

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

CIRCULAR

Dated: 21.06.2023

Sub: Online application for submission of proposals to the Institutional Ethics Committee Interventional Studies for July 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 of submission of proposals to reach the office of the undersigned for consideration of approval by Institutional Ethics Committee – Interventional studies for the month of July is on or before **03-07-2023** (Monday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held **tentatively after 3rd week of July 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.

The screenshot shows the 'Application Form for Initial Review' on the eEC portal. The user is logged in as Kundan Yadav, Principal Investigator. The form is for the institution 'Jawaharlal Institute of Postgraduate Medical Education and Research'. The 'SECTION A - BASIC INFORMATION' includes:

- 1. ADMINISTRATIVE DETAILS
 - (a) Name of Organization: Jawaharlal Institute of Postgraduate Medical Education and Research
 - (b) Name of Ethics Committee: Institutional Ethics Committee for Intervention studies
 - (c) Name of Principal Investigator: Kundan Yadav
 - (d) Department/Division: Dean Research office
 - (e) Date of submission: 07/11/2020
 - (f) Type of review requested: Full committee review (selected)
 - (g) Title of the study: asbd

Logos for FERC, GRATE, e-EC, CDSA, and thsti are visible at the top. A note at the bottom refers to the National Ethical Guidelines for Biomedical and Health Research.

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.

iecmanger.org/cfis-declaration/eyJpdil6lRzQ3l2b3R5U3M2ZWQ1MEEdjOTJlZUE9PSlslZhbHVlIjoWUjONzISS0yVFZ3a2UwZGhCbGR1dz09liiwibWJlYjoiNjY2YTYxYVYjOWZlZmNmN2Y4NjMwMTU...

Publication, Benefit Sharing And IPR Issues

Declaration

Checklist

ANNEXURES

Expedited Review

Exemption from Review

Clinical Trials

Human Genetics Testing Research

Socio-Behavioural and Public Health Research

Documents Upload

Uploaded Document(s)

* I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.

* I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.

* I/We confirm that we will maintain accurate and complete records of all aspects of the study.

I/We will protect the privacy of participants and assure confidentiality of data and biological samples.

I/We hereby declare that I/any of the Investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.

I/We have the following conflict of interest (PI/Co-I):

I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: Kundan Yadav Date: 07/11/2020

Name of Guide: Dr Subitha L Date: 07/11/2020

Name of HOD: Dean Date: 07/11/2020

Upload Signed Declaration Form

1604725195_initialSubmission_Declaration.pdf

Preview Download Save Save & Continue

Kindly download the completed declaration form, take a print out and sign this page. Please, upload the signed declaration page as a part of your application to the Ethics Committee.
Please note - applications submitted without this document may not be considered for review by your institute's Ethics Committee.

Activate Windows
Go to Settings to activate Windows.

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

iecmanger.org/cfis-annexure-socio-beh-research/eyJpdil6lnNWYXZjZhbVBlbnVhZS9wamZ3V3pxTWJhUj1E9PSlslZhbHVlIjoVzZSY0Rlcmx3anZUPdob3BFRU1vUT09liiwibWJlYjoiNDk0NjYxYzQ4MWMzZTlZn2EzOTM...

FERCI

CR@TE

CDS

thsti

Dashboard My Projects Project Notifications Reminders My IEC My Account

My Projects > vdasv

Kundan Yadav
Principal Investigator
Logout

Project Summary

Basic Information

Overview of Research

Methodology

Recruitment And Research Participants

Benefits And Risks

Informed Consent

Payment/Compensation

Storage And Confidentiality

Publication, Benefit Sharing And IPR Issues

Declaration

Checklist

ANNEXURES

Expedited Review

(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

(Name of the Institution) Jawaharlal Institute of Postgraduate Medical Education and Research

EC Ref. No. (For office use): EC Ref. No.

Title of study *: vdasv

Principal Investigator *: Kundan Yadav

Name: Kundan Yadav Designation: MTS Affiliation: Dean Research office, Jawaharlal Institute of Postgraduate Medical Education and Research

1. Data collection method used in the study *: Focus group Questionnaire/Survey Observation Interviews Documents and records Ethnographies/Oral history/Case studies Others (specify)

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing. *: Max 500 words

Activate Windows
Go to Settings to activate Windows.

