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: 21st February 2018

Sub: Submission of proposals for approval from Institutional Ethics Committee (Human Studies) for the month of March 2018 - Reg.

Faculty, Residents and UG Students are invited to submit research proposals approved by JSAC/PGRMC/NRMC/SCTRC/GJ-STRAUS for approval by Institute Ethics Committee (Human Studies) in the prescribed proforma available on website-

http://jipmer.puducherry.gov.in/research/research-committees/jipmer-scientific-advisory-committee-jsac/proformas/ - For Faculties and PhD Scholars
http://jipmer.puducherry.gov.inresearch/research-committees/postgraduate-research/proformas/ -For Residents

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

1. **Fifteen** hard copies 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. PIs are required to bring the soft copy of the protocol in pen drive while submitting the hard copy to the IEC office and same has to be mailed to iechumanstudiesjipmer@gmail.com (soft copy to be named as **Investigator's Name__Department**).
2. **Waiver of consent application form is enclosed as an annexure with this announcement for reference.**
3. The consent form needs to be submitted as per the format given in JIPMER website (available on - **http://jipmer.edu.in/research/research-committees/jipmer-scientific-advisory-committee-jsac/proformas/**). **FORMATS DEVIATING FROM THIS WILL NOT BE CONSIDERED FOR PRESENTATION.**
4. Investigators are requested to include title of the study in the signature page. **IN THE ABSENCE OF SIGNATURE(S) OF ANY OF THE INVESTIGATORS AND OR HEAD(S) OF THE COLLABORATING DEPARTMENT(S) THE PROPOSAL WILL NOT BE TAKEN UP FOR THE MEETING.**
5. The investigators are requested to ensure that English and Tamil informed consent forms are in concurrence with respect to the information provided in both part 1 and 2 of consent form. **THE PROPOSAL WILL NOT BE TAKEN UP FOR THE MEETING IN CASE OF**
   - 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)
6. Investigators are requested to **provide complete answers** to the following details asked in the consent form and are asked to **avoid answering as Yes or No:**
   - **Provision of free treatment for research related injury.**
   - **Compensation for participating in the study.**
   - **Compensation to participants for foreseeable & unforeseeable risks related to research study leading to disability or death.**
   - **Freedom to withdraw from study at any time during study period without loss of benefits that the participant would otherwise be entitled.**
   - **Possible current and future uses of biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others.**
   - **Include thumb impression in addition to signature for participants & only signature for witness.**
   - **ICMR declaration should come on signatures page.**
7. **In consent form part 1 - Below signature of the investigator, signature of participant needs to be included**.
8. **In consent form part 2**,
   - **Title of the study needs to be above the participant's name.**
   - **Clause on storage of biological samples needs to be removed, if the samples are not going to be stored for secondary purpose**.
   - **A sentence on "risk-benefit of the study has been explained to me' needs to be included.**
   - **Below signature of the witness, name and address of the witness needs to be included.**
9. **The proposal should be submitted with signatures of all investigators failing which it will not be taken up for discussion.**
10. Proposals submitted with the following criteria will be taken up in the sub-committee meeting to be held on **15-03-2018 (Thursday)** and the remaining proposals will be considered in full committee meeting to be held on **22-03-2018 (Thursday)**
    i. Proposals involving instructional techniques, curricula or class room management methods.
    ii. Minor modifications of proposals already approved by full review Institute Ethics Committee (IEC).
    iii. Proposals involving clinical materials that have been collected for non-research or clinical purposes (i.e. patient care records and specimens).
    iv. Proposals involving emergency outbreaks and disasters for pilot study if IEC full review is not possible.
    v. Proposals **NOT** involving therapeutic, diagnostic, prophylactic and screening interventions.
    vi. Proposals **NOT** involving vulnerable and special groups.

The hard copies should be typed in Arial font using both sides of A4 size paper, in 11 font size with 1.5 spacing. Research proposals deviating from the format will not be accepted. No subsequent modification will be accepted.

The last date of submission of proposals to reach the office of the undersigned for consideration of approval by IEC (Human Studies) for the month of November is **on or before 05-03-2018 (Monday).**

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Dr. Medha R
Member Secretary,
Institutional Ethics Committee (Human 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) & IEC Vice-Chairman, Dean (Academics) for information
- Medical Superintendent for information

ANNEXURE-I

Application form for requesting waiver of consent

1. Principal Investigator's name:
2. Department:
3. Title of project:
4. Names of co-investigators and Department/s:
5. Request for waiver of informed consent:

☐ Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

[1] Research involves 'not more than minimal risk'
[2] There is no direct contact between the researcher and participant
[3] Emergency situations as described in ICMR Guidelines
[4] Any other (please specify)

☐ Statement assuring that the rights of the participants are not violated :

☐ State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant :

Principal Investigator's signature with date: _____

Final decision at full board meeting held on: _____

Waiver granted: Yes …….No…….

If not granted, reasons, _____

Signature of the Chairperson with Date: _____