Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)
Institutional Ethics Committee- Interventional Studies
CDSCO Reg. No: ECR/342/Inst/ PY/2013/RR-19

<u>CIRCULAR</u>

Dated: 28.10.2023

Sub: Online application for submission of proposals to the Institutional Ethics Committee Interventional Studies for November 2023 - Reg.

   Faculty, PhD scholar, P.G. and U.G. Students are invited to submit research proposals approved by JSAC/PGRMC/SCTRC/GJ-STRAUS for approval by Institutional Ethics Committee – Interventional studies in the prescribed proforma available on website.

1. Kindly use the link https://iecmanager.org/institution/283 for filling the **online version of JIEC application form** and relevant annexures.

2. PIs are required to **upload the soft copy** of their signed declaration form, consent forms and scientific proposal to https://iecmanager.org/institution/283.

3. **One original hard copy** of the following documents is required to be submitted to Member-Secretary, Institutional Ethics Committee – Interventional studies (IEC-IS) at Institute Ethics Committee office, First floor, Administrative block, JIPMER.

   a) Covering letter (Forwarded by Guide & HoD)
   b) JSAC/ UGRMC/PGRMC certificate
   c) GCP certificate of student & guide
   d) Original signed research proposal (JSAC ver. August 2020) / PGRMC proposal dated 15.11.2020)
   e) Printout of the online IEC application
   f) Signed Original Declaration form
   g) Informed Consent Documents (PIS, Consent forms, Assent form etc.)
   h) Data collection proformas, Questionnaire etc.
   i) CV of PI / Co-PI (s) / Guide& Co-Guide (s)
   j) Any other documents

   (PIs / Students are requested to attach the documents in the above given order i.e. a to j)

4. Procedure and guidelines to upload proposal on e-EC portal is available in the JIPMER website https://jipmer.edu.in/research/research-committees/institute-ethics-committee/important-information

5. The hard copy should be typed using **both sides** of A4 size paper, in 12 font size with 1.5 spacing and page numbering.

6. The last date for submission of proposals to reach the office of the undersigned for consideration of approval by Institutional Ethics Committee – Interventional studies for the month of November is on or before **10-11-2023** (Friday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held **tentatively on 24.11.2023**

                   Dr. Sandhiya S.,
                   Member Secretary,
                   IEC – Interventional Studies

To:
- All Heads of the Departments - with a request to bring the same to the knowledge of the faculty and residents of their departments.
- Director, JIPMER for information
- Dean (Research) and Dean (Academics) for information

Procedure for Online application for Ethics approval

Step – 1: Click the link https://iecmanager.org/institution/283 to visit the eEC portal. Click on *Register* as Principal Investigator to open Online Application Form.

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.

Step – 3: Reopen the webpage again and login with user ID (Personal E-mail ID) and password as Principal Investigator.

Step – 4: Click on *Submit new project* on the left menu.

Step – 5: Fill the required details under *Project Summary*.

Under Review type, choose one of the following:

Full Board Review	:	For Fresh proposal
Expedited Review	:	For Major / Minor revision For waiver of consent
Exemption from Review	:	For Exemption from Review

Step – 6: Answer the *FILTER QUESTIONS* suitably to proceed with online filling of the application form:

     1. Does your research involve human genetic testing? Yes / No

     2. Will participants be prospectively recruited? Yes / No

     3. Is your research socio-behavioural and/or public health research? Yes / No

     4. Is your research a clinical trial? (both academic and regulatory clinical trials of drugs, devices, innovative procedures, IND, BA, BE, ISM,) Yes No

Step 7: Fill the Application form for Initial review as per project requirements.

Step – 8: Download the Declaration page and affix signatures of all the investigators. If required, use an additional blank sheet. Scan and upload on the same webpage. Click save and Continue.

Step – 9: Fill the checklist page as required. Continue filling the Annexures.

Step – 10: In the *Documents section*, upload essential documents after selecting the appropriate option from drop-down menu (*Covering letter forwarded by guide, JSAC Protocol INCLUDING data collection proforma, Informed Consent Documents in English &***Tamil)** in pdf format only and click on save button.

Step – 11: Once you click *Next*, the incomplete sections will be highlighted in orange. Revisit the sections and complete the must enter fields in the suitable formats.

Step – 12: The last tab on CV can be used to save your CV profile on the website for future use.

Step – 13: Finally, all the tabs appear green. Click on *Submit to IEC review* button to finish the submission**.**

For downloading the filled in application for hard copy submission:

Step 1: In the home page, click on *My projects* tab and look for your submission. Click on the eye icon for project overview.

Step 2: Click on the *Projects documents* tab and check the bottom half for downloading the IEC application.

Step – 3: View the application and download it.