Proforma 1A: Application Form for Initial Review for Regulatory and Academic Clinical trials (Non-Regulatory trials)
Submit it to NIEC-I for Clinical Trials (NIEC I-CT)
NIEC-AP-02A Version No.: 6.0 Effective Date: 03/06/2024
EC Ref. No.*(for office use):*

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
b) Attach additional sheets if required

Adapted from ICMR- Common forms for ethical review.https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

SECTION A – BASIC INFORMATION

1. ADMINISTRATIVE DETAILS		
A.	Name of Principal Investigator:	
B.	Department:	C. Date of Submission to NIEC:
D.	Type of review requested**:** Expedited Review ☐ Full Committee Review ☐ If applying for Expedited Review, Kindly also fill the Expedited review application form	
E.	Title of the study:	
	Acronym / Short title, (If any):	
F.	Protocol number: Version number: Dated:	
G.	Details of Investigators:	

Name	Designation and Qualification	Department	Address for communication and Contact Number
Principal Investigator			
Co-Principal investigator / Co-investigator			

H.	Number of studies where applicant is a:	
	i) Principal Investigator at time of submission:	2. Co-Principal Investigator at time of submission:
I.	Proposed Duration of the study:	

	1. **FUNDING DETAILS AND BUDGET**
a.	Total estimated budget for site:

Self-funding ☐	Institutional funding ☐	Funding agency ☐
Pharmaceutical Industry sponsored: ☐	*Others (Specify)*:	

SECTION B - RESEARCH RELATED INFORMATION

2. OVERVIEW OF RESEARCH

(a)	Summary of research project (within 300 words)
(b)	Type of study:

Regulatory clinical trials	☐	Academic clinical trials	☐
BA/BE studies	☐	Any other type of trial *(Specify)*	☐

3. METHODOLOGY

(a)	Sample size: Total estimated sample size for the study: No of participants to be enrolled at the Site:
(b)	Is there an external laboratory / outsourcing involved for investigations? Yes No NA If yes, specify:

SECTION C - PARTICIPANT RELATED INFORMATION

4. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer	☐	Patient	☐	Vulnerable person / Special groups (Specify)	☐	Others *(Specify)*	☐

(b) If study includes Vulnerable population:

(i). Provide justification for inclusion:

(ii). Are there any additional safeguards to protect research participants?

(c) Is there any reimbursement / payment to the subject for participation?

Yes ☐ No ☐

If yes, provide details

5. BENEFITS AND RISKS

(a) Are there any anticipated physical / social / psychological discomforts / risk to participants

Yes ☐ No ☐

If yes, specify

Describe the risk management strategy:

(b) What are Potential benefits from study participation (tick as applicable)

	Direct	Indirect
For the participant	☐	☐
For the society / community	☐	☐
For improvement in science	☐	☐

(c) Will advertisement be used to recruit subjects? ☐ Yes ☐ No

If yes, specify details of advertising:

6. INFORMED CONSENT

(a) Are you seeking waiver of consent? Yes ☐ No ☐
If yes, kindly fill the waiver of consent form

(b) Specify details of english Consent document
Version number and date of Participant Information Sheet (PIS) and Informed Consent Form (ICF):

(c) List the languages (apart from English) in which translations of Participant Information Sheet (PIS) and Informed Consent Form (ICF) were provided:
Telugu ☐ Hindi ☐ Urdu ☐ any other specify:

Specify the version number and date of translated forms in each language:

Are certificate(s) of translations provided: Yes ☐ No ☐

If yes, provide a copy of the certificates:

(d) Will Any tools be used to determine whether the subject understood the study
- Yes ☐ No ☐

If yes, specify:
By Questionnaire: ☐ Feed Back: ☐ Others: ☐ (Specify)

(e) Tick the elements contained in the Participant Information Sheet (PIS) and Informed Consent Form

