Jawaharlal Nehru Institute of medical Sciences

Imphal, Manipur

INSTITUTIONAL ETHICS COMMITTEE

Registration No. ECR/1333/Inst/MN/2020/RR-25 (DCGI, CDSCO)

Registration No. EC/NEW/INST/2021/MA/0022 (DHR, MOHFW)

Application for Ethics Review

Section I: ADMINISTRATIVE

Application No.....

Date of receipt.....

(A) INVESTIGATORS detail:

	Name, designation & Qualifications	Address Tel& fax Nos. Email ID	Signature
Principal Investigator			
Co-Principal investigators/ Collaborators			
(1)			
(2)			
(3)			

Send correspondence to:	**PI only ( )**	**PI & Co-PI No.( )**	**Only to Co-PI No.( )**

Please attach brief CV of each investigator with subject specific publications limited to previous 5 years

(B) TITLE AND DURATION OF THE STUDY:

Study title:
Month & Year of likely commencement of the study:
Study Duration:

(C) Sponsor Details:

Type of funding:
1.Contract ☐ 2.Subcontract ☐ 3.Gift/Donation of drugs/devices ☐
4. student project ☐ 5. Other (specify) ☐
Source of funding:
1. Government ☐ : specify: Central ( ) State ( ) Local ( ) 2. Private foundation ☐ : specify: Indian ( ) Foreign ( ) 3. Industry ☐ : specify: Private ( ) Public ( ) Other ( ) 4. Other ☐ 5. No funding required ☐
If multiple source of funding, give information on secondary sources
Status of funding:
1. Funding awarded/available ☐ 2. Funding partially awarded/available ☐ 3. Fund application pending ☐ 4. No funding application made ☐ 5. No funding required ☐
Name, address, tel/fax/email of Sponsor with name of contact person
Budget details showing fund allocation various head
Total budget
Are the study subjects protected by insurance coverage? Yes ☐ **No** ☐ *If yes, specify amount and condition of coverage*

(D) Drugs , Devices and Biologics:

Does your study require permission from regulatory authority? **Yes** ☐ **No** ☐
If yes, specify: 1. From drug controller: **Yes** ☐ **No** ☐ whether permission obtained **Yes** ☐ **No** ☐
2. From ICMR : **Yes** ☐ **No** ☐ whether permission obtained **Yes** ☐ **No** ☐
3. From other Govt. Dept(s): **Yes** ☐ **No** ☐ If yes, specify dept: i. Dept of whether permission obtained **Yes** ☐ **No** ☐ ii. Dept of whether permission obtained **Yes** ☐ **No** ☐
Does your study require you to send human biological material outside India? **Yes** ☐ **No** ☐
If yes, have : i. Obtained permission from the Director, JNIMS? **Yes** ☐ **No** ☐ ii. Has JNIMS and the foreign party signed agreement/MoU? **Yes** ☐ **No** ☐ (If yes, attach a copy of the agreement/MoU)

(E) STATEMENT ON CONFLICT OF INTEREST, IF ANY:

Describe briefly, if any, the financial and other interests of any of the ivestgators and/or close relatives, with the sponsor(s) and outcome of the study.

Section II: STUDY DESIGN, SUBJECT/PARTCIPANT SELECTION AND DATA COLLECTION PROCEDURES

Note: complete items A to F given below using non-technical language. Give full form or definitions of all abbreviations and acronyms. As far as possible try to keep within the prescribe word limit of each item.

(A) STUDY BACKGROUND:

Give summary of literature review and rationale of the study (300 words)

(B) STUDY PURPOSE:

Specific hypothesis, aim and objectives (200 words)

(C) DESIGN (check all applicable)

Phase I ☐ **Phase II** ☐ **Phase III** ☐ **Phase IV** ☐ **Clinical trial** ☐ **Multi-centric** ☐ **Observational study** ☐ **Experimental study** ☐ **Social Sciences** ☐ **Survey** ☐ **Focus group** ☐ **In-Depth Interviews** ☐ **Case studies** ☐ **Any other (specify).....**
Any general description of design (100 words)

