Standard Operating Procedure (SOP)

Institute Ethics Committee of Indian Institute of Technology Delhi (IEC-IITD)

Version: July 2018

Contents

Annexure

1. Introduction:

Institute Ethics Committee, Indian Institute of Technology Delhi (IEC-IITD) has been constituted by Director, IIT Delhi to facilitate research involving human subjects following due guidelines set by the ICMR Ethical guidelines. This standard operating procedure document will define the role, operation and management of the committee.

2. Objective:

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health, biomedical and research involving human subjects for all proposals submitted by the faculty and students of IIT Delhi as prescribed by the Ethical guidelines for biomedical research on human participants of ICMR (2006).

3. Role and responsibilities of the committee:

IEC-IITD will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, privacy, rights, safety and well-being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects/participants. The IEC-IITD will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IEC-IITD will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

4. Composition of the committee:

IEC-IITD should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC-IITD. The number of persons in an ethical committee will be around 8-14 members.

The Chairperson of the Committee should be from outside the Institute with a legal background and not head of the Institute to maintain the independence of the Committee. The Member Secretary will be a faculty member from the Institute to conduct the business of the Committee. Other members will be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect different viewpoints.

The composition will be as follows:-

a. Chairperson
b. 1-2 basic medical scientists.
c. 1-2 clinicians from various Institutes
d. One legal expert or retired judge
e. One social scientist / representative of non-governmental voluntary agency
f. One philosopher / ethicist / theologian
g. One lay person from the community
h. Member-Secretary

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The members will be appointed by the Director of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

4.1 Membership requirement and appointment:

The Director of IIT Delhi constitutes the IEC-IITD. Based on the guidelines set by Drugs Controller of India, Central Drugs Standard Control Organization, Drugs and cosmetics (Third Amendment) Rule, 2013, Ministry of Health and Family Welfare (Dept. of Health), Govt. of India.

Membership requirement

a. The duration of appointment will be initially for a period of 3 years

b. At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.

c. A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.

e. All members should maintain absolute confidentiality of all discussions during the meeting.

f. Conflict of interest should be declared by members of the IEC-IITD

4.2 Quorum:

The minimum of 5 members + Chairperson are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. This quorum must include at least one non-scientific member that may either be a lawyer, philosopher or a lay person from the community.

4.3 Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities.

They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC-IITD.

4.4 Resignation, removal and reconstitution:

The members who have resigned may be replaced at the discretion of the appointing authority for the same i.e., Director, IIT Delhi. IEC-IITD members who decide to resign must provide the Director, IITD and Chairman, IEC-IITD the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Director, IITD would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative. The recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairman

A member may be relieved or terminated of his/her membership in case of

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds
- If a regular member fails to attend more than 3 meetings of IEC.
- Relocate to another city or any such matter

The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Director, IITD, by the Chairman IEC for necessary action

4.5 Office and conduct procedures:

Member secretary will be responsible to schedule the meeting every two months in consultation with Chairman and members of IEC-IITD. Office of member secretary will receive all the application and maintain record of the activities of IEC. He/she will prepare the minutes of the meetings and get it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority.

4.6 Training of Members:

a. All relevant new guidelines should be brought to the attention of the members.

b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record.

4.7 Conflict of Interest policy:

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC-IITD and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the proposal review or approval except to provide information requested by the Committee.

If an applicant submitting a protocol believes that an IEC-IITD member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC-IITD member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict. Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

5. Application procedure:

a. All proposals should be submitted in the prescribed application form (see annexure).

b. All relevant documents should be enclosed with application form (see annexure).

c. A soft copy of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the member secretary.

d. The date of meeting will be intimated to the researcher to be present for clarification.

e. The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

5.1 Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

a. Name of the applicant with designation
b. Name of the Institute/ Hospital / Field area where research will be conducted.
c. Forwarded by the Head of the Institution /Head of the Department. (should be there)
d. Protocol of the proposed research
e. List of Ethical issues in the study and plans to address these issues.
f. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
g. Informed consent process, including patient information sheet and informed consent form in local language(s).
h. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
i. Curriculum vitae of all the investigators with relevant publications in last five years.
j. Any regulatory clearances required.
k. Source of funding and financial requirements for the project.
l. Other financial issues including those related to insurance
m. An agreement to report all Serious Adverse events(SAEs)
n. Statement of Conflict of interests,if any
o. An agreement to comply with all national and international guidelines
p. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable;

q. All significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

r. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.

s. Any other information relevant to the study

5.2 Review procedures:

a. The meeting of the IEC should be held on scheduled intervals of about 12 months

b. The proposals will be send to members at least 2 weeks in advance.

c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

d. Researchers will be invited to offer clarifications if need be.

e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writing.

5.3 Element of review

a. Scientific design and conduct of the study.

b. Approval of appropriate scientific review committees.

c. Examination of predictable risks/harms.

d. Examination of potential benefits.

e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

f. Management of research related injuries, adverse events.

g. Compensation provisions.

h. Justification for placebo in control arm, if any.

i. Availability of products after the study, if applicable.

j. Patient information sheet and informed consent form in local language.

k. Protection of privacy and confidentiality.

l. Involvement of the community, wherever necessary.

m. Plans for data analysis and reporting

n. Adherence to all regulatory requirements and applicable guidelines

o. Competence of investigators, research and supporting staff

p. Facilities and infrastructure of study sites

q. Criteria for withdrawal of patients, suspending or terminating the study

5.4 Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub-committee consisting of the member secretary, a non-scientific and a scientific member maybe constituted under the Deputy chairman to review the proposal and approved by the chairperson.

