ETHICS REVIEW COMMITTEE

Postgraduate Institute of Medicine
University of Colombo

Part III

Instructions to applicants, specimen information sheet and consent form

(Please do NOT submit copies of this section)

This application can be preferably filled on-line and the space will expand as you type.

a. Conditions of application

The ERC will review all types of research proposals involving human, animal and cadaver studies. Review of proposals will incur a handling fee.

All sections of the application form should be filled concisely, giving pertinent information according to instructions given below and in the application form. Failure to comply with these instructions would result in the application being returned, leading to a considerable delay in obtaining ethical clearance.

b. Instructions and guidelines for completing the application form

Item 12 - Objectives of the project should be clearly stated.

Item 13 - This should consist of a precise description of all proposed interventions involving human/animal or cadavers for which clearance is being sought, and should include the following:

a) Criteria used in the selection of subjects (who, how, where):

b) Procedure to be carried out on the test group by whom, when, where:

c) Safety measures employed during the procedure: e.g. handling of biological specimens, radioactive materials and disposal, safety measures for the investigators/staff/patients.

d) Treatment for the control group: e.g. conditions applied to the control group including special & concurrent therapies & treatment, how/what concomitant therapies will be allowed.

Post graduate trainees should forward the applications through the supervisor/s.

Instructions for submitting information sheet and consent form

All studies involving human participants must have;

A) Information sheet/s (for verbal and written consent) addressing each category of participant
B) A consent form

Forms A and B must be on separate sheets of paper

C) An assent form: for studies involving children aged 16 years – 18 years child's assent must be obtained in addition to the parent's or guardian's consent.

Form A – Information sheet

Information about the research project should be presented in the form of an information sheet, written in simple language that is easily understood by the potential research subject. The following format is given as guidance and could be adopted to suit your study.

The information sheet should be prepared by the researcher addressing the participant where as the consent form is declaration by the participant.

The subjects must be given adequate time to study the information sheet and to consult their families and their family doctors where appropriate.

Specimen – Information sheet

I/We (name of principal investigator/s) attached to (institute/s of affiliation) would like to invite you to take part in …..

- The title of the research project
- The purpose of the investigation;
- The procedures;
- The risks (including psychological distress) and benefits, or absence of them, to the individual or to other or future individuals or to society;
- A statement that the subjects may decline to participate (without incurring displeasure or any sort of penalty in the case of a dependent relationship, i.e. patient, student, employee) and also will be free to withdraw at any time without giving a reason and without in any way impairing their care; and
- An invitation to ask questions
- The names and contact information of investigators

Form B – Volunteer consent form

For written consent, the respondent must sign a form which states that the information sheet has been read and discussed with the investigator and that the subject agrees to participate.

Specimen – Volunteer consent form

Name(s) of the investigator/s:
Personal contact information of principal investigator/s:
Address of the institution where the study is to be carried out:

The title of the research project:

I ……. (the participant's name) have read the information sheet and understand

a. What the study involves
b. That refusal to participate in the study will not affect my treatment or care in any way.
c. That I may withdraw at anytime and it will not affect me adversely in any manner

I …….. (the participant) have had an opportunity to discuss the matters related to the study and ask questions and they have been satisfactorily answered.

I therefore agree to participate in this study

Signature of the participant

Full name
Date
Postal address

I have been present while the procedure has been explained to the participant and I have witnessed his/her consent to take part in the study.

Signature of witness
(The witness should be person NOT connected with the study)

Full name
Date
Postal address