Annexure 5. Application Form for Initial Review

General Instructions:

a) Tick one or more as applicable. Mark NA if not applicable

b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1.

a) Name of Organization:

b) Name of the Ethics Committee:

c) Name of Principal Investigator:

d) Department/Division:

e) Date of Submission:

f) Type of review requested:

Exemption from Review	Expedited Review	Full Committee Review

Refer to Table 1 & 2 above of SOPs and National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review

g) Title of the study:

Acronym/ Short title, (If any):

h) Protocol number (If any): Version number:

h) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication

			including telephone/mobile, and email id
Principal Investigator/Guide			
Co-investigator/student/fellow			

i) Number of studies where applicant is a:

Principal Investigator at time of submission	Co-Investigator at the time of submission

j) Duration of the study:

2. FUNDING DETAILS AND BUDGET

a) Total estimated budget for site:

At site	In India	Globally

b) Funding details

Self-funding	Institutional funding	External Funding agency

Specify, if any other

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study (within 300 words)

b) Type of study:

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

4. METHODOLOGY

a) Sample size/ No. of Participants (as applicable)

At site	In India	Globally

Control group	Study Group

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation (*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it)*

b) Is there an external laboratory/ outsourcing involved for investigations?

Yes	No	NA

c) How was the scientific quality of the study assessed?

Independent external review	Review by Sponsor/Funder	Review within PI's institution
Review within multi-centre research group	No Review	

Date of review:

Comments of Scientific Committee, if any (100 words)

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a) Type of participants in the study:

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

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters		TV/Radio ads/social media/Institution website		Patients / Family/Friends visiting hospitals	
Telephone		Any other (Specify)			

b)

Children under 18 y		Pregnant or lactating women	
Differently abled (Mental/Physical)		Employees/Students/Nurses/ Staff	

Elderly		Institutionalized	
Economically and socially disadvantaged		Refugees/Migrants/Homeless	
Terminally Ill (stigmatized or rare diseases)		Any other (Specify):	

If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.

i. Will there be vulnerable person/special groups involved?

Yes	No	NA

ii. If yes, type of vulnerable person /special groups

iii. Provide justification for inclusion/exclusion

iv. Are there any additional safeguards to protect research participants?

c) Is there any reimbursement to the participant?

Yes	No

If yes, provide details

Monetary	Non-monetary

d). Are there any incentives to the participant?

Yes	No

If yes, provide details

Monetary	Non-monetary

d) Are there any participant recruitment fees / incentives the study provided to the PI/ Institution?

Yes	No

If yes, provide details

Monetary	Non-monetary

6. BENEFITS AND RISKS

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

For categories of risk refer to Table 1 of SOPs and for further details National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1

ii. Describe the risk management strategy:

b)

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

Please describe how the benefits justify the risks

c) Are Adverse Events expected in the study?

Yes	No	NA

The term adverse events in this regard encompass both serious and non-serious adverse events.

d). Are reporting procedures and management strategies described in the study?

Yes	No

If yes, Specify

7. INFORMED CONSENT

a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8.

Yes	No

b) Version number and date of Participant Information Sheet (PIS):

Version number and date of Informed Consent Form (ICF):

c) Type of consent planned for:

Signed consent		Verbal/ oral consent		Witnessed consent		Audio-Video (A/V) consent	
Consent from LAR (If so, specify from whom)		For children<7 y parental/LAR consent		Verbal assent from minor (7-12 y) along with parental consent		Written Assent from Minor (13-18 y) along with parental consent	
Other *(specify)*							

d) Who will obtain the informed consent?

PI/Co-I		Nurse/Counselor		Research Staff		Other (Specify)	

Any tools to be used (Specify)

e) Language of the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English	Local language	Other (Specify)

List the languages in which translations were done

If translation has not been done, please justify

f) Provide details of Consent requirement for previously stored samples, if used in the study (*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8; Enclose undertaking from PI confirming the same)*

g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Simple language		Data/ Sample sharing		Compensation for study related injury	
Risks and discomforts		Need to recontact		Statement that consent is voluntary	
Alternatives to participation		Confidentiality		Commercialization/benefit sharing	
Right to withdraw		Storage of samples		Statement that study involves research	
Benefits		return of research results		Use of photographs/ identifying data	
Purpose and procedure		Payment for participation		Contact information of PI and Member Secretary of EC	
Others *(Specify)*					

8. PAYMENT/COMPENSATION

a) Who will bear the costs related to participation and procedures?

PI	Institution	Sponsor	Other agency (Specify)

b) Is there a provision for free treatment of research related injuries?

Yes	No	NA

If yes, then who will provide the treatment?

c) Is there a provision for compensation of research related SAE?

Yes	No	NA

If yes, specify.

Sponsor	Institution/Corpus funds	Project Grant	Insurance

d) 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	NA

If yes, specify.

e). Is there a provision for ancillary care for unrelated illness during the study period?

Yes	No	NA

If yes, please specify.

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data.

Yes	No	NA

If Yes, Specify

Anonymous/unidentified	Anonymized: reversibly coded	Irreversibly coded
Identifiable		

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g., data stored in a cabinet, password protected computer etc.)

b) Who will be maintaining the data pertaining to the study?

c) Where will the data be analyzed and by whom?

d) For how long will the data be stored?

e) Do you propose to use stored samples/data in future studies (*For example, a data entry room, a protected computer etc.*)?

Yes	No	May be

If yes, explain how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

	Publication, Benefit Sharing and IPR Issues	Yes	No	NA
a)	Will the results of the study be reported and disseminated? If yes, specify.			
b)	Will you inform participants about the results of the study?			
c)	Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words)			

d)	Is there any plan for post research benefit sharing with participants? If yes, specify			
e)	Is there is any commercial value or a plan to patent/IPR issues. If yes, please provide details.			
f)	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.			

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 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 comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
	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.
	If applicable, 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 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.
	I/We have the following conflict of interest (PI/Co-PI):
	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:		Signature:	Date:
Name of Co-PI:		Signature:	Date:
Name of Guide:		Signature:	Date:
Name of HOD:		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					
3.	Good Clinical Practice (GCP) training of investigators in last 3 years					
4.	Approval of Scientific Committee					
5.	EC clearance of other centers					
6.	Agreement between collaborating partners					
7.	MTA between collaborating partners					
8.	Insurance policy/certificate					
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification					
10.	Copy of contract or agreement signed with the sponsor or donor agency					
11.	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						
12.	Copy of the detailed protocol					
13.	Investigators Brochure (If applicable for drug/biologicals/device trials)					
14.	Participant Information Sheet (PIS) and Informed Consent Form (ICF)(English and translated)					
15.	Assent form for minors (12-18 years) (English and Translated)					
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)					
17.	Advertisement/material to