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: 22.01.2022

Sub: Online application for submission of proposals to the Institutional Ethics Committee Interventional Studies for February 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 (IEC) 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

(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 for the month of February is on or before 04-02-2022 (Friday). Proposals submitted before the last date will be taken up for discussion in IEC Interventional committee meeting scheduled to be held on 25-02-2021 (Friday).

Dr. Jayanthi M., 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.

FERGI	
	Dashboard My Projects Project Notifications Reminders My IFC My Account
Kundan Yadav Principal Investigator © Logout	Application Form for Initial Review (Name of the Institution) EC Ref. No. (For affice use):
Project Summary	Jawaharlal Institute of Postgraduate Medical Education and Research EC Ref. No.
Basic Information	
Overview of Research	
Methodology	SECTION A - BASIC INFORMATION
 Recruitment And Research Participants 	1. ADMINISTRATIVE DETAILS
➔ Benefits And Risks	(a) Name of Organization: Jawaharial 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 @ Full committee review
-> Checklist	(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 pages.)
ANNEXURES	(g) Title of the study * : Go to Settings to activate Windows
Expedited Review	asbd

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.

Publication, Benefit Sharing And IPR		 I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable. 	
Issues Declaration		 I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, of the study if needed. 	progress reports (if required) and a final report and also participate in any audit
Checklist		* I/We confirm that we will maintain accurate and complete records of all aspects of the study.	
NNEXURES		I/We will protect the privacy of participants and assure confidentiality of data and biological samples.	
Expedited Review		I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Finance	cial/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:		Date:
Socio-Behavioural and Public Health Research	Kundan Yadav		07/11/2020
Documents Upload	Name of Guide		Date:
Uploaded Document(s)	Dr Subitha L		07/11/2020
	Name of HOD: Dean		Date: 07/11/2020
	1604725195_Init Kindly download t declaration page	Igned Declaration Form alSubmission_Declaration pdf to constlet of declaration from take a print out and sign this page. Please, upload the signed is a part of your application to the Ethics Committee Kadiona submittee inthout this document may not be considered for review by your institute's Ethics	Preview Download Save Save & Continue
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Step – 9: Fill the checklist page as required. Continue filling the Annexures.

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Kundan Yadav Principal Investigator O Logout	(Annexu Application Form for Socio-Behavio (Name of the Institution)	
 Project Summary 		
Basic Information	Jawaharlal Institute of Postgraduate Medical Education and Re-	searcn EC Ref. NO.
Overview of Research		
Methodology	Title of study * :	
 Recruitment And Research Participants 	vdssv Principal Investigator * >	
Benefits And Risks	Principal investigator * :- Name: Designation:	Affiliation:
Informed Consent	Kundan Yadav MTS	Dean Research office, Jawaharlal Institute of Postgraduate Medical
Payment/Compensation		Education and Research
Storage And Confidentiality	1. Data collection method used in the study * :	
 Publication, Benefit Sharing And IPR Issues 	Data conection method uses in the study . Focus group Questionnaire/Survey Questionn Interviews Documents and records Ethnograph	hies/Oral history/Case studies
Declaration	Others (specify)	
Checklist		
ANNEXURES	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.
Fynedited Deview	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.

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Kundan Yadav Principal Investigator				· · · · ·			
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Publication, Benefit Sharing And IPR ssues							
Declaration							
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Expedited Review							

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.

Kundan Yadav Principal Investigator	DOCUMENT SECTION	DOCUMENT SECTION							
Ċ Logout	SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM								
roject Summary	Document Type	Document Version	Document Date	Actions					
sic Information	Approval of JSAC / PGRMC / UGRMC / NRMC	1	07/11/2020	۰ 🕹					
verview of Research	CV of PI / Co-PI (s) / Guide / Co-Guide (s)	1	07/11/2020	• 4					
ethodology	Informed consent documents in English and Tamil or Waiver of Consent Form	1	07/11/2020	• •					
cruitment And Research		1	07/11/2020	• •					
articipants	Letter to Member Secretary/ Chairperson	1	07/11/2020	۵ (۲)					
enefits And Risks	Protocol	1	07/11/2020	۵ (۲					
formed Consent	Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy)		Not Updated						
ayment/Compensation	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one		Not Updated						
torage And Confidentiality	сору)								
ublication, Benefit Sharing And IPR	Any other Documents submitted		Not Updated						
sues	Case Record Form		Not Updated						
eclaration	DCG (I) approval letter [if the study falls in new drug category.]		Not Updated						
hecklist	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.] Informed consent document in Other languages		Not Updated						
EXURES	Investigator's undertaking to DCG (i) [if the study falls in new drug category.]		Not Updated						
cpedited Review	Investigator's undertaking to UCs (i) (if the study fails in new drug category.) Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready)		Not Updated						
	Questionnaire		Not Updated Not Updated						
emption from Review	Questionnaire Research participants recruitment procedures: advertisement, notices (if applicable)		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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Dr. Subitha L	a¥ ≻ M My C	y Account > My CV ℃							
Principal Investigator		0	Jawaharlal Insti	tute of Postgradu	Format for Curr	(Annexure 13) iculum Vitae for I arch	nvestigators		
		Name:							
		Dr. Subitha L							
		Present affiliation	i:-						
		Job title			Department		Organisation		
					Preventive and Social Medici	e			
		Address (Full work	k address):						
		Telephone numbe	er:			Email address:			
						subitha.l@amail.com		Activate Windows	e Windows

