

MINISTRY OF HEALTH, WELLNESS AND THE ENVIRONMENT
RESEARCH ETHICS COMMITTEE
CHECKLIST FOR DOCUMENTS - REQUIRED FOR PROTOCOL SUBMISSION

- 1. COMPLETED APPLICATION FORM**
- 2. SUMMARY OF PROPOSED STUDY** – not more than 250 words
- 3. THE PROJECT PROPOSAL/PROTOCOL**
- 4. THE INFORMED CONSENT FORM**
- 5. CURRICULUM VITAE OF ALL RESEARCHERS, COLLABORATORS**

A. THE PROJECT PROPOSAL must include:

- A. An Introduction and Background information on the research topic
- B. A clear statement of the Objectives of the research proposal
- C. The Justification for the research (*This should include a review of the current knowledge from the literature on the topic, with an explanation why this project is necessary, and how it will contribute to the overall knowledge in this area*)
- D. Materials and methods. These include:
 - Details of procedures to be performed (*e. g. volume of blood, the frequency, timing, and possible site of the blood-taking; any drug administration, physiological measures, etc.*)
 - Which procedures may cause pain and/or discomfort for research participants, which are new (i.e. experimental), and which are routine procedures that would have been done on the participants even if they were not involved in the study.
 - Choice of participants, inclusion and exclusion criteria, number of participants (and a justification for that number), any controls, etc.
 - A statement that participants were selected only because of the specific problem under investigation, and not because of their easy availability, diminished autonomy, or any social bias.
- E. The name, address, telephone and fax numbers, as well as email address of a contact person
- F. A statement confirming that reasonable time will be given for the participant to consider his/her involvement.
- G. Procedures for obtaining informed consent, including statements that the researcher/s will read the informed consent form to the participant or his/her legal guardian and will provide that person with a copy of the form, that questions from the person will be invited, and that all efforts will be made to ensure that s/he understands its content before the seeking of consent
- H. A copy of the informed consent form and recruitment posters

I. Methods to protect the confidentiality of participants, and methods to ensure that a participant who opts out of the research is well protected as far as health care delivery is concerned and not disadvantaged in any way.

J. Details of Methods for data collection, analysis and secure storage

K. Assumptions made

L. Relevant references (i.e. literature citation)

M. A copy of any questionnaires to be administered

(Also note – pages of the Project Proposal should be numbered)

B. SUMMARY OF THE PROPOSED STUDY (SEE TEMPLATE)

Should include:

- I. Summary of the research question
- II. The hypothesis and scientific basis or justification for the Study
- III. The usefulness and significance of the Study (the potential value of the research for public health, etc.)
- IV. The population and interventions involved
- V. An assessment of the benefits (to participants and/or groups in the community or to the entire community), and the risks for participants
- VI. An outline of the Study design, methods, and main outcomes
- VII. Names of participating institutions and countries
- VIII. An indication of steps taken to ensure and maintain confidentiality