

Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)

(An Institution of National Importance under Ministry of Health & Family Welfare, Government of India)

CIRCULAR

Dated: 27.05.2022

Sub: Online application for submission of proposals to the Institutional Ethics Committee **Interventional Studies for June 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) Approved 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
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 **10-06-2022** (Friday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held on **30-06-2021** (Thursday).

**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.

Application Form for Initial Review

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

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

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 * :
Kundan Yadav

(d) Department/Division * :
Dean Research office

(e) Date of submission:
07/11/2020

(f) Type of review requested * :
 Exemption from review
 Expedited review
 Full committee review

(g) Title of the study * :
asbd

(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.)

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.

Declaration

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 (P/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.




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

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

Title of study * :
vdasv

Principal Investigator * :-

Name: Kundan Yadav	Designation: MTS	Affiliation: Dean Research office, Jawaharlal Institute of Postgraduate Medical Education and Research
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1. Data collection method used in the study * :

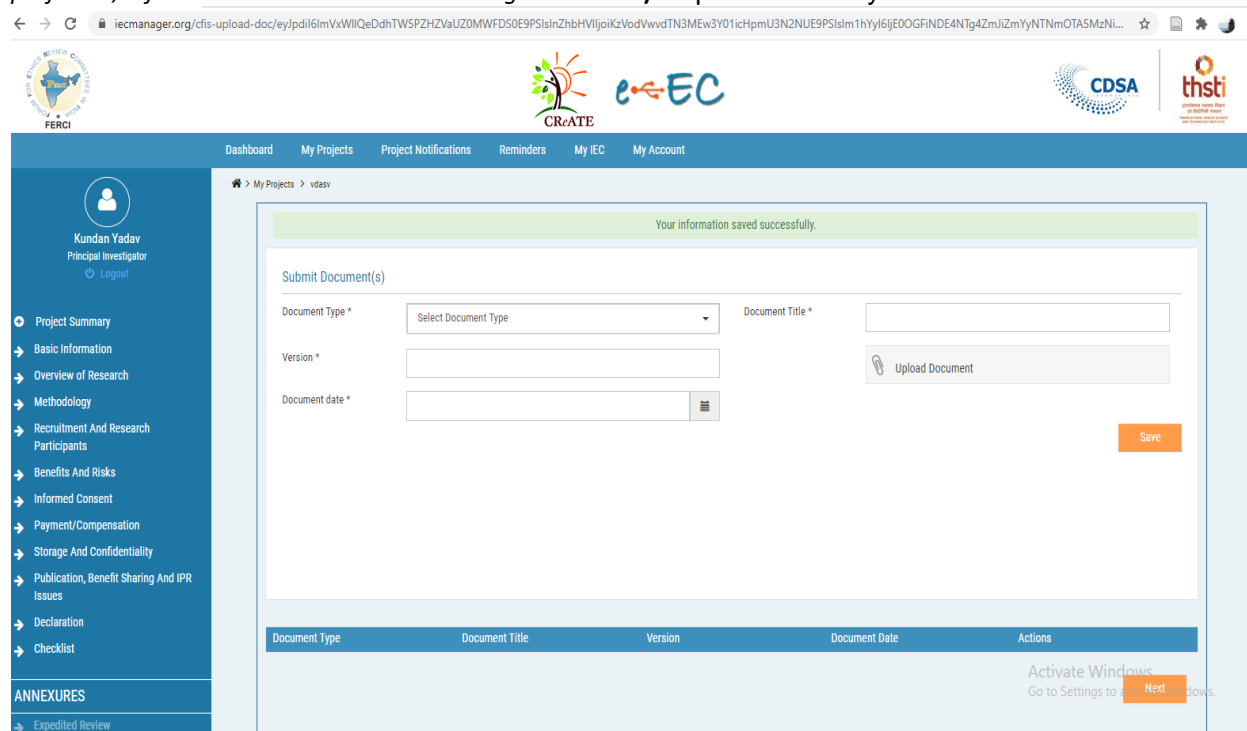
Focus group Questionnaire/Survey Observation Interviews Documents and records Ethnographies/Oral history/Case studies

Others (specify)

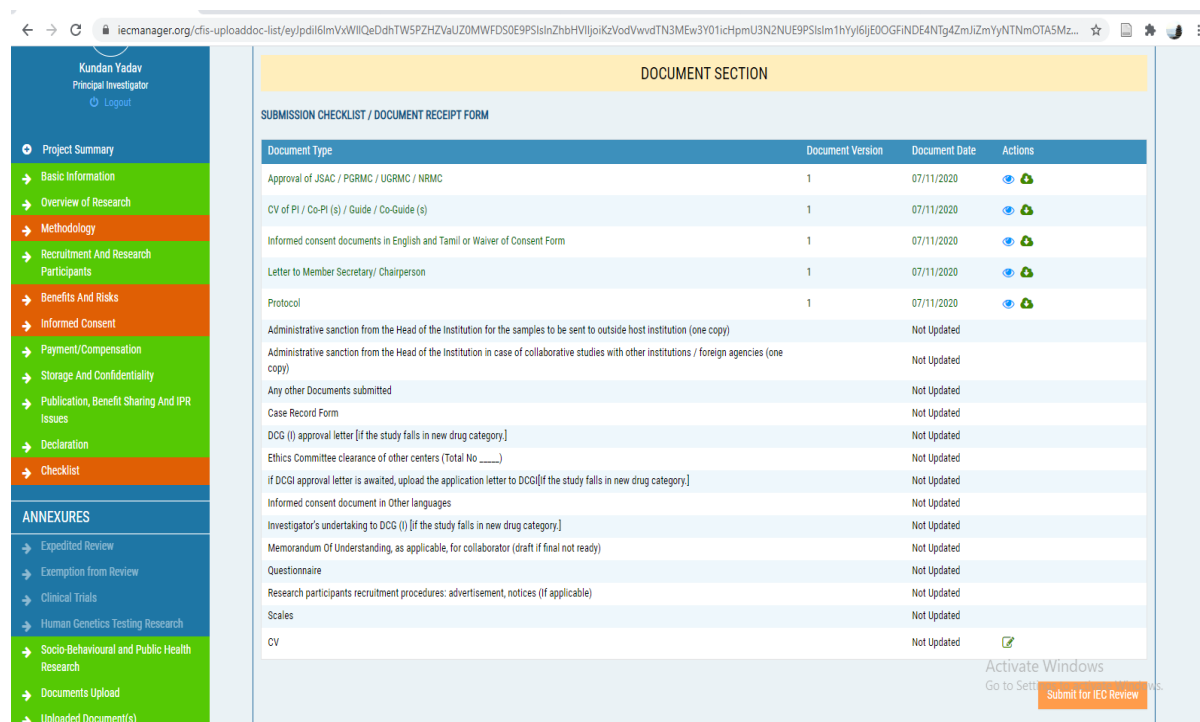
3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing. * :

[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.



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.



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 system. The user is logged in as Dr. Subitha L, Principal Investigator. The page displays a table of projects with the following data:

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 Overview (Project Initial Submission)' page in the IEC Manager system. The user is logged in as Dr. Subitha L, Principal Investigator. The page displays a table of project documents with the following data:

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 / NRMIC		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' with the following data:

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.

← → C iecmanager.org/project/preview/eyJpdil6lmV3djB5VTBvdXZqTjhUTmFTbDNNa0E9PSlsinZhbHVlIjoITWNGOmpxRjhsaXZTM2daeExoaTGRZa09liibWfFjloiMDQ1YWlxZTAzZVJOGZmYmlwNjM4Zml2YzVhZkZWMx... ☆

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