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

Kulluali Tauav	DOCUMENT SECTION					
Principal Investigator	DOCUMENT SECTION					
	SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM					
Project Summary	Document Type	Document Version	Document Date	Actions		
Basic Information	Approval of JSAC / PGRMC / UGRMC / NRMC	1	07/11/2020	۰ 🕹		
Overview of Research	CV of PI / Co-PI (s) / Guide / Co-Guide (s)	1	07/11/2020	۰ 🕲		
Methodology	Informed consent documents in English and Tamil or Waiver of Consent Form	1	07/11/2020	• •		
Recruitment And Research		•				
Participants	Letter to Member Secretary/ Chairperson	1	07/11/2020	۵ 🕲		
Benefits And Risks	Protocol	1	07/11/2020	۵ (۵		
Informed Consent	Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy)		Not Updated			
Payment/Compensation	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one		Not Updated			
Storage And Confidentiality	copy) Any other Documents submitted		Not Updated			
Publication, Benefit Sharing And IPR	Case Record Form		Not Updated			
Issues	DCG (I) approval letter [if the study falls in new drug category.]		Not Updated			
Declaration	Ethics Committee clearance of other centers (Total No)		Not Updated			
Checklist	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			
NNEXURES	Investigator's undertaking to DCG (I) [if the study falls in new drug category.]		Not Updated			
Expedited Review	Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready)		Not Updated			
Exemption from Review	Questionnaire		Not Updated			
Clinical Trials	Research participants recruitment procedures: advertisement, notices (If applicable)		Not Updated			
Human Genetics Testing Research	Scales		Not Updated			
Socio-Behavioural and Public Health	cv		Not Updated	6		
Research						
Documents Upload				Activate Submit for IEC	Review	
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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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Dr. Subitha L Principal Investigator O Logout	Search Projects by:	۹					0
My Projects							View 1-5 of 7
Submit New Project	Project Number	 Project Title 	 Project Status 	 Latest Submission 	 Latest Submission Date 	 Document(s) Status 	Actions
Archived Projects	31139	wd	Submitted to IEC	Project Initial Submission	11-11-2020	Submitted to IEC	
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	22224	RGS	Pending Submission	Project Initial Submission	11-11-2020	Pending Submission	۲ 🔁
	22137	afea	Pending Submission	Project Initial Submission	10-11-2020	Pending Submission	۲ 🖉
	Int-2018/300	TB; LION	Approved	Project Initial Submission	10-02-2020	Approved	۲
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Step 2: Click on the *Projects documents* tab and check the bottom half for downloading the IEC application.

Principal Investigator		Project Summary Submissi	ons List Project Documents Queries O						
	-	Project Documents							0
Overview Study Team Member		Submissions	Project Initial Submission_11-11-2020	~	Search		De	ownload All Documents	
Project History								View 1	1-5 of 5
Submit New Documents	-	 Document Type 			🔺 Document Title	 Version 	Document Date	Action	
Submit New Project		CV of PI / Co-PI (s) / Guide	/ Co-Guide (S)		1	1	04-11-2020	ی 🕲 🕚	
		Approval of JSAC / PGRMC	/ UGRMC / NRMC		1	1	04-11-2020	• • • • • • • • • • • • • • • • •	
		Informed consent documen	ts in English and Tamil or Waiver of Consent Form		1	1	04-11-2020	۰ 🕹 📢	
		Letter to Member Secretary	/ Chairperson		1	1	04-11-2020	• 4	
		Protocol			1	1	04-11-2020	۰ ۵۰	
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		Project Initial Submission			2020-11-11			• • •	
		Signed Declaration Form			2020-11-11			A View Document	
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Step – 3: View the application and download it.

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Appli	ication Form for Initial Review EC Ref. No. (For office use): n and Research 31139
uestions in the form that do not apply for this application are greyed out. eneral instructions :a) Tick one or more as applicable. Mark NA if not applicable b) Attach additional sheets if required	
SECTION	A - BASIC INFORMATION
. 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 Human Participants, by the Indian Council of Medical Research, for cotegorisation of the review spes.)
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