEFT), and the Ministry of Health and Social Services (MoHSS). Permission should also be sought from an employer/organisation if their employees/members will be invited to participate in the study. In addition, permission to use archives/data collection instruments that is not in the public domain should be sought from the relevant curators/copyright holders. If the applicant does not have the official letter granting permission, the applicant may attach the letters used to request such permission for the Committee's acknowledgement.

9. Recruitment material (where applicable)

If flyers, email correspondence or advertisements will be used to recruit participants to participate inthe research study, the documents/emails should be attached for review.

10. All other documents relevant to and in support of the application, including statements that may be required by elements of this application.

Including

(a) Sponsorship Agreement(s) Including Full Budget item lines - An agreement or relevant correspondence of funders or bursars if this Research Project is supported by a bursary, grant or any other source of funding, the conditions of funding must be disclosed.

(b) Investigator's Declaration

*** Compulsory**

Checklist for ethics applications (what documents to include in the application?)

- ☐ * Research proposal
- ☐ * Executive summary or synopsis of the project
- ☐ Research tool or data collection instruments i.e. questionnaire or interview questions (where applicable)
- ☐ * CVs of researchers/investigators
- ☐ Consent form (where applicable)
- ☐ Assent form (where applicable)
- ☐ Information sheet (where applicable)
- ☐ Permission letters (where applicable)
- ☐ Recruitment material (where applicable)
- ☐ Sponsorship Agreement(s) (where applicable)
- ☐ Investigator's Declaration

*** Compulsory**

You may use the checklist below as a guide to check whether the required documents that are applicable to your research study have been attached to your application. Please note that the checklist is a list of most frequently requested documents that are necessary for ethics review. Additional documents may be requested, depending on the nature and ethical risk assessment ofyour study.

It is the responsibility of the researcher to ensure that the necessary permission(s) from relevant authorities/organisations/institutions have been obtained to conduct data collection.

Please note that this checklist serves as a guide for applicants to check whether they have all the necessary documents to ensure a timeous and relevant review of their proposal. This checklist is notrequired for ethics review.

Checklist for research proposal (what information to include in the research protocol?)

- ☐ General information - Comprises of protocol title, name and address of sponsors and investigators, and research settings institutions.
- ☐ Rationale and Background information - It should give concrete reasons for doing the study and its relevance.
- ☐ Study goal and objective - These statements should indicate the proposal hopes to accomplish both broadly and specifically.
- ☐ Study design - It should give detailed information on the type of study, population, sampling frame and both inclusion and exclusion criteria for participants.
- ☐ Methodology - This is the essential part of the protocol, which needs to clearly show the interventions, procedures, and measures to be taken in the study. For social sciences research, interventions can be training for participants and procedures can be questionnaire surveys or focus group discussions.
- ☐ Safety consideration - How will the health and rights of participants be safeguarded and protected.
- ☐ Data management and statistical analysis - How will the data be collected, will it be paper-based or with an Electronic Data software.
- ☐ Quality assurance - Includes all techniques employed to ensure quality control, data integrity, and reliability. For example, Good clinical research practice ensures standards in designing, conducting and recording data in clinical research involving human beings.
- ☐ Expected outcome of the study - It should clearly show how the study will contribute to advancing knowledge.
- ☐ Dissemination of results and publication policy - Where will the results be disseminated and in what format, for example academic paper, reports or social media publications.
- ☐ Duration - What is the schedule for data collection, analysis and reporting.
- ☐ Anticipated challenges -What makes this study particularly challenging or what primary risks should be addresses for the success of this study.
- ☐ Project management - It should detail each team member's responsibility and roles in the study.
- ☐ Ethics - It should highlight issues that might raise ethical concerns and an informed consent process.
- ☐ Conflicts of interest - A conflict of interest occurs when the team behind the study could perceive an external economical benefit if this study would be carried out. An example of this

is if the researchers are conducting a clinical trial to validate the clinical benefits of an invention of their own.

- Data sharing - The impact of your research can be multiplied when you make your raw data openly available to other researchers. For this to be successful and ethical, there is a need for proper planning.