Statement that study involves research and explain purpose of research	☐	Statement that consent and participation is voluntary	☐	Expected Risks and benefits to the study subject	☐
Alternatives procedures / therapies available	☐	Description of procedures to be followed	☐	Treatment schedule and random assignment of treatment (for RCT)	☐
Right to withdraw from study at any time	☐	Maintenance of Confidentiality	☐	Contact information of PI and Member Secretary of EC	☐
Expected duration of participation	☐	Anticipated prorated payment if any	☐	Responsibility of subject	☐
Financial compensation and medical management in SAE	☐	Statement that placebo shall not have any therapeutic effect (if placebo controlled trial)	☐	Others specify	☐

7. PAYMENT / COMPENSATION	
(a)	Is there a provision for providing treatment free of cost for research related injuries? Yes ☐ No ☐ NA ☐ If yes, specify details
(b)	Is there a provision for compensation of research related SAE? Yes ☐ No ☐ NA ☐ If yes, specify:
(c)	Has application been reviewed by any other hospital / Institute / DCGI / appropriate regulatory authority: Yes ☐ No ☐ under review: ☐ NA ☐ If yes, specify details If applicable provide copy of the regulatory approval letter

8. STORAGE AND CONFIDENTIALITY- drugs / devices / documents under access control	
(a)	Will the study documents be under access control Yes ☐ No ☐ If yes, Specify
(b)	Will the study drugs / devices be under access control Yes ☐ No ☐ If yes, Specify details

SECTION D: OTHER ISSUES

9. Additional Information	
(A)	Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide the details. Yes ☐ No ☐

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal / related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest NDCT RULES, ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulatory guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated / collaborating institutions wherever applicable
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We agree to inform all trial subject, that the drugs are being used for investigational purposes. I/we ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
☐	I/We confirm that we shall submit any protocol amendments, serious adverse events report, significant deviations from protocols, regular progress reports 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 safety and confidentiality of study 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. If Conflict of interest is present, kindly declare and specify details
☐	I/We declare / confirm that all necessary regulatory approvals will be obtained as per requirements wherever applicable.

Name of PI:	Signature:	Date:
Name of Co-PI: Signature:	Signature:	Date:
Name of Co- investigators:	Signature:	Date:
Name of Co- investigators:	Signature:	Date:
Name of Co- investigators:	Signature:	Date:

12. CHECKLIST						
S.No	***Items***	***Yes***	***No***	***NA***	***Enclosure No.***	***EC Remarks(If applicable***
ADMINISTRATIVE REQUIREMENTS						
1.	*Cover letter*	☐	☐	☐		
2.	*Brief CV of all Investigators- Updated, signed and dated*	☐	☐	☐		
3.	*Good Clinical Practice (GCP) training of investigators in last 3 years*	☐	☐	☐		
4.	*EC clearance of other centers*	☐	☐	☐		
5.	*Agreement between collaborating partners*	☐	☐	☐		
6.	*MTA between collaborating partners*	☐	☐	☐		
7.	*Insurance policy / certificate*	☐	☐	☐		
8.	*Copy of CTA signed with the sponsor*	☐	☐	☐		
9.	*Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs / Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol*	☐	☐	☐		
	PROPOSAL RELATED					
10.	*Copy of the detailed protocol (clearly identified numbered and dated) and synopsis (summary as far as possible in non-technical language, flowchart, diagrammatic representation of the protocol)*	☐	☐	☐		
11.	*Investigators Brochure (If applicable for drug / biologicals / device trials)*	☐	☐	☐		

12.	*Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) with version number and dated*	☐	☐	☐		
13.	*Assent form for minors (12-18 years) (English and Translated)*	☐	☐	☐		
14.	*Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated)*	☐	☐	☐		
15.	*Advertisement / material to recruit participants (fliers, posters, etc.)*	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

16.	***Other Registration / permissions***	***Required***	***Not required***	***Received***	***Applied dd/mm/yy***	***EC Remarks***
17.	*DCGI*	☐	☐	☐		
18.	*Others specify*	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION / DOCUMENTS RELATED TO THE STUDY

19.	***Item***	***YES***	***NO***	***NA***	***Enclosure no.***	***EC remarks***
20.		☐	☐	☐		
21.		☐	☐	☐		