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.

- 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) 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 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 <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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	Dashboard My Projects Project Notifications Reminders My IEC My Account
	★ > My Projects > vdsav
Kundan Yadav Principal Investigator & Logout	Application Form for Initial Review (Name of the Institution) EC Ref. No. (For office 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 types.)
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.

		I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.	
Publication, Benefit Sharing And IPR Issues			
Declaration		 I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from pr of the study if needed. 	rotocols, 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	st (Financial/Non-Financial) with the sponsor(s) and outcome of study.
Exemption from Review		I/We have the following conflict of interest (PI/Co-I):	
Clinical Trials		I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever app	licable.
Human Genetics Testing Research	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:		Date:
	Dean		07/11/2020
	🕅 Upload	igned Declaration Form	Preview Download Save Save & Continue
	1604725195_Ini	alSubmission_Declaration.pdf	
	declaration page	he completed declaration form, take a print cut and sign this page. Please, upload the signed s a part of your application to the Ethics Committee. Ications submitted without this document may not be considered for review by your institute's Ethics	
			Activate Windows Go to Settings to activate Windows

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

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Kundan Yadav			(Annexure 11)
Principal Investigator		Application Form for Socio-Be	havioural and Public Health Research
• <u>,</u>	(Name r	of the Institution)	EC Ref. No. (For office use):
Project Summary			
Basic Information	Jawa	harlal Institute of Postgraduate Medical Education ar	nd Research
Overview of Research			
Methodology	Title of study * :		
methodology			
Recruitment And Research	vdasv		
	vdasv Principal Investigator * :-		
Recruitment And Research Participants		Designation:	Affiliation:
Recruitment And Research Participants Benefits And Risks	Principal Investigator * :-	Designation: MTS	Dean Research office, Jawaharlal Institute of Postgraduate Medical
Recruitment And Research Participants Benefits And Risks Informed Consent	Principal Investigator * :- Name:	•	
Recruitment And Research Participants Benefits And Risks Informed Consent Payment/Compensation	Principal Investigator * - Name: Kundan Yadav	МТS	Dean Research office, Jawaharlal Institute of Postgraduate Medical
Recruitment And Research Participants Benefits And Risks Informed Consent Payment/Compensation Storage And Confidentiality Publication, Benefit Sharing And IPR	Principal Investigator * Name: Kundan Yadav 1. Data collection method used in the	MTS study*:	Dean Research office, Jawaharial Institute of Postgraduate Medical Education and Research
Recruitment And Research Participants Benefits And Risks Informed Consent Payment/Compensation Storage And Confidentiality Publication, Benefit Sharing And IPR Issues	Principal Investigator * Name: Kundan Yadav 1. Data collection method used in the Focus group Questionnaire/	МТS	Dean Research office, Jawaharial Institute of Postgraduate Medical Education and Research
Recruitment And Research Participants Benefits And Risks Informed Consent Payment/Compensation Storage And Confidentiality Publication, Benefit Sharing And IPR Issues Declaration	Principal Investigator * Name: Kundan Yadav 1. Data collection method used in the	MTS study*:	Dean Research office, Jawaharial Institute of Postgraduate Medical Education and Research
Recruitment And Research Participants Benefits And Risks Informed Consent Payment/Compensation Storage And Confidentiality Publication, Benefit Sharing And IPR	Principal Investigator * Name: Kundan Yadav 1. Data collection method used in the Focus group Questionnaire/	MTS study*:	Dean Research office, Jawaharial Institute of Postgraduate Medical Education and Research