(D) SUBJECT/PARTICIPANT SELCTION

(i)TYPE: Explain who will be the subjects/participant and rationale for selecting them (specific explanation if participants include minor, Pregnant women, Neonate, Person incompetent to give informed consent, Prisoner, Normal/Healthy Volunteer, student, staff of the institute) (100 words)
(ii)NUMBER: Explain about subject/participant selection: (a)Total number (b) rationale for having that number or sample size (b) sampling method (c) what proportion of them will be women (d) from where they will be recruited (e) whether screening of larger number will be required (200 words)
(iii)ELIGIBILITY: Explain inclusion and exclusion criteria, with specific explanation if the gender, class, caste, ethnicity, race will be used as inclusion or exclusion(50 words)
(iv)RECRUITMENT: Explain who will do the recruitment of subjects and how (50 words)

(E) DATA COLLECTION PROCEDURES:

Explain in sequence, the conduct of study and all data collection procedures. Please include information on (a) medical/surgical procedures, tests (b) treatment (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom (200 words)

(F) DATA ANALYSIS:

Plan of data analysis- by whom and how. Please mention whether data will be analysed to understand gender, caste, class, ethnicity, race differentials (150 words)

Section III: RISKS, BENEFITS PRIVACY AND CONFIDENTIALITY

(A) RISKS:

(a)RISKS, DISCOMFORT AND SIDE EFFECTS: Describe all possible risks and discomfort for

subject/participants due to intervention and/or interaction procedure/data collection method. Describe expexted degree and frequency of such risk, discomfort, side effects of drug etc.
(b)MINIMISATION:Describe steps you have taken or propose to take to minimise such risk, discomfort or early recognition of side effects and their management
(c)DATA SAFETY AND MONITORING:
i) Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events. Describe data safety and monitoring Plan of your project.
ii)Does the project require appointment of an Internal Data Safety Monitoring Board(DSMB)? If yes, suggest 5 or 6 names and addresses of the proposed DSMB members for the IEC approval.
(d)PRIVACY AND CONFIDENTIALITY : describe (i) how you propose to provide privacy to subjects/participants while conducting the study (ii) what level of confidentiality you propose to promise, (iii) what are the likely consequences to the subject/participants in the evnt of violation of confidentiality.
(e)IDENTIFIERS:Describe (i) the types of identifiable information on subject/participant you intend to collect (ii) how do propose to mask/remove identifiers (iii) how do you propose to ensure safe keeping and storage of identifiable data.
(f)BENEFITS: Describe benefits to the subject/participanting in the study. Also describe the benefit to the society if any.
(g)RISK/BENEFIT: Analyse the extent to which the benefits of the study out weigh the risk to the subjects/participants.

Section IV: INFORMED CONSENT PROCESS

(a) TYPE: (check all applicable)	
1.Signed witnessed consent ☐	**2. Signed non witnessed consent** ☐
3. Witnesses Thumb impression ☐	**4. Non witnessed Thumb impression** ☐
5.Verbal consent ☐	**6. No consent will be obtained** ☐

7. Consent from surrogate will be obtained (specify whom)
(b) PROCESS: Describe (i) How, Where, when and by whom the Consen will be obtained. (ii)How much time the subject/participants will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant women, neonates, prisoners etc. (iv)Describe how you will assess that information is correctly understood by the participant.
(c) INFORMATION CONTENT: Please attach informed consent form in engish and translated local language(s).The IC form must contain the following information: (1) a statement that consent is for a study/research/experiment, (2) an explanation of the purpose of research and nature of procedure, (3) all foreseeable risks/discomforts to participants due to research, (4) any benefits to be expected, (5) alternative procedures or courses of treatment in case subject does not want to participate, (6) the extent of confidentiality protection provided, (7) explanation on provision of compensation for injury caused to participant during the study, (8) whom to contact to know more about the study and participants' rights, (9) a statement that participation is voluntary, (10) A statement that participant can withdraw consent and from the study at any time without any facing any penalty.
(d) **COST AND PAYMENT: Describe the cost for participating in the study to the subject/participant. Describe plan to reimburse or compensate participant – if yes, the amount of payment proposed.**

LIST OF ATTACHMENTS:

1.

2.

3.

4.

5.

Principal Investigator's Certification

- I certify that the information provided in this application is complete and correct.

- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the IEC JNIMS and affiliated/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.
- I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC JNIMS approved protocol. I will not modify this JNIMS IEC certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Date **Name and signature**