Government of West Bengal

Nil Ratan Sircar Medical College, Kolkata.

Application Form for Review for Approval for Research Funding

SECTION A - BASIC INFORMATION

1. Name of Principal Investigator:
2. Name of the Department:
3. Date of submission:
4. Title of the study:

    a. Acronym/Short title, (If any):

    b. Duration of the Study:

5. Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication
Principal Investigator/Guide			
Co-investigators/student/fellow			

6. Total estimated budget for site:

Self-funding ☐ Institutional funding ☐ Funding Agency *(Specify)* ☐

…… …… …… ……

…… …… …… …… ……

7. Requirements for Research and Source in Tabulated Form:

Category	Source	Specifications	Approximate costs
Investigations			
Consumables			
Equipment			
Others (specify)			

SECTION B - RESEARCH RELATED INFORMATION

Overview of Research:

1. Summary (within 300 words):

2. Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/	☐	Case Control	☐
Prospective	☐	Public Health		Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

3. Methodology:

Sample size/ number of participants *(as applicable)*

Control group..... Study group .....

Justification for the sample size chosen (50 words) .....

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Is there an external laboratory/outsourcing involved for investigations? Yes ☐ No ☐ NA ☐

If yes, specify:

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Comments of scientific committee and IEC, if any (100 words)

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SECTION C - PARTICIPANT RELATED INFORMATION

1. Recruitment and Research Participants

   a. Type of participants in the study:

   Healthy volunteer ☐ Patient ☐ Vulnerable persons/Special groups ☐

   Others ☐ *(Specify)*

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   Is there any reimbursement to the participants? Yes ☐ No ☐

   If yes, Monetary ☐ Non-monetary ☐ Provide details

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   Are there any incentives to the participants? Yes ☐ No ☐

   If yes, Monetary ☐ Non-monetary ☐ Provide details

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   b. Are there any participant recruitment fees/incentives for the study provided to the PI / Institution? Yes ☐ No ☐

   If yes, Monetary ☐ Non-monetary ☐ Provide details

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2. Benefits and Risks

   i. Are there any anticipated physical/social/psychological discomforts/risk to the participants? Yes ☐ No ☐

   If yes, categorize the level of risk

   Less than Minimal risk ☐
   Minimal risk ☐
   Minor increase over minimal risk or low risk ☐
   More than minimal risk or high risk ☐

   ii. Describe the risk management strategy: .....

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What are the potential benefits from the study?	Yes	No	Direct	Indirect
For the participant	☐	☐	☐	☐
For the society/community	☐	☐	☐	☐
For improvement in science	☐	☐	☐	☐

Please describe how the benefits justify the risks .....

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Are adverse events expected in the study? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

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Payment/Compensation

Who will bear the costs related to participation and procedures?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ (specify)

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Is there a provision for free treatment of research related injuries? Yes ☐ No ☐

If yes, then who will provide the treatment?

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Is there a provision for compensation of research related SAE? Yes ☐ No ☐ If yes, specify.

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Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes ☐ No ☐ If yes, specify.

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SECTION D - OTHER ISSUES

Publication, Benefit

Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐

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Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details

Yes ☐ No ☐

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

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SECTION E - DECLARATION

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 guide- lines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	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 confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) 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 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.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. …… …… …… 2. …… …… …… Name of PI: …… Signature: … …… Name of Co-PI: …… Signature: …… Name of Co-PI: …… Signature: …… Date:

SECTION F - CHECKLIST

S. No.	Items	Yes	No	NA	Enclosure No	IEC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	IEC clearance	☐	☐	☐		
6	Agreement between collaborating partners	☐	☐	☐		
PROPOSAL RELATED						
7	Copy of the detailed protocol	☐	☐	☐		
8	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF) (English and translated)	☐	☐	☐		
9	Proforma/Questionnaire/Case Report Forms (CRF)/Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		

Signature of PI/Applicant: Date: