

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

CIRCULAR

Dated: 01.08.2022p

Sub: Online application for submission of proposals to the Institutional Ethics Committee **Interventional Studies for August 2022 - 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
 - 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 June is on or before **10-08-2022** (Wednesday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held on **26-08-2021** (Friday).

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 form is divided into sections, with 'SECTION A - BASIC INFORMATION' currently visible. It includes fields for 'Name of Organization', 'Name of Ethics Committee', 'Name of Principal Investigator', 'Date of submission', and 'Title of the study'. There are also radio buttons for selecting the review type: 'Exemption from review', 'Expedited review', and 'Full committee review'. The 'Full committee review' option is selected. 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/eyJpdil6lRzQ3I2b3R5U3M2ZWQ1MEEdjOTJlZUE9PSlslZhbHVlIjoWnUONzISS0yVFZ3a2UwZGhCbGR1dz09liiWbWVjJioiNDk0NjYxYzQ4MmMzZTlZnEzOTM...

- 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 [Preview] [Download] [Save] [Save & Continue]

1604725195_initialSubmission_Declaration.pdf

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.

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

iecmanger.org/cfis-annexure-socio-beh-research/eyJpdil6lnNWYXZjZhbVBlbnVzZSY0Rlcmx3anZUPUdob3BFRU1vUT09liiWbWVjJioiNDk0NjYxYzQ4MmMzZTlZnEzOTM...

FERCI CRaTE EC CDSA thsti

Dashboard My Projects Project Notifications Reminders My IEC My Account

My Projects > vdasv

(Annexure 11)
Application Form for Socio-Behavioural and Public Health Research

(Name of the Institution) EC Ref. No. (For office use)
 Jawaharlal Institute of Postgraduate Medical Education and Research EC Ref. No.

Title of study * : vdasv
 Principal Investigator * :
 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

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' selected.
- Document Title ***: A text input field.
- Version ***: A text input field.
- Document date ***: A date picker field.
- Upload Document**: A button with a paperclip icon for uploading files.
- Save**: An orange button to save the document.

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. It displays a 'SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM' with the following table:

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' section in the left sidebar is highlighted in orange, indicating it is incomplete. An orange button labeled 'Submit for IEC Review' is visible at the bottom right of the page.

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

Activate Windows
Go to Settings to activate Windows.

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

iecmanger.org/cfs-uploaddoc-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	

Below the table, there is a section for 'Submitted Form/Annexure':

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

