Form IA

Proforma to be submitted to the Pondicherry University

Format for Ph.D/MSc Students/Faculty research

Details of the proposal

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Sources of funding :
5. Objectives of the study :
6. Justification for the conduct of the study:
7. Methodology: It should provide details of number of subjects, inclusion criteria, exclusion criteria, control(s), study design, dosages of sample, duration of treatment, investigations to be done etc.
8. Permission from Drug Controller General of India (DCGI) if applicable:
9. Ethical issues involved in the study as assessed by the investigator:
10. Whether Consent forms in English and in local language are enclosed?
11. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

Certificate

We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigator 1 (Student): Date :

Signature of the Investigator /Supervisor: Date :

Signature of the Head of the Department Date:

Form IB

Proforma to be submitted to the Institute Ethics Committee (Human Studies)

(for projects other than those mentioned in Form I A)

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Sources of funding:
5. Objectives of the study:
6. Justification for the conduct of the study:
7. Methodology: It should provide details of number of subjects, inclusion criteria, exclusion criteria, control(s), study design, dosages of samples duration of treatment, investigations to be done etc.
8. Permission from Drug Controller General of India (DCGI) if applicable
9. Costs involved (Appx. in Rs.)
   a) Investigations
   b) Disposables
   c) samples

   Who will bear the costs of the requirements? 1.☐ Subject 2.☐ Project 3☐ Exempted
   4. ☐ Other Agencies (Name)
10. Ethical issues involved in the study:

    Less than minimal risk / minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines - at PONDICHERRY UNVERSITY website)
11. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.
12. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
13. Documents attached
    (a) Brief CV of investigators (including no. of projects with him/her)
    (b) Investigator's Brochure
    (c) Others
14. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
15. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigators: Date :

Signature of the Head of the Department Date:

(Note: The proforma must be accompanied by Consent forms I & II in English and Tamil. Consent form I is equivalent to Subject Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

CONSENT FORM I

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the subject information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the subject/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants for disability or death resulting from such injury
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The subject information sheet must be duly signed by the investigator

CONSENT FORM II

PARTICIPANT CONSENT FORM

Participant's name: Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

*(**Note**: Consent form II should be appropriately worded for adults and children (less than 18 years)*
e.g. If the participant is less than 18 years of age, instead of 'my participation', 'my child's/ward's participation' needs to be replaced.)