Proforma 1B: Application Form for Initial Review of Biomedical and Health research studies (Academic Research)- Submit it to NIEC II-AR

Nizam's Institute of Medical sciences

NIEC-AP-02B **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 / Researcher:	
B.	Department:	C. Date of Submission:
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 / Researcher(s):	

Name	Designation and Qualification	Department and Institution	Address for communication
Principal Investigator / Researcher:			
Co-investigator(s) / Guide(s):			

2. FUNDING DETAILS AND BUDGET			
(a)	Total estimated study budget:		
(b)	Self-funding ☐	Institutional funding ☐	Funding agency ☐ *(Specify)*

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Summary of study (within 300 words)

(b) Type of study:

Interventional studies	☐	Case Control / Cohort	☐
Retrospective	☐	Epidemiological / Public Health	☐
Cross-sectional	☐	Socio-behavioral	☐
Biological samples / Data	☐	Any others *(Specify)*	☐

4. METHODOLOGY

(a) Sample size:
Justification for the sample size chosen;

(b) Is there an external laboratory / outsourcing involved for investigations?
Yes No NA
If yes, specify:

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT OF RESEARCH PARTICIPANTS

(a) Type of participants in the study:

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

(b) If study includes Vulnerable population, then

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 ☐ NA ☐

If yes, provide details

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

If yes, specify details of advertising:

6. BENEFITS AND RISKS

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

Yes ☐ No ☐ NA ☐

If yes, specify:

i. Describe the risk management strategy:

(b) Are there potential benefits from the study

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

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? Yes ☐ No ☐
If yes, kindly fill the request for 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 & explain purpose of research	☐	Statement that consent & participation are voluntary	☐	Expected Risks and benefits to the study subject	☐
Alternatives procedures / therapies available	☐	Contact information of PI and Member Secretary of EC	☐	Financial compensation and medical management in SAE	☐
Right to withdraw from study at any time	☐	Expected duration of participation	☐	Maintenance of Confidentiality	☐
Description of procedures to be followed, treatment schedule and probability of random assignment	☐	Anticipated prorated payment if any	☐	Responsibility of subject	☐
		Statement that placebo shall not have any therapeutic effect (if placebo-controlled trial)	☐	Others specify	☐

8. PAYMENT / COMPENSATION	
(a)	Is there a provision for treatment free of cost for research related injuries? Yes ☐ No ☐ NA ☐ Kindly specify:
(b)	Is there a provision for compensation of research related SAE? Yes ☐ No ☐ NA ☐ Kindly specify:

9. STORAGE AND CONFIDENTIALITY				
(a)	Identifying Information: Study Involves samples / data. Yes ☐ No ☐ NA ☐ *If yes, Specify* Anonymous / unidentified ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / confidentiality is maintained? (e.g. data stored in a cabinet, password protected computer etc.) Kindly specify?			
(b)	Will the study documents be under access control? Yes ☐ No ☐ NA ☐ If yes, Specify			
(c)	Will the study drugs / devices be under access control? Yes ☐ No ☐ NA ☐ If yes, Specify			

SECTION D: OTHER ISSUES	
10. 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 ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We will comply with all policies and guidelines of the institute and affiliated / collaborating institutions wherever applicable.
☐	I/We confirm that we shall submit any protocol amendments, 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.

Name of PI / Researcher: Signature: Date:

Name of Co-PI / Guide: Signature: Date:

Name of Co- investigator / Co-Guide: Signature: Date:

Name of Co- investigators / Co-Guide: Signature: Date:

Name of Co- investigators / Co-Guide: Signature: Date:

12. CHECKLIST						
S.No	**Items**	**Yes**	**No**	**NA**	**Enclosure No.**	**EC Remarks (If applicable)**
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter enlisting all documents enclosed	☐	☐	☐		
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.	MOU between collaborating partners	☐	☐	☐		
PROPOSAL RELATED						
6.	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)	☐	☐	☐		
7.	Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) with version number and dated	☐	☐	☐		
8.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
9.	Application for waiver of consent if applicable					
10.	Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated) which are numbered and dated	☐	☐	☐		
11.	Advertisement / material to recruit participants (fliers, posters, etc.)	☐	☐	☐		
12.	Insurance policy / A description of arrangement for insurance coverage for research participants, if applicable					
OTHER DOCUMENTS IF ANY						
13.						
14.						