FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTE HUMAN ETHICS COMMITTEE OF IIT Roorkee

IIT Roorkee ethics committee will be operating following Standard operating procedure (SOP) uploaded in IITR website. The committee is scheduled to meet with a frequency of every three months. Institute human ethics committee will review following three types of communications;

5.3.1 Fresh project submission and reply to comments from IHEC

5.3.2 Amendments to ongoing projects

5.3.3 Progress report of approved projects

You are required to submit your research project through email and hard copy of the Research Project in original along with Covering letter to the Member-Secretary, Institute Human Ethics Committee at Room No. 011, Office, Department of Biosciences and Bioengineering, IIT Roorkee.

Internal telephone: 4316

Email: ihec@bt.iitr.ac.in

- Hard copy will be used for record and soft copy will be used for all review process.
- All soft copy should be summited in PDF format only
- Check list of documents to be submitted for each application

5.3.3.1 Institute human ethics application form (dually signed by all investigators)

5.3.3.2 Covering letter forwarded through department/center head Complete research proposal (Justification, methodology, safety, confidentiality and budget)

5.3.3.3 2-3 ppt slides (Overview of study, methods flow chart and other details)

5.3.3.4 Patient information sheet (English & Hindi)

5.3.3.5 Patient informed consent sheet (English & Hindi)

5.3.3.6 CV of all the investigators

5.3.3.7 Investigators brochure (infrastructure available)

5.3.3.8 Undertaking that the study will done in accordance with ICMR and GCP guidelines

5.3.3.9 Undertaking of who will bear the expenditure in case of injury related to study

5.3.3.10 In case of multi-centric study, IHEC clearance of other centers must be provided

5.3.3.11 Investigator should provide dated undertaking what they will do with the leftover sample tissue (if applicable)

5.3.3.12 Other documents as applicable

The Principal Investigator must submit the protocol forwarded by Head of The Department. All submissions should be made in the prescribed Format of the **Institute Human Ethics Committee** with signatures of all the investigators on the hard copy. All the pages must be numbered. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi, **in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website,** before it can be considered for placing before the Institute Human Ethics Committee. No research project shall be / can be started unless ethics clearance/approval is obtained. Please understand that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institute Human Ethics Committee.

Annexure.I **Application format to IHEC-IITR:**

1. Full Title of Study:		
2. Name of Investigators / co- investigators (permanent IITR Staff) with designation and departments 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ (Expand if more co-investigators) 2.6 Email ID of the Principal Investigator	Signatures 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____	No. of projects already with investigator
3. Objectives of the study	3.1_____ _ 3.2_____ _ 3.3_____ _ 3.4_____ _ 3.5_____ _	
4. Justification for conduct of this study		
5. Type of study	Epidemiological ☐ Basic Science ☐ Animal Studies ☐ Clinical: Single center ☐ multicentric ☐ Behavioral ☐	

6. Methodology	6.1. Number of Patients/Participants: 6.2. Inclusion criteria a) b) c)_____ _____ d)
	6.3. Exclusion criteria a) b) c)_____ _____ d)

	6.4 Control(s) _____ 6.5 Study design _____
7. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not Required 3. ☐ Received 4. ☐ Applied when:
8. Permission from DGFT if applicable	1. ☐ Required 2. ☐ Not Required 3. ☐ Received 4. ☐ Applied when:
9. a) Safety measures for proposed interventions. b) Results of relevant laboratory tests c) Result of studies in human	a) _____ b) _____ c) _____
10. Plans to withdraw standard therapy during conduct of research	☐ Yes ☐ Remarks: _____
11. Plan for provision of coverage for medical risk (s) during the study period	
12. How you will maintain confidentiality of subject?	
13. **Total Budget (Approx. in Rs.)** Who will bear the cost of investigation/ implants drugs / contrasts?	12.1 _____ 1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies (Name)
14. Participant Information Sheet **(mark √ if yes)**	☐ English ☐ Hindi
15. Participant Informed Consent Form **(mark √ if yes)**	☐ English ☐ Hindi
16. Conflict of interest for any other investigator(s) (if yes, please explain in brief	1. _____ ☐es ☐ 2. _____ ☐es ☐ 3. _____ ☐es ☐ 4. _____ ☐es ☐
17. Whether any work on this project has started or not?	☐ **(mark √ if yes, X if no)** (Please enclose a separate certificate to this effect).
18. Attached documents (If any)	18.1 Covering letter, through proper channel. 18.2 Copy of the detailed protocol is mandatory. 18.3 Brief CV of Investigators not more than two pages (including No. of projects with Principal Investigator) 18.4 Investigator's Brochure (facility available)

