CIRCULAR

Dated: 20.08.2022

Sub: Online application for submission of proposals to the Institutional Ethics Committee Interventional Studies for September 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.

- Kindly use the link <u>https://iecmanager.org/institution/283</u> 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 <u>https://iecmanager.org/institution/283</u>.
- 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 <u>https://jipmer.edu.in/research/research-committee/institute-ethics-committee/important-information</u>
- 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 September is on or before 10-09-2022 (Saturday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held on 30-09-2021 (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 <u>https://iecmanager.org/institution/283</u> 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.

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Kundan Yadav Principal Investigator O Logout	Application Form for Initial Review	
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Basic Information		
Overview of Research	SECTION A - RASIC INFORMATION	
Methodology		
Recruitment And Research Participants	1. ADMINISTRATIVE DETAILS	
Benefits And Risks	(a) Name of Organization: Jawaharlal Institute of Postgraduate Medical Education and Research (b) Name of Ethics Committee * :	
Informed Consent	Institutional Ethics Committee for Intervention studies	~
Payment/Compensation	(c) Name of Principal Investigator *: (d) Department/Division *:	
Storage And Confidentiality	Kundan Yadav Dean Research office	
 Publication, Benefit Sharing And IPR Issues 	(e) Date of submission: (f) Type of review requested * :	
Declaration	07/11/2020 Expedited review Sull committee review	
→ Checklist	(Note: Refer to Table 4.2 on pages 36 and 37 of the National Ethical Guidelines for Biomedical and Health Resea Involving Human Participants, by the Indian Council of Medical Research, for categorisation of the review types,	irch)
ANNEXURES	(g) Title of the study * : Go to Settings to activate W	Vindows.
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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.

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Jes	I/We co	nfirm 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
laration	of the s	tudy if needed.	
ecklist	I/We co	nfirm that we will maintain accurate and complete records of all aspects of the study.	
XURES	V I/We wi	Il protect the privacy of participants and assure confidentiality of data and biological samples.	
adited Daviaw	V I/We he	reby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of	f interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
mption from Review	I/We ha	we the following conflict of interest (PI/Co-I):	
ical Trials	☑ I/We de	clare/confirm that all necessary government approvals will be obtained as per requirements where	ver applicable.
nan Genetics Testing Research			
cio-Behavioural and Public Health earch	Name of PI: Kundan Yadav		07/11/2020
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oaded Document(s)	Dr Subitha L		07/11/2020
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Step – 9: Fill the checklist page as required. Continue filling the Annexures.

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 Publication, Benefit Sharing And IPR Issues 	Focus group Questionnaire/Survey Observation Interviews Documents and records Ethnograp	nies/Oral history/Case studies
Declaration	Others (specify)	
Checklist		
ANNEXURES	 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.
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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.

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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.

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Expedited Review	Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready)		Not Updated						
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Step – 12: The last tab on CV can be used to save your CV profile on the website for future use.

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

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Clinical Trials Research participants recruitment procedures: advertisement, notices (if applicable)		Not Updated	
Human Genetics Testing Research Scales		Not Updated	
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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

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

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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	A - BASIC INFORMATION	
1. ADMINISTRATIVE DETAILS		
(a) Name of Organization:	(b) Name of Ethics Committee:	
Jawaharlal Institute of Postgraduate Medical Education and Research	Institutional Ethics Committee for Intervention studies	
(c) Name of Principal Investigator:	(d) Department/Division:	
Dr. Subitha L	Preventive and Social Medicine	
(e) Date of submission:	(f) Type of review requested:	
11/11/2020	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 Participants, by the Indian Council of Medical Research, for categorisation of the review types.)	Human
(g) Title of the study:		
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