

CIRCULAR

Dated: 12.05.2023

Sub: Online application for submission of proposals to the Institutional Ethics Committee Interventional Studies for June 2023 - Reg.

Faculty, PhD scholar, P.G. and U.G. Students are invited to submit research proposals approved by JSAC/PGRMC/SCTR/C/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 June is on or before **03-06-2023** (Saturday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held **tentatively in the Third week of June 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*.

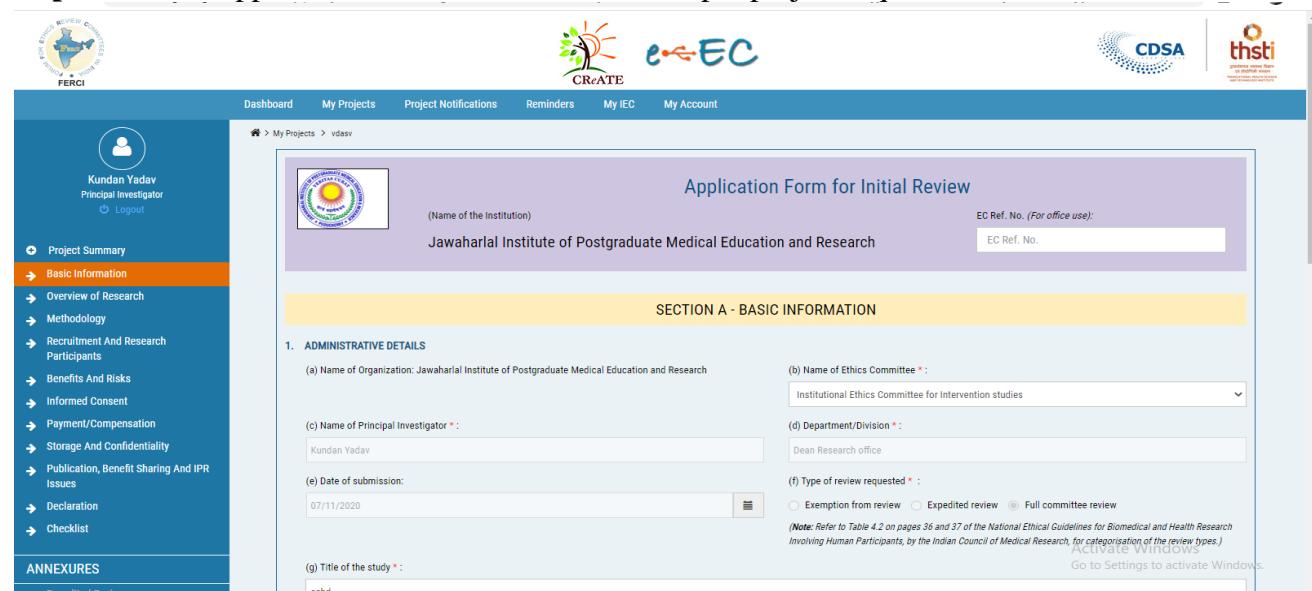
Under Review type, choose one of the following:

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 form is structured with sections for basic information and administrative details. The 'Basic Information' section is currently active, showing fields for the name of the organization (Jawaharlal Institute of Postgraduate Medical Education and Research), the name of the principal investigator (Kundan Yadav), the date of submission (07/11/2020), and the type of review requested (Exemption from review). The 'Admin Details' section is also visible, containing fields for the name of the ethics committee, department/division, and type of review requested. Logos for FERCI, CDSA, and THSTI are displayed at the top right of the page.

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.

iecmanager.org/cfis-declaration/ey/pdil6lkRzQ3l2b5R5U3M2ZWQ1MEdjOTjZUE9PSlslnZhbHVlijoiWnJONzISS0yyVFZ3aUwZGhCbGR1dz09liwibWFjijoYjNjNc4NjRjYj2YTyYwJiOWZjYzNmN2Y4NjMwMTU...

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

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

Preview Download Save Save & Continue

Activate Windows
Go to Settings to activate Windows.

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

iecmanager.org/cfis-annexure-socio-beh-research/ey/pdil6lnNlWYXFjczhVbE9wamZ3VpxTWhjU1E9PSlslnZhbHVlijoiVzZ3Y0Rlcmv3anZPUTdob3BFRU1vUT09liwibWFjijoINDk0NjYxQ4MWmZTlzN2EzOTM...









Dashboard My Projects Project Notifications Reminders My IEC My Account

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 > vdasy

(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 *: vdasy

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. *:

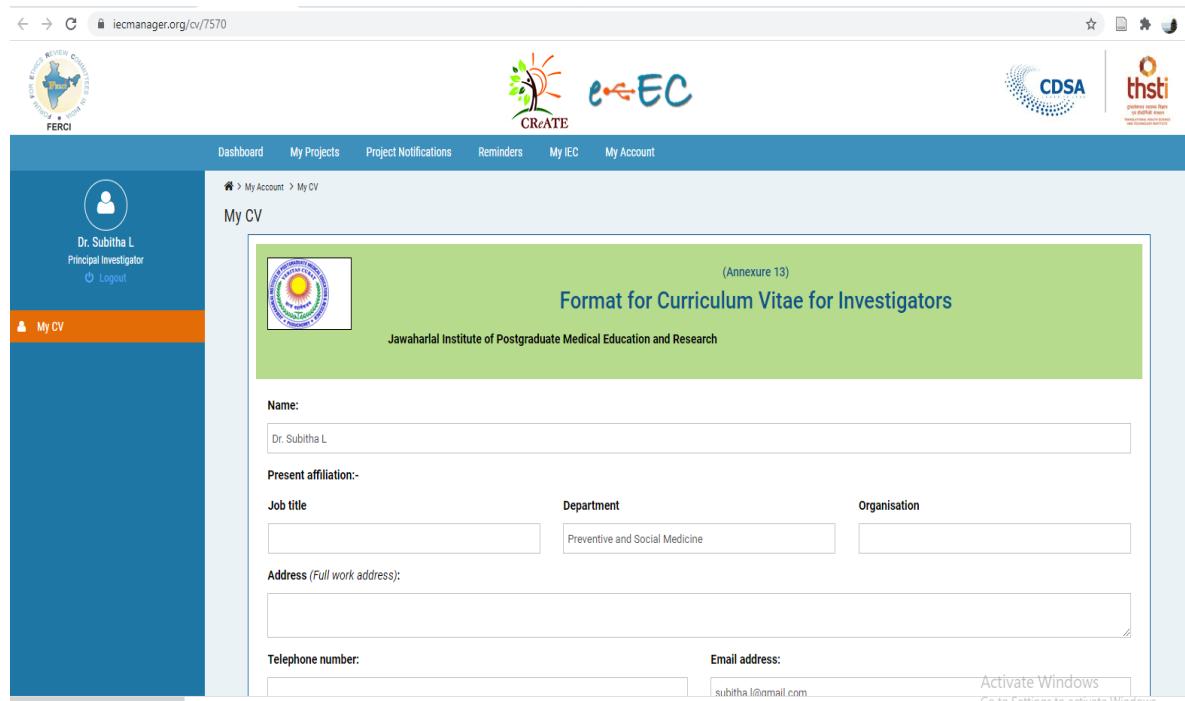
Max 500 words

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.

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



My CV

(Annexure 13)

Format for Curriculum Vitae for Investigators

Jawaharlal Institute of Postgraduate Medical Education and Research

Name: Dr. Subitha L

Present affiliation:-

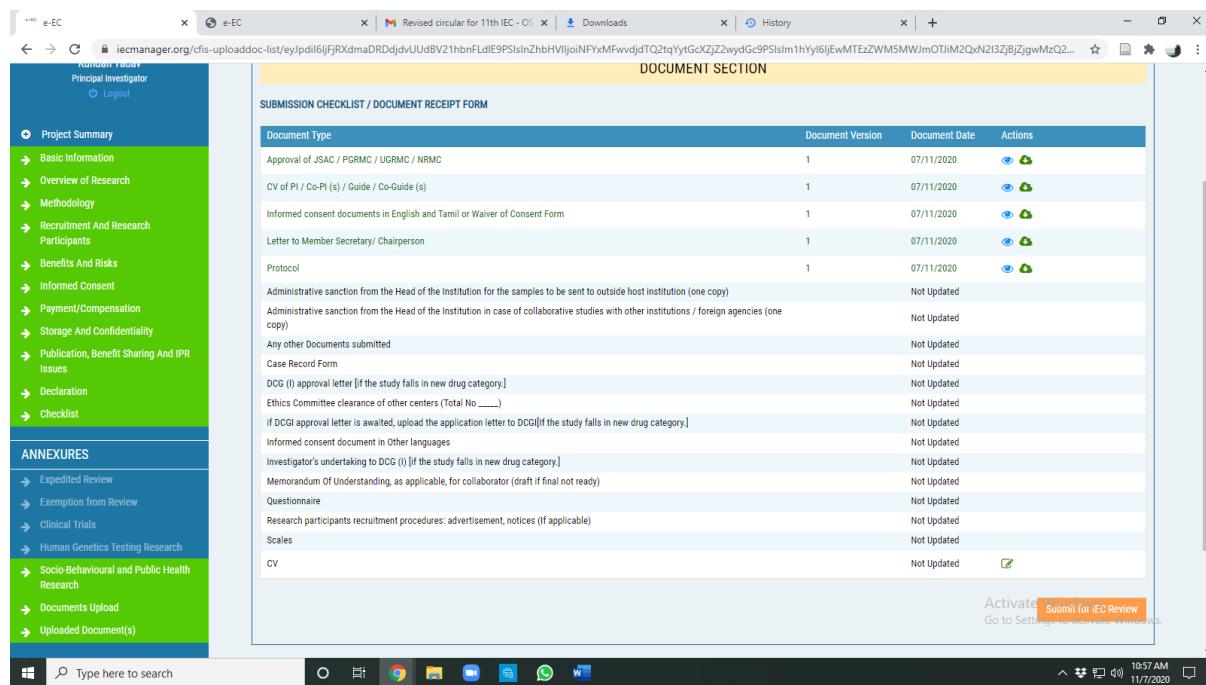
Job title	Department	Organisation
	Preventive and Social Medicine	