	18.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 18.6 In case of multicentric study, IHEC clearance of other centers must be provided 18.7 Definite undertaking as to who will bear the expenditure of injury related to the project 18.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 18.9 Permission as mentioned in column 5.9 18.10 Investigator should provide dated undertaking what they will do with the leftover sample tissue 18.11 Others
19. In case of clinical trials CTRI status	

Annexure II PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Hindi, in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website, which can be understood by them:

i) Title of the Study/Project

ii) Aims and methods of the research.

iii) Expected duration of the subject participation.

iv) The benefits to be expected from the research to the subject or to others.

v) Any risk to the subject associated with the study.

vi) Maintenance of confidentiality of records.

vii) Provision of free treatment for research related injury.

viii) Compensation of subjects for disability or death resulting from such injury.

ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

x) Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned.

xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned. xii) Telephone number/contact number of Principal Investigator and Co investigator at the top of each page.

xii) In case of drug trials: a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned b) Initial Bio equivalent study of the drug / references should be provided

xiii) Self-certification should be given that translation to vernacular is accurate.

xiv) Statement that there is a possibility of failure of IP to provide intended therapeutic effect

xv) Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect

Annexure III **PARTICIPANT INFORMED CONSENT FORM (PICF)**

Protocol / Study number:_____

Participant identification number for this trial: _____

Title of project:_____

_____

Name of Principal Investigator: _____Tel.No(s)._____

The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from IIT Roorkee. I give permission for these individuals to have access to my records.
I agree to take part in the above study.

---------- Date:

(Signatures / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter / Spouse of:_____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

- - - - - - - - - - - - - - - - - -
Signatures of the Principal Investigator Date:

Place:

1) Witness – 1

- - - - - - - - - - - - - - - - - -
Signatures
Name:
Address:

2) Witness – 2

- - - - - - - - - - - - - - - - - -
Signatures
Name:
Address:

NB Three copies should be made, for (1) patient, (2) researcher, (2) Institution

(Investigators are required to prepare the translation of PICF in simple understandable Hindi)

Annexure IV Sample : Undertaking - "No work has started"

19/07/2021

The proposal along with this undertaking is being submitted for purpose of obtaining ethical clearance. It is being stated that the research study titled **"……"** requires human blood samples as a part of its research experimental protocol. Until date, no work on humans or human blood samples has been carried out. It will only be started after the clearance from the Institutional Ethical Committee. The research is being jointly carried out by the Department of …….

It is also being undertaken that the Participant Information Sheet has been translated into an easy and understandable Hindi format for the convenience and wider acceptability of the participants.

Principal Investigator

Dr ….,
Department of….
Indian Institute of Technology Roorkee

Co-Investigators

Sample : Undertaking – "To Follow ICMR/GCP Guidelines"

19/07/2021

Is being stated that the research study titled **"……."** requires human blood samples as a part of its research experimental protocol. The proposal is being submitted for obtaining ethical clearance and this undertaking is being given stating that the clinical research will be performed as per ICMR and Good Clinical Laboratory Practice guidelines.

Principal Investigator

Dr. …
Department of
Indian Institute of Technology Roorkee

Co-Investigators

Sample : Undertaking – "To dispose biological waste"

19/07/2021

is being stated that the research study **"……"** requires human blood sample as a part of the research experimental protocol. The proposal is being submitted for ethical clearance and this undertaking is being given for the assurance that the biological waste will be discarded as per the hospital waste management system at MAMC.

Principal Investigator

Dr.
Department of
Indian Institute of Technology Roorkee

Co-Investigators