5.5 Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d. Only members can make the decision. The expert consultants will only offer their opinions.

e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

g. Modified proposals may be reviewed by an expedited review through identified members.

h. Procedures for appeal by the researchers should be clearly defined.

5.6 Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.

b. Suggestions for modifications, if any, should be sent by IEC-IITD.

c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by the IEC-IITD should be communicated to the PI.

5.7 Follow up procedures

a. Reports should be submitted at annually for review.

b. Final report should be submitted at the end of study.

c. Protocol deviation, if any, should be informed with adequate justifications.

d. Any amendment to the protocol should be resubmitted for renewed approval.

e. Any new information related to the study should be communicated.

f. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

h. Change of investigators / sites should be informed.

5.8 Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of IEC.

b. Copy of all study protocols with enclosed documents, progress reports, and Serious Adverse Events.

c. Minutes of all meetings duly signed by the Chairperson.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

e. Copy of all correspondence with members, researchers and other regulatory bodies.

f. Final report of the approved projects.

g. All documents should be archived for prescribed period.

5.9 Policy to protect vulnerable population and compensation:

A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence. Projects that involve vulnerable population and special groups should be subjected to full review by all the members.

Compensation: If a participant volunteers to involve him/her in the study. If the study requires more than one hour of his time, he/she has to be compensated with suitable compensation. No study should involve financial burden to the participant. All financial expenditure should be included in the project proposal.

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

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

1. Fresh project submission and reply to comments from IEC
2. Amendments to ongoing projects
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 Ethics Committee at Room No. 328, Block I, Department of Biochemical Engineering, IIT Delhi. Internal telephone: 1057.
Email: elangovan@dbeb.iitd.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
    a) Institute ethics application form (dually signed by all investigators)
    b) Covering letter forwarded through department/center head
    c) Complete research proposal (Justification, methodology, safety, confidentiality and budget)
    d) 2-3 ppt slides (Overview of study, methods flow chart and other details)
    e) Patient information sheet (English & Hindi)
    f) Patient informed consent sheet (English & Hindi)
    g) CV of all the investigators
    h) Investigators brochure (infrastructure available)

i) Undertaking that the study will done in accordance with ICMR and GCP guidelines
j) Undertaking of who will bear the expenditure in case of injury related to study
k) In case of multi-centric study, IEC clearance of other centers must be provided
l) Investigator should provide dated undertaking what they will do with the leftover sample tissue (if applicable)
m) 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 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 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 Ethics Committee.

Annexure.I **Application format to IEC-IITD:**

1. Full Title of Study:		
2. Name of Investigators / co- investigators (permanent IITD 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. Methodology	5.1. Number of Patients/Participants: 5.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 5.3. Exclusion criteria a)_____ b)_____ c)_____ d)_____	

	5.4 Control(s) _____ 5.5 Study design _____
6. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not Required 3. ☐ Received 4. ☐ Applied when:
7. Permission from DGFT if applicable	1. ☐ Required 2. ☐ Not Required 3. ☐ Received 4. ☐ Applied when:
8. a) Safety measures for proposed interventions. b) Results of relevant laboratory tests c) Result of studies in human	a)_____ b)_____ c)_____
9. Plans to withdraw standard therapy during conduct of research	☐ Yes ☐ Remarks:_____
10. Plan for provision of coverage for medical risk (s) during the study period	
11. How you will maintain confidentiality of subject?	
12. **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)
13. Participant Information Sheet **(mark √ if yes)**	☐ English ☐ Hindi
14. Participant Informed Consent Form **(mark √ if yes)**	☐ English ☐ Hindi
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief	1. _____ ☐ es ☐ 2. _____ ☐ es ☐ 3. _____ ☐ es ☐ 4. _____ ☐ es ☐
16. Whether any work on this project has started or not?	☐ **(mark √ if yes, X if no)** (Please enclose a separate certificate to this effect).
17. Attached documents (If any)	17.1 Covering letter, through proper channel. 17.2 Copy of the detailed protocol is mandatory. 17.3 Brief CV of Investigators not more than two pages (including No. of projects with Principal Investigator) 17.4 Investigator's Brochure (facility available)

	17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 17.6 In case of multicentric study, IEC clearance of other centers must be provided 17.7 Definite undertaking as to who will bear the expenditure of injury related to the project 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 17.9 Permission as mentioned in column 5.9 17.10 Investigator should provide dated undertaking what they will do with the leftover sample tissue 17.11 Others
18. 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 DELHI. 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 advised to prepare the translation in simple understandable Hindi on their own.)

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

19/05/2016

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 Medicine at MAMC, Department of Biochemical Engineering and Biotechnology, Kusuma School of Biological Sciences and Chemical Engineering at IIT Delhi.

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

Co-Investigators

[redacted]	[redacted]	[redacted]

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

19/05/2016

Is is being stated that the research study titled **"** [redacted] **"** 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

[redacted]

Co-Investigators

[redacted]

[redacted]	[redacted]	[redacted]

Sample : Undertaking – "To dispose biological waste"

19/05/2016

Is is being stated that the research study **"** [redacted] **"** 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

[redacted]

Co-Investigators

[redacted]

[redacted]	[redacted]	[redacted]

INSTITUTE ETHICS COMMITTEE (IEC)
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Content of the minutes:

1. List of members present in the meeting
2. Approval condition and reference to the protocol