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.

The screenshot shows the 'Submit Document(s)' form in the IEC Manager application. The form is titled 'Submit Document(s)' and contains the following fields:

- Document Type ***: A dropdown menu with 'Select Document Type' as the current selection.
- Document Title ***: A text input field.
- Version ***: A text input field.
- Document date ***: A date selection field.
- Upload Document**: A button with a paperclip icon for uploading files.
- Save**: An orange button to submit the form.

A green banner at the top of the form area displays the message: 'Your information saved successfully.'

Below the form is a table with the following columns: Document Type, Document Title, Version, Document Date, and Actions. The table is currently empty.

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.

The screenshot shows the 'DOCUMENT SECTION' in the IEC Manager application. The section is titled 'SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM' and contains a table with the following columns: Document Type, Document Version, Document Date, and Actions.

| Document Type | Document Version | Document Date | Actions |
|---|------------------|---------------|---------|
| Approval of JSAC / PGRMC / UGRMC / NRMCC | 1 | 07/11/2020 | |
| CV of PI / Co-PI (s) / Guide / Co-Guide (s) | 1 | 07/11/2020 | |
| Informed consent documents in English and Tamil or Waiver of Consent Form | 1 | 07/11/2020 | |
| Letter to Member Secretary/ Chairperson | 1 | 07/11/2020 | |
| Protocol | 1 | 07/11/2020 | |
| Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy) | | Not Updated | |
| Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) | | Not Updated | |
| Any other Documents submitted | | Not Updated | |
| Case Record Form | | Not Updated | |
| DCG (I) approval letter [if the study falls in new drug category.] | | Not Updated | |
| Ethics Committee clearance of other centers (Total No _____) | | Not Updated | |
| If DCGI approval letter is awaited, upload the application letter to DCGI [if the study falls in new drug category.] | | Not Updated | |
| Informed consent document in Other languages | | Not Updated | |
| Investigator's undertaking to DCG (I) [if the study falls in new drug category.] | | Not Updated | |
| Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready) | | Not Updated | |
| Questionnaire | | Not Updated | |
| Research participants recruitment procedures: advertisement, notices (if applicable) | | Not Updated | |
| Scales | | Not Updated | |
| CV | | Not Updated | |

The 'Methodology' row in the table is highlighted in orange, indicating it is incomplete. At the bottom right of the page, there is a 'Submit for IEC Review' button.

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

iecmanger.org/cv/7570

FERCI | CRATE | e-EC | CDSA | thsti

Dashboard | My Projects | Project Notifications | Reminders | My IEC | My Account

My Account > My CV

My CV

Dr. Subitha L
Principal Investigator
Logout

My CV

(Annexure 13)
Format for Curriculum Vitae for Investigators
Jawaharlal Institute of Postgraduate Medical Education and Research

Name:
Dr. Subitha L

Present affiliation:-

| Job title | Department | Organisation |
|-----------|--------------------------------|--------------|
| | Preventive and Social Medicine | |

Address (Full work address):
[Empty field]

Telephone number: [Empty field] **Email address:** subitha.l@gmail.com

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

iecmanger.org/cfs-uploadoc-list/eyJpdil6lFJRxdmaDRDjdjvUudBv21hbnFldiE9PSlsinZhbHVIjoIFxMfFwvdJtQ2tYytGxZjZ2wydGc9PSlsm1hYy6lEjEwMTExZWMSMWJmOTJIM2QxN2l3ZjBjZjgwMzQ2...

