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:

- ☐ Fresh Proposal
- ☐ Or Revised Proposal (Attach Coving Letter Mentioned Below)
- ☐ This Checklist (signed)
- ☐ Initial Review Form(signed)
- ☐ Proof of protocol approved by thesis committee
- ☐ Signed by all the guides and co-guides.
- ☐ Signed by the candidate.
- ☐ Role of Investigator page with sign of all guides and co-guides.
- ☐ 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 cost for participation in the study.
  - ☐ Mention sample size
- ☐ 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, simple size, study duration with participant etc.
  - ☐ Should mention that “You will not bear any 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 forms and Parental Information sheets if study participant age is >7 years and <18 years (format given below)
- ☐ Undertaking(For Research or Funded Proposal)
- ☐ 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. Submit online through service plus portal.
- ☐ Read all points of this checklist carefully and attach with thesis after tick/cross mark.

Form for Initial Review by IEC

Government Medical College Hosptial, Chandigarh

EC Ref. No.*(for office use):*

Title of study	
Primary objective	
Population to be studied	☐ Healthy volunteers ☐ Patients ☐ Vulnerable group ☐ Others _____
Vulnerable group of patients	☐ Children (age <18 years) ☐ Pregnant women ☐ Lactating women ☐ Differently abled ☐ Prisoners ☐ Students/nurses/staff ☐ Terminally ill ☐ Any other group _____
Intervention/exposure	
Control/Standard	
Primary outcome	
Secondary outcomes	
Study design	
Start date of study	☐ RCT ☐ Cohort ☐ Case-control ☐ Cross-sectional ☐ Diagnostic test assessment ☐ Other _____
Subject recruitment	☐ Prospective ☐ Retrospective
Target sample size	
Is this a drug/device/vaccine/procedure trial?	
If the answer to the above question is "Yes", does it need DCGI approval?	
Which biological material will be used in the study?	
Is the study funded by a foreign organization? If yes, enclose HMSC clearance.	

Will biological samples be sent abroad?	
Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?	
Are there any anticipated physical/social /psychological discomforts/ risk to participants? ***(For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1)***	☐ No ☐ Less than minimal risk ☐ Minimal risk ☐ Minor increase over minimal risk or Low Risk ☐ More than Minimal Risk or High Risk
Are Adverse Events expected in the study?	☐ No ☐ Yes
If yes, what are reporting procedures and management strategies?	
Lay summary of the proposal for non-medical members of the IEC (maximum 200 words):	

DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.
	Name of PI: Signature: _____ Name of Co-PI: Signature: _____ Name of Co-PI: Signature: _____ Name of Co-PI: Signature: _____ Name of Co-PI: Signature: _____

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

Details of sample size if any

Xxxx

Duration of study with participant

XXXX

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

*__No cost for participating in the study from participant.__

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)

Place:
Date:

(Signature/thumb impression of the participant)

Place:
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 cost for participation in the study.**

UNDERTAKING

We certify that:

● The project proposal is our/my original work and has not been copied from another project/published work.

● The contents of the proposal are plagiarism checked.

● If funded, the project has not been funded to more than one funding agency at a time.

● I/we have taken consent from other faculty members/another unit (s) in the department to use the clinical data of their primary patients OR I/we would not be using the primary patients of other faculty members/another unit (s)

(cross what is not applicable)

Signature of PI and
Guides

*(For Research or Funded Project Only)

Details of Investigators

Name of Investigators	Role of Investigators	Signature
1.		
2.		
3.		

Covering Letter for Revised Proposal to Ethics Committee after IEC Meeting

Queries raised by IEC	Reply	Page Number & Highlight the Correction.
1.		
2.		
3.		
4.		

Sign and Date