

# Guide for thesis protocol submission to IEC

## Checklist for Submission

(only for thesis protocols, not for faculty/other research projects)

For smooth processing of the thesis protocols by the IEC, any protocol will be accepted only once all the following requirements are fulfilled:

- Proof of protocol approved by thesis committee
- Signed by all the guides and co-guides
- Signed by the candidate
- Ethical justification on a separate page immediately after methods. Should mention the following:
  - Will follow the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants given by ICMR in 2017
  - Benefits and risks of participation in the study
  - How the risks will be minimized
  - How adverse events will be monitored and reported to IEC
  - The study participant will not bear any extra cost for participation in the study
- Patient information sheet (or Parent information sheet if study participant is minor)
  - English, Hindi, and Punjabi
  - In IEC format (English format given below)
  - Hindi and Punjabi translations - fonts and write-up should be legible
  - Should be addressed to the study participant - "You are (or your child) invited to participate in the study ....."
  - In simple language with no use of medical terms
  - Should clearly explain the study procedure to the study participant including amount and frequency of sampling, follow-up visits etc.
  - Should mention that "You will not bear any extra cost for participation in the study"
- Patient Informed consent form
  - English, Hindi, and Punjabi
  - Hindi and Punjabi formats - fonts and write-up should be legible
  - In IEC format (format given below)
- Child assent form if study participant age is >7 years and <18 years (format given below)
- Plagiarism check by iThenticate
- Four hard copies
- A single compiled soft copy in PDF format in which only the signatures page is inserted as a scanned page. Emailed to [iec.gmch32@gmail.com](mailto:iec.gmch32@gmail.com)

# Patient Information Sheet

Title of the project

xxx

Name and department of the student

xxx

Name and departments of guide and co-guides

xxx

Purpose of this project/study

xxx

Procedure/methods of the study

xxx

Expected duration of the subject participation

xxx

The benefits to be expected from the research to the participant or to others

xxx

Any risks expected from the study to the participant

xxx

Maintenance of confidentiality of records

xxx

Provision of free treatment for research related injury

xxx

Compensation for participating in the study

xxx

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

xxx

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

xxx

Address and mobile number of the investigator

xxx

### Contact details of IEC

In case of any query, you can contact member secretary IEC, 6th floor, E block, GMCH, Chandigarh. Phone number: 0172-2505703

(Signature of the investigator)

(Signature/thumb impression of the participant)

Place:

Place:

Date:

Date:

# INFORMED CONSENT FORM

**Title of the project:**

Participant's name:

Address:

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.

(I also consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No – if applicable)

Signature of the participant: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of the witness: \_\_\_\_\_ Date: \_\_\_\_\_

Name and address of the witness:

Signature of the investigator: \_\_\_\_\_ Date: \_\_\_\_\_

# INFORMED CONSENT FORM

(for participants less than 18 years of age)

Parent/Legally acceptable representative (LAR)

**Title of the project:**

Participant's name:

Address:

Parent/LAR's name:

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 child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward 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 for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 7 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the parent/ LAR: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of the witness: \_\_\_\_\_ Date: \_\_\_\_\_

Name and address of the witness:

Signature of the investigator: \_\_\_\_\_ Date: \_\_\_\_\_

# ASSENT FORM

(for children above 7 years and below 18 years of age)

**Title of the project:**

Child Participant's name:

Date of birth/Age:

Parent/LAR' s name:

Address:

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 understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:

(If child knows to sign/Thumb impression)

Signature of the parent or guardian : Date:

Name and address of the witness :

Signature of the witness : Date:

Signature of the Investigator : Date:

# ETHICAL JUSTIFICATION

The study will be conducted following the principles outlined in the Declaration of Helsinki and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants given by the Indian Council of Medical Research. The following points will be taken into consideration and will be adhered to:

1. The study shall be conducted on ----- . The study plans to investigate-----.
2. Description of intervention planned in the study: -----
3. Each patient will be adequately informed of the aims, methods, the anticipated benefits and the potential risks of the study and discomfort it may entail to him/her and the remedies thereof.
4. Every precaution will be taken to respect the privacy of the patient, the confidentiality of the patient's information and to minimize the impact of the study on his/her physical and mental integrity and his/her personality.
5. Written informed consent will be taken from all the patients/participants included in the study. The patient will be given the right to abstain from participation in the study or to withdraw consent to participate at any time of the study.
6. Due care and precaution will be taken at all stages of the research to ensure that the patient is put to the minimum risk, suffer from no irreversible adverse effects and generally benefit from and by the research. Standard treatment will not be withheld from the study participants. If any adverse events are noted, these will be notified to the IEC as per national guidelines.
7. The study participant will not bear any extra cost for participation in the study.