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 O Logout		Submit Document	(s)								
 Project Summary 		Document Type *	Select Document	Туре		•	Document Title *				
Basic Information		/ersion *							Upload Document		
 Overview of Research 									Upload Document		
Methodology		Document date *				iii iii					
 Recruitment And Research Participants 											Save
Benefits And Risks											
Informed Consent											
Payment/Compensation											
Storage And Confidentiality											
 Publication, Benefit Sharing And IPR Issues 											
Declaration	De	cument Type	Decu	ment Title		Version		Decum	ent Date	Actions	
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ANNEXURES										Activate Window Go to Settings to acti	vs v <mark>Next</mark> Nin <mark>dows.</mark>
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			
🖒 Logout	SUBMISSION CHECKLIST / DOCUMENT RECEIPT FORM			
ect Summary	Document Type	Document Version	Document Date	Actions
c Information	Approval of JSAC / PGRMC / UGRMC / NRMC	1	07/11/2020	۰ 🕹
view of Research	CV of PI / Co-PI (s) / Guide / Co-Guide (s)	1	07/11/2020	۵ 🕹
nodology	Informed consent documents in English and Tamil or Waiver of Consent Form	1	07/11/2020	•
uitment And Research		1	07/11/2020	O
icipants	Letter to Member Secretary/ Chairperson	1	07/11/2020	۵ (۵
fits And Risks	Protocol	1	07/11/2020	۰ ۵
med Consent	Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy)		Not Updated	
nent/Compensation	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one		Not Updated	
age And Confidentiality	copy)			
ication, Benefit Sharing And IPR	Any other Documents submitted		Not Updated	
es	Case Record Form		Not Updated	
aration	DCG (I) approval letter [if the study falls in new drug category.]		Not Updated	
xlist	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	
URES	Informed consent document in Other languages		Not Updated	
dited Review	Investigator's undertaking to DCG (I) [if the study falls in new drug category.] Memorandum Of Understanding, as applicable, for collaborator (draft if final not ready)		Not Updated	
	Questionnaire		Not Updated Not Updated	
nption from Review	Questionnaire Research participants recruitment procedures: advertisement, notices (if applicable)		Not Updated	
cal Trials	Research participants recontinent procedures, adventisement, notices (n'applicable) Scales		Not Updated	
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o-Behavioural and Public Health arch	cv		Not Updated	C Activate Windows
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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 Principal Investigator Corport	off > My A My CV	kcount > My OV	Jawaharlal Insti	tute of Postgrad	Format for Curi	(Annexure 13) iculum Vitae for arch	[,] Investigators		
		Name:							_
		Dr. Subitha L							
		Present affiliation	÷						
		Job title			Department		Organisation		
					Preventive and Social Medici	e			
		Address (Full work	address):						
		Telephone numbe	r:			Email address:			
						subitha.l⊚amail.com		Activate Windows	Windows

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

Kulluali Lauav	DOCUMENT SECTION					-
Principal Investigator	DOODMENT GEOTION	•				
	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	۵ 💌		
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	• 6		
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)				_	
Publication, Benefit Sharing And IPR	Any other Documents submitted Case Record Form		Not Updated 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			
ANNEXURES	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	Q						0
My Projects								View 1-5 of 7
Submit New Project	A Project Number	 Project Title 	-	Project Status	s 🔺 Latest Submission	 Latest Submission Date 	 Document(s) Status 	Actions
Archived Projects	31139	wd	s	ubmitted to IEC	Project Initial Submission	11-11-2020	Submitted to IEC	
	63228	EWF	P	ending Submiss	sion Project Initial Submission	11-11-2020	Pending Submission	Project Overview
	22224	RGS	P	ending Submiss	sion Project Initial Submission	11-11-2020	Pending Submission	۲ 🔁
	22137	afea	P	ending Submiss	sion Project Initial Submission	10-11-2020	Pending Submission	۲ 🔁
	Int-2018/300	TB; LION	A	pproved	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.

Dr. Subitha L Principal Investigator O Logout		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 1-5 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	⊛ ۵ ﴿		
	Approval of JSAC / PGRMC	/ UGRMC / NRMC		1	1	04-11-2020	۵ 🖇		
		Informed consent documen	ts in English and Tamil or Waiver of Consent Form		1	1	04-11-2020	۵ 🖇 🗶	
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		Project Initial Submission	-		2020-11-11	<u>_</u>			
		Signed Declaration Form			2020-11-11			View Document	
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App Jawaharlal Institute of Postgraduate Medical Educati	Dication Form for Initial Revie	EC Ref. No. (For office use): 31139		
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stions in the form that do not apply for this application are greyed out. eral Instructions :a) Tick one or more as applicable. Mark NA if not applicable b) Attach additional sheets if required				
SECTIO	IN A - BASIC INFORMATION			
DMINISTRATIVE DETAILS				
a) Name of Organization:	(b) Name of Ethics Committee:			
awaharlal Institute of Postgraduate Medical Education and Research	Institutional Ethics Committee for	Intervention studies		
:) Name of Principal Investigator:	(d) Department/Division:			
Dr. Subitha L	Preventive and Social Medicine			
e) Date of submission:	(f) Type of review requested:			
1/11/2020	 Exempt from Review Expedit 	lited Review 🍥 Full Board Review		
	(Note: Refer to Table 4.2 on pages 36 and Participants, by the Indian Council of Medi	137 of the National Ethical Guidelines for Biamedical and Health Research Involving Human lical Research, for categorisation of the review types.)		
g) Title of the study:				