

APPLICATION FOR ICMR-STS PROJECTS

Proforma for submitting protocols to the Institutional Ethics Review Board

Kindly submit 01 copy of protocol and consent forms in 2 parts (in English and local language) and one copy of undertaking by the investigators to the Member Secretary.

1. Title of the project:

2. Name of the investigators/Guide with designation & department:

a) Student/Internee Name :

Address:

Phone & e-mail:

b) Guide Name:

Address:

Phone & e-mail

3. Number of projects already with the Student/Internee in hand:

4. Sources of funding if any:

5. Introduction & Review of Literature (100 words)

6. Objectives of the study:

a)

b)

c)

6. Justification for the conduct of the study (50 Words)

7. Methodology:

- a) Number of patients,
- b) Inclusion criteria,
- c) Exclusion criteria,
- d) Study design (Procedures, Investigations, study group(s))
- e) References (7 to 10 recent references and citation as per the Vancouver style)
- f) Method of statistical analysis
- g) Questionnaire proforma (Attach separately) and any other points relevant to the study:

8. Whether Consent forms part in English and in local language is enclosed?

9. Conflict of investigator (s) interest: Y/N

10 Enclose One page recent Bio-data of Principal Investigator indicating qualification and experience

Declaration by Investigator

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 guidelines given by the apex bodies.

Signature of the Investigators with date:

1.

2.

Declaration by HOD

I have no objection in permitting staff / student to conduct research work in the department. I take complete responsibility in supervise, produce and present the final research work to the Institutional Ethical & Review board

Signature , Seal & date

UNDERTAKING BY ALL THE INVESTIGATORS

01. Title of the protocol :

02. We the undersigned authors of the above said protocol declare that we do not reveal the identity of the study participants, his/her personal details as well as the treating doctor if any under any circumstances.

03. We further declare that we do not have any conflict the order of authorship that is submitted for ethical approval. If the necessity arises for change in the order of authorship, we will obtain a written consent from IEC.

Investigators name

Signature with date

1.

2.

INFORMED CONSENT FORM

Study title:

Subject's name..... Age..... Sex.....

I confirm that I have read and understood/have been explained the information given by the researcher/moderator and I had an opportunity to ask questions.

I understand that the participation in the study is voluntary and I am free to withdraw at any time without giving any reason and without being my medical care and legal rights being affected.

I understand that my identity will not be revealed to any third party or in publication.

I understand that the researchers/ regulatory authorities/ ethics committee will not need my permission to access my health records if necessary for the current study.

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 agree to take part in the above study.

Signature of the subject..... Date.....

Name of the Investigator (printed).....

Signature of the investigator.....Date.....

Name and signature of the impartial witness with date if required

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CHILD ASSENT FORM

Study Title:

I _____, exercising my free power of choice, hereby give my consent for participation in the study entitled: ".....". I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug/investigation/procedure.

I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so.

Name and Signature of the study participantDate:

Name and Signature of the parent/guardianDate:

Name and Signature of the attending PhysicianDate: