

IMPORTANT INFORMATION FOR SUBMISSION TO IEC

- Institutional Ethics Committee (IEC) meetings for Observational and Interventional studies will be held every month on specified dates as mentioned in the Call for proposals circular.
- All research proposals by Faculty, PhD scholar, P.G. and U.G. Students must be submitted to IEC review after approval by JSAC/PGRMC/PhD doctoral committee/SCTRC/GJ-STRAUS.

A. Instructions for Initial project submission to IEC:

- Kindly use only the **ICMR Common form on the EC portal** for submission to IEC.
- PIs are requested to use the revised versions of the **consent forms**.
- Please submit a **brief CV** in the prescribed template (not more than two pages).
- **Two hard copies** (One original and One Xerox) of the research proposal are required to be submitted to Member-Secretary, Institutional Ethics Committee (IEC) at Room no. 106, Institute Ethics Committee office, First floor, Administrative block, JIPMER.
- The hard copies should be typed in Arial font using **both sides** of A4 size paper, in 11 font size with 1.5 spacing. Please avoid submitting volumes of pages in spiral bound copies. Investigators are requested to include title of the study in the signature page.
- PIs are required to **upload the soft copy** of their proposal on the e-EC portal at <https://iecmanager.org/institution/283> before the last date as intimated in the Announcements section. PIs / Student Researchers should ensure that they upload the soft copy of their proposal on e-EC portal failing which it will not be taken up for the discussion.

Procedure to upload proposal on e-EC portal

1. **Step – 1:** Candidates are first required to go to Ethics Committee website <https://iecmanager.org/institution/283> and click on REGISTER as **Principal Investigator** to open On-Line Application Form.
2. **Step – 2:** In online form, investigators are required to fill their background information. After submission of the online form, investigator will receive an e-mail to create a password for their account. Password must include an uppercase letter, a lower case letter, a number and a special character.
3. **Step – 3:** Reopen the webpage again and login with user ID (Personal E-mail ID) and password as Principal Investigator.
4. **Step – 4:** Click on submit new project and fill all the required details under **Project Summary** and proceed to **upload documents** only after clicking on save button.
 - a) **Under Review type** PI / Student Researchers have to select:
 - Full Board Review: In case of fresh proposal/ waiver of consent/ exemption application

- Expedited Review: In case of a Major / minor revision

5. Upload essential documents after selecting the appropriate option from drop-down menu (*Covering letter forwarded by guide, Protocol, Informed Consent Documents in English & Tamil and data collection proforma etc.* in pdf format only) and click on save button.

6. Click on **next button** to finally submit your proposal.

THE PROPOSAL WILL NOT BE TAKEN UP FOR THE MEETING IN CASE OF

- Application form deviating from the revised format.
- Consent forms deviating from the prescribed format.
- Version number and date of revision not mentioned in revised Consent forms.
- Incomplete Signature page
- Lengthy CV
- Voluminous submissions on account of singled sided print copies
- Not uploading the Soft copy in pdf format on or before the last date.
- Discrepancies between English and Tamil consent forms

B. Instructions for resubmission to IEC:

- Minutes of the meeting will be available in your eEC portal. It will be communicated to the PI as a query in your mail.
- Please submit the revised protocol highlighting the changes with a yellow highlighter.
- The covering letter should be accompanied by a reply letter signed by PI / Guide in tabular format mentioning page number enumerating the comments from the IEC minutes for their proposal, with point to point mention of where the revision has been highlighted.
- **One original copy** of revised proposal must be submitted to IEC Office (Room No: 106, Next to Dean Research Chamber, 1st floor, Administrative Block).
- The Investigators are required to upload the soft copy on e-EC portal
@ <https://iecmanager.org/institution/283>.
 - 1) Covering letter forwarded by Guide.
 - 2) Reply letter signed by PI / Guide in tabular format mentioning page number.
 - 3) Single PDF file of Revised Protocol incorporating suggestions of IEC (changes must be highlighted).
- Please label the proposal as revised, along with the IEC number (JIP/IEC/2020/.....) and meeting number (eg. 7th observational studies – 28.06.2020) in the header of the first page of the proposal and covering letter correctly.

- Kindly submit corrected protocol with both English and Tamil consent forms stapled together. Protocols and consent forms submitted separately will not be considered for approval process.
- If the revision is satisfactory, the **approval certificate** will be issued on e-EC portal.
- The investigators whose proposals need **major corrections** to be submitted for full board review are required to submit one original and a xerox copy of revised proposal along with soft copy to IEC and it will be taken up in the next meeting for consideration of approval.

C. Other submissions related to IEC:

- Annual report to IEC should be submitted every year for ongoing studies, including project completion report.
- Report of any Serious Adverse Events (SAE) should be intimated by mail to IEC with a copy to the Member secretary of the concerned IEC within 24 hours of knowledge. A detailed report must be submitted to the IEC within 14 days of occurrence of SAE in prescribed formats. They should be informed to the IEC office through email.
- Amendments, protocol deviation/violation, premature termination or discontinuation need to be reported to the IEC in prescribed formats.

PROFORMAS:

A. Covering letter

Duly fill the covering letter and address it to the Member Secretary for appropriate committees in the format prescribed <https://iecmanager.org/institution/283>

B. Scientific proposal : To be submitted as per the original version approved by the respective committees

C. Application form for Ethics review (to be filled online). In case of other submissions related to ethics committee, the following documents will be auto-generated on the EC portal

- Amendments
- Protocol violation/ deviation
- Premature termination/ discontinuation
- Continuing review/ Annual report
- SAE reporting
- Study completion

D. Consent forms: <https://iecmanager.org/institution/283>

- Informed Consent Document should comprise Patient Information Sheet and the consent forms in English and Tamil.
- The investigator must provide information to the subjects in a simple language (avoid medical jargons). Please avoid copying & pasting from other study protocol.

- It should address the subjects, in a dialogue format. (eg. You will be asked some questions regarding....)
- A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable.
- In case of telephonic contact, please add a telephonic script in addition to the PIS format.

Studies involving children

If participants are children, the participant information sheet should address the parents/LAR of the children and should be worded accordingly.

- o Children <7 years - include parent / LAR consent form
- o Children 7-12 years - in addition to parent / LAR consent form, record verbal assent in LAR form
- o Children 12 - 18 years of age - include written assent form
 - Assent form should provide information about the study in a simple language comprehensible to a child from 12-18 years.
 - Language used should be simpler for children in the age group 7-12 years compared to children in the age group 12-18 years.