Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)
(An Institution of National Importance under Ministry of Health & F.W., Government of India)

CIRCULAR

Dated: 01st July 2019

Sub: Submission of proposals for approval from Institutional Ethics Committee – Observational studies for the month of July 2019 - Reg.

Faculties, PhD scholars, 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 – Observational studies in the prescribed proforma available on website (instructions for submission are attached). Kindly use only the **proforma version 3.0 dated 27th July 2018** for submission to IEC (JIPMER website http://jipmer.edu.in/research/research-form and attached with this call for proposals circular).

1. Two hard copies (One original and One Xerox) of the research proposal are required to be submitted to Member-Secretary, Institute Ethics Committee (IEC) at Institute Ethics Committee office, First floor, Administrative block, JIPMER.
2. PIs are required to **upload the soft copy** of their proposal to https://iecmanager.org/institution/283 (procedure to upload the proposal is attached).
3. Please use the covering letter attached with the circular to upload the proposal.

The last date of submission of proposals to reach the office of the undersigned for consideration of approval by Institutional Ethics Committee for the month of **July** is **on or before 06-07-2019 (Saturday).** Proposals submitted before the last date will be taken up for discussion in IEC (Human Studies) Observational committee meeting scheduled to be held on **17-07-2019 (Wednesday).**

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Dr. Subitha L.,
Member Secretary,
IEC for Observational 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.

Copy to:

- Director, JIPMER for information
- Dean (Research) and Dean (Academics) for information
- Medical Superintendent for information

INSTRUCTIONS FOR SUBMISSION

The research proposals need to be submitted as per the instructions given below.

1. The consent form needs to be submitted as per the format given in JIPMER website. Research proposals deviating from the format will not be accepted. Kindly use only the proforma version 3.0 dated 27th July 2018 for submission to IEC (JIPMER website http://jipmer.edu.in/research/research-form and attached with this call for proposals circular).
2. The hard copies should be typed in Arial font using both sides of A4 size paper, in 11 font size with 1.5 spacing. No subsequent modification will be accepted.
3. Investigators are requested to include title of the study in the signature page.
4. **The proposal should be submitted with signatures of all investigators failing which it will not be taken up for discussion.**
5. Investigators are requested to **provide complete answers** to ALL questions asked in the informed consent form and to **avoid answering as Yes or No.**
6. Include thumb impression in addition to signature for participants & only signature for witness.
7. **Add address and contact details** of IEC (Human studies) secretariat above the signature of the participant in addition to the contact details of PI/Student researcher and guide in informed consent document as follows:

   "For other queries/ complaints, contact Member Secretary, Room No. 106, IEC (Human studies), Dean Research Office, First floor, Administrative Block, JIPMER. Ph: 0413-2296106"
8. **In Patient information sheet, avoid using technical terms. Mention volume of biological samples to be collected and number of contact points with the patient.**
9. **In ICD part 2, retain the clause on storage of biological samples and telephone consent only if relevant to the study.**

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

- Not submitting the Soft copy of complete proposal in pdf format on or before the last date.
- discrepancies between English and Tamil consent forms..
- major errors in translation in Tamil consent form.
- absence of parent/LAR consent form (For studies involving children below 7 yrs).
- absence of parent/LAR consent form along with assent form (For studies involving children above 7 yrs to below 18 years of age).

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 : If it's a fresh proposal
        - Expedited Review : If it's a Major / minor revision and waiver of consent
        - Exemption from Review : If PI / Student Researcher is asking for "Exemption of Review" from Ethics Committee
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.

From, Date:

Dr. / Mr. / Ms./ ……
Designation
Department
JIPMER, Puducherry

To,

The Member Secretary,
Institutional Ethics Committee
Interventional Studies / Observational Studies / Nursing College (Delete whichever is not applicable)
JIPMER, Puducherry

Sub: Submission of initial protocol / revised protocol / amendment in protocol for IEC approval – Reg.

Sir, Madam,

I am hereby submitting my initial protocol / revised protocol / amendment in protocol for the approval of IEC -Interventional Studies / Observational Studies / Nursing College.

Title of the project:

Name & contact details of the Principal Investigator / Student Researcher	Name & contact details of Guide / Co-investigator
Name & contact details of co-guide-1 / Co-investigator -2 (if applicable)	Name & contact details of co-guide-2/ Co-investigator -3 (if applicable)

Yours Sincerely,

(Name of PI / Student Researcher)