Address (Full work address):

Telephone number: Email address: subitha.l@gmail.com

Activate Windows

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



DOCUMENT SECTION

SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM

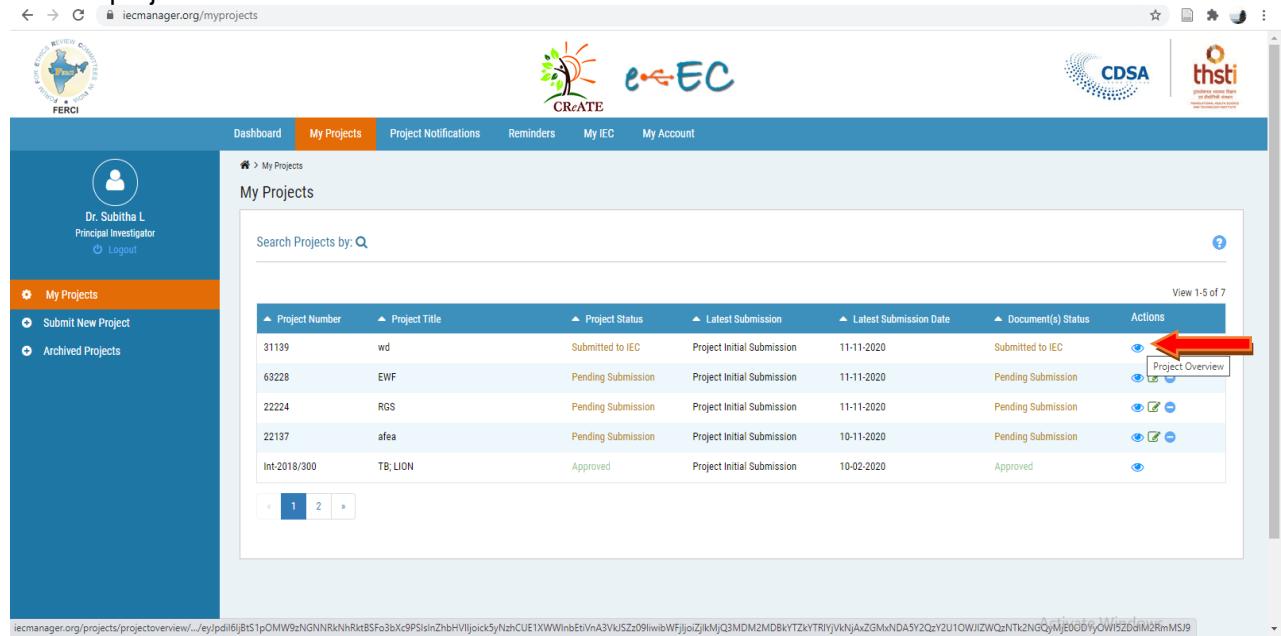
Document Type	Document Version	Document Date	Actions
Approval of JSAC / PGRMC / UGRMC / NRMC	1	07/11/2020	
CV of PI / Co-PI (s) / Guide / Co-Guide (s)	1	07/11/2020	
Informed consent documents in English and Tamil or Waiver of Consent Form	1	07/11/2020	
Letter to Member Secretary/ Chairperson	1	07/11/2020	
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
DCGI 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 DCGI [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