DOCUMENT SECTION

SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM

| Document Type | Document Version | Document Date | Actions |
|---|------------------|---------------|---------|
| Approval of JSAC / PGRMC / UGRMC / NRMIC | 1 | 07/11/2020 | 👁️ 🗑️ |
| CV of PI / Co-PI (s) / Guide / Co-Guide (s) | 1 | 07/11/2020 | 👁️ 🗑️ |
| Informed consent documents in English and Tamil or Waiver of Consent Form | 1 | 07/11/2020 | 👁️ 🗑️ |
| Letter to Member Secretary/ Chairperson | 1 | 07/11/2020 | 👁️ 🗑️ |
| Protocol | 1 | 07/11/2020 | 👁️ 🗑️ |
| Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy) | | Not Updated | |
| Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) | | Not Updated | |
| Any other Documents submitted | | Not Updated | |
| Case Record Form | | Not Updated | |
| DCG (I) approval letter [if the study falls in new drug category.] | | Not Updated | |
| Ethics Committee clearance of other centers (Total No ____) | | Not Updated | |
| if DCGI approval letter is awaited, upload the application letter to DCGI [if the study falls in new drug category.] | | Not Updated | |
| Informed consent document in Other languages | | Not Updated | |
| Investigator's undertaking to DCG (I) [if the study falls in new drug category.] | | Not Updated | |
| Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready) | | Not Updated | |
| Questionnaire | | Not Updated | |
| Research participants recruitment procedures: advertisement, notices (if applicable) | | Not Updated | |
| Scales | | Not Updated | |
| CV | | Not Updated | 🗑️ |

Submit for IEC Review

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.

The screenshot shows the 'My Projects' page in the IEC Manager. The user is logged in as Dr. Subitha L. The page displays a table of projects:

| Project Number | Project Title | Project Status | Latest Submission | Latest Submission Date | Document(s) Status | Actions |
|----------------|---------------|--------------------|----------------------------|------------------------|--------------------|------------------|
| 31139 | wd | Submitted to IEC | Project Initial Submission | 11-11-2020 | Submitted to IEC | Project Overview |
| 63228 | EFW | Pending Submission | Project Initial Submission | 11-11-2020 | Pending Submission | |
| 22224 | RGS | Pending Submission | Project Initial Submission | 11-11-2020 | Pending Submission | |
| 22137 | afea | Pending Submission | Project Initial Submission | 10-11-2020 | Pending Submission | |
| Int-2018/300 | TB; LION | Approved | Project Initial Submission | 10-02-2020 | Approved | |

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

The screenshot shows the 'Project Documents' page for project 31139. The page displays a table of documents:


| Document Type | Document Title | Version | Document Date | Action |
|---|----------------|---------|---------------|--------|
| CV of PI / Co-PI (s) / Guide / Co-Guide (s) | | 1 | 04-11-2020 | |
| Approval of JSAC / PGRMC / UGRMC / NRMCM | | 1 | 04-11-2020 | |
| Informed consent documents in English and Tamil or Waiver of Consent Form | | 1 | 04-11-2020 | |
| Letter to Member Secretary/ Chairperson | | 1 | 04-11-2020 | |
| Protocol | | 1 | 04-11-2020 | |

| Submitted Form/Annexure | Submission Date | Action |
|----------------------------|-----------------|---------------|
| Project Initial Submission | 2020-11-11 | View Document |
| Signed Declaration Form | 2020-11-11 | |

Step – 3: View the application and download it.

← → iecmanger.org/project/preview/eyJpdil6lmV3dj85VTBYdXZqTjhUTmFTbDNNa0E9PSlnZhbHVlIjoITWNGQmpxRjhsaXZTM2daeEocaaTdRZz09liwbWfjJoiMDQ1YWlxZTAzZjYjOGZmYmlwNjM4Zml2YzV6ZWxMx... ☆

Print Download



Application Form for Initial Review

Jawaharlal Institute of Postgraduate Medical Education and Research

EC Ref. No. (For office use):
31139

Questions in the form that do not apply for this application are greyed out.

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

| | |
|--|---|
| (a) Name of Organization: Jawaharlal Institute of Postgraduate Medical Education and Research | (b) Name of Ethics Committee: Institutional Ethics Committee for Intervention studies |
| (c) Name of Principal Investigator: Dr. Subitha L | (d) Department/Division: Preventive and Social Medicine |
| (e) Date of submission: 11/11/2020 | (f) Type of review requested: <input type="radio"/> Exempt from Review <input type="radio"/> Expedited Review <input checked="" type="radio"/> Full Board Review |
| (g) Title of the study: wdsA | <small>(Note: Refer to Table 4.2 on pages 36 and 37 of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, by the Indian Council of Medical Research, for categorisation of the review types.)</small> |

Activate Windows