



सत्यमेव जयते

जवाहरलाल स्नातकोत्तर आयुर्विज्ञान शिक्षा एवं अनुसंधान संस्थान  
JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH  
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के अधीन राष्ट्रीय महत्व का संस्थान)  
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**INSTITUTIONAL ETHICS COMMITTEE – INTERVENTIONAL STUDIES**  
**JIPMER, PUDUCHERRY**

No. JIP/IEC/APR/2022-23

Date: 22-06-2023

**CIRCULAR**

**Sub: Submission of Annual / Periodic status report of the approved projects to the IEC -  
Interventional Studies, JIPMER**

All Faculty, Residents, PhD scholars, post and undergraduate students are informed to submit an original copy of “annual / periodic status report” of their research projects in the attached proforma for both ongoing and completed projects, approved on or before **April 2022** to the Member Secretary, Institutional Ethics committee- Interventional Studies as per the proforma attached with this circular on or before **14-07-2023** and soft copy of same needs to be forwarded to [iechumanstudies@jipmer.edu.in](mailto:iechumanstudies@jipmer.edu.in). The annual / periodic status report must be forwarded by the guide and Head of the Department.

Dr. Sandhiya S.,

Member Secretary,

IEC – Interventional Studies

**MEMBER SECRETARY**

**INSTITUTE ETHICS COMMITTEE  
(HUMAN STUDIES) JIPMER, PUDUCHERRY**

Copy to:

1. All the Faculties / MD / MS/ DM / MCh / PhD Scholars / PG Students / UG students

**Institutional Ethics Committee – Interventional Studies  
Continuing Review Application Form for the period 2022-23**

1. Summary of protocol participants: IEC No& Approval Date.:
  - No. of participants approved by IEC
  - No. of participants screened
  - No. of ongoing participants
  - No. of completed participants
  - No. of participants who refused to consent
  - No. of recruited participants
  
2. Have any participants been withdrawn from this study? Yes .....No.....  
If no, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)
  
3. Have there been any amendments in protocol/ Informed Consent Document since the last review?  
Yes .....No.....
  
4. Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?  
Yes .....No..... If no, mention the amendments not approved
  
5. Which protocol amendment is the site following at present?
  
6. Which ICD amendment is the site following at present?
  
7. Has any information appeared in literature, or evolved from this or similar research that might affect evaluation of the risk/benefit analysis of participants involved in this protocol?  
Yes .....No..... If Yes (attach separate sheet if needed)
  
8. Whether reports of SAEs so far have been reviewed by the IEC-
  - a.) Whether reports of SAEs at other sites have been submitted to the IEC
  
9. Have any participating investigators been added or withdrawn since last review?  
Yes .....No..... If Yes (Identify all changes in the attached narrative)
  
10. Is report of interim data analysis available?  
Yes .....No..... If Yes (submit as an attachment)
  
11. Is report of the data safety and monitoring board available?  
Yes .....No..... If Yes (submit as an attachment)

12. Have any investigators developed consultative relationship with or acquired equity / shares from a source related to this protocol which might be considered a conflict of interest?

Yes .....No..... If Yes (submit as an attachment)

Signature of the Student Researcher / Principal Investigator with Seal & Date:

Signature of Guide & HoD with Seal & Date: \_\_\_\_\_

Assessment of Continuing Review Report by the IEC to be reviewed by

- Chairperson / Member Secretary only and informed to the IEC members at Full Board
- Full Board
- Any 2 IEC members and informed to the IEC members at Full Board

Names of IEC members:

Member Secretary

Signature with date

IEC Decision on the Continue Review Report

Date:

Decision:

- Approved and the project can be continued without any modifications
- Modifications recommended - requiring protocol resubmission

- State the recommendations:

- Protocol should be discontinued

State the reasons for discontinuation:

Date of Full Board discussion

Signature of reviewer/s with date:

Member Secretary Signature with date:

**(Attach a copy of IEC approval letter with this report)**