Activate Windows

Submit for IEC Review

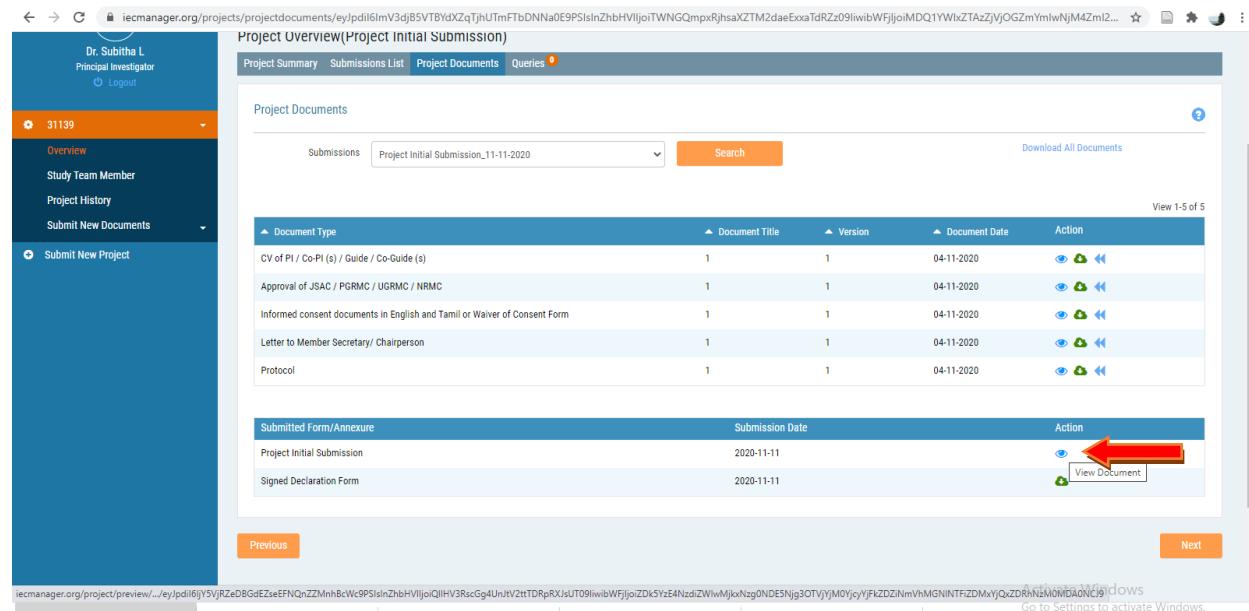
For downloading the filled in application for hard copy submission:

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 iecmanager.org home page with the 'My Projects' tab selected. On the left, a sidebar shows 'My Projects' is selected. The main area displays a table of projects with columns for Project Number, Project Title, Project Status, Latest Submission, Latest Submission Date, Document(s) Status, and Actions. The 'Actions' column contains icons for viewing, editing, and deleting. A red arrow points to the 'Project Overview' link in the Actions column for the first project (Project Number 31139). The URL in the address bar is: <http://iecmanager.org/projects/projectoverview/.../ey/pdil6j8t51pOMW9zNGNNRkNhRktBSFo3lsXc9PSlslnZhbHVljoick5yNzhCUE1XWWlnbEtA3VkJkS209lwibWFjjoizJikMjQ3MDM2MDBkYTzkYTRlYVkhjAxZGMxNDA5Y2QzY2U1OWjIZWQzNTk2NGDyMjE0ODYyOWI5ZD9mZmJ9>

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



The screenshot shows the 'Project Overview' page for Project Number 31139. The left sidebar shows 'Overview' is selected. The main area has tabs for Project Summary, Submissions List, Project Documents, and Queries. The 'Project Documents' tab is selected. It shows a table of documents with columns for Document Type, Document Title, Version, Document Date, and Action. A red arrow points to the 'View Document' link in the Action column for the 'Signed Declaration Form' in the 'Submitted Form/Annexure' section. The URL in the address bar is: <http://iecmanager.org/project/preview/.../ey/pdil6j8t51pOMW9zNGNNRkNhRktBSFo3lsXc9PSlslnZhbHVljoick5yNzhCUE1XWWlnbEtA3VkJkS209lwibWFjjoizJikMjQ3MDM2MDBkYTzkYTRlYVkhjAxZGMxNDA5Y2QzY2U1OWjIZWQzNTk2NGDyMjE0ODYyOWI5ZD9mZmJ9>

Step – 3: View the application and download it.

Application Form for Initial Review

Print Download 

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: Exempt from Review Expedited Review Full Board Review

(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.)

(g) Title of the study: wdsA

Activate Windows