INSTITUTIONAL ETHICS COMMITTEE
(DHR File No. EC/NEW/INST/2020/1079)
INDIAN INSTITUTE OF TECHNOLOGY MADRAS
Sardar Patel Road, Adyar Chennai – 600 036.
Email: iec@iitm.ac.in **Phone:** 044 – 2257 4929

APPLICATION FOR INITIAL REVIEW OF RESEARCH PROPOSAL

(Form to be filled by the Principal Investigator)

For IEC Office Use			
IITM – IEC Proposal No.			
Date of submission of proposal			
Category of the proposed study			
A.	Basic Sciences (BS)	D.	Social Sciences (SS)
B.	Medical Sciences (MS)	E.	Medical Devices (MD)
C.	Data Sciences (DS)	F.	Others (OT)

BASIC INFORMATION

1. Title of the proposal:

2. Details of the Investigator:
   Name of the Principal Investigator (PI)
   Designation
   Contact address
   Email Id & Mobile No.

3. Details of the Co-Investigator or Co-PI:
   Name of the Co-Investigator or Co-PI
   Designation
   Contact address
   Email Id & Mobile No.

4. Attach brief CV of the PI & Co-PIs (showing latest 5 publications and experience in the relevant field of research, not more than 5 pages)

5. If the collaborators are within the institute; provide details

6. If the collaborators belong to other institute / organization; provide details
   Name of the collaborator & designation :
   Contact address, Email Id & Mobile No. :
   MoU with the partnering institute : Submitted / Not Submitted
   (Give reason, if not submitted)

7. Duration of the project / study:

8. Name and contact address of the IIT Laboratory where the research would be carried out

9. Details of the collaborating / partnering institute's ethical clearance

   Tile of the work :
   Date of approval :
   IEC certificate : Attached / Not attached (Give reason if not attached)

10. **DETAILS OF FUNDING / SPONSORS (Please tick the appropriate option)**

Institute Funding	☐	Private Funding	☐
Govt. of India Funding	☐	Self-Funding	☐
International Funding	☐	Others	☐

11. Details of source of funding, address and contact information:

12. Total estimated budget (INR):

13. **TECHNICAL DETAILS OF THE RESEARCH PROPOSAL:**

i. Brief background & motivation of the study (not more than 500 words)
ii. Main objectives (mention in bullet points)
iii. Brief methodology & technical approaches
iv. Justify why the study with human participants is needed to answer the research questions.
v. No. of samples / participants to be collected / recruited
vi. Justify how the sample size for the study was arrived at (explain the power of study and confidence interval etc.)

10. **DETAILS OF THE RECRUITMENT AND RESEARCH PARTICIPANTS:**

i. Name of the Institute / Organization where the human participants will be recruited
ii. Participant recruitment process, inclusion & exclusion criteria for the selection of participants
iii. Will participant from both sexes be recruited?

iv. Type of participants in the study

Healthy volunteer	☐	Patient	☐
Vulnerable persons or special group	☐	Others	☐

v. Does the study involve any vulnerable persons / special group participants?

Children under 18 years	☐
Pregnant or Lactating women	☐
Differently abled (mental / physical)	☐
Economically or socially disadvantaged	☐

vi. Expected 'benefits' to volunteer / participants

vii. Usefulness of the project / trial

viii. Whether 'wage compensation' for the research participants will be provided?

11. DETAILS OF THE INFORMED CONSENT:

i. Describe the Informed consent process to be followed in the study

Signed Consent	☐
Audio-Video Consent	☐
Others (specify)	☐

ii. List of languages in which translations of Informed consent form & Participant information sheet have been made and will be used in the study

Tamil	☐
English	☐
Local Language	☐

iii. Copy of translated Informed consent form (ICF) attached: Yes / No
(If not attached, please justify)

iv. Copy of Participant information sheet (PIS) attached: Yes / No
(If not attached, please justify)

12. **DETAILS OF NATURE OF SAMPLES:**

i. Does the study involve the use of biological hazardous materials?
ii. Provide details about the hospital and disposal methods (for use of tissues, organs or body fluids)
iii. Provide the details on plan of containment and waste disposal for use of pre-existing / stored / leftover / bio hazardous samples
iv. Are the collected samples for bio-banking / future research?
v. Are the samples collected from the participants will be sent abroad? (If so, mention the reason and also submit the clearance from appropriate ministry)
vi. Will the research proposal be submitted to any Ministry Screening Committee for International Collaboration?
vii. Does the study involve use of genetically modified organism (GMO) / animals / stem cells? If yes, attach the appropriate regulatory body clearance
viii. Does the study involve the use of clinical information / medical imaging (Ultrasound, CT scan) data / demographic details?
ix. Does the study involve the use of autopsy data?

13. **PRIVACY AND CONFIDENTIALITY DETAILS:**

i. Does the study involve direct identifiers / indirect identifiers / completely anonymized / delinked?
ii. Provide the details on the approaches taken to maintain the Confidential handling of data
iii. Is the data going to be shared with a third party? If yes, attach the Data sharing and Data management policy agreement
iv. Explain all anticipated 'risks' of the project
v. Efforts taken to minimize the 'risks'
vi. Explain the plans of publication of results while maintaining confidentiality of personal information / identity of the research participants

14. Disclose the conflict of interest, if any

Note: 1. Students cannot be Co-PI
2. Volunteers cannot be from the PI's laboratory

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UNDERTAKING

I/We hereby declare that the information given in the IEC application form for the project titled _____.
The related documents submitted by me/us are true to the best of my/our knowledge and belief. I/We undertake that we/I shall comply with Indian Council for Medical Research's (ICMR) "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants", Guidelines 2017. We are/I am aware that these guidelines are in accordance with Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules, 1945, as amended, guidelines therein in Schedule Y, Drugs and Clinical Trial Rules, 2019, Medical Devices Rules 2019 as amended, Indian Good Clinical Practices Guidelines, 2001 and World Health Organization's Standard and Operational Guidelines for Ethics Review of Health-Related Research on Human Participants.

We/I agree to start the proposed project only upon receiving the approval for the same from the IIT Madras-Institutional Ethics Committee (IITM-IEC) and assure that we/I will inform the IITM-IEC about any observed adverse events noticed during the project. Should there be a change in the study protocol We/I agree to seek approval from the committee for the proposed changes before executing such changes in the study protocol of the project.

Name of the Principal Investigator :
Signature & Seal :
Date :

Name of Co-Principal Investigator :
Signature & Seal :
Date :

Note: For more Co-PIs please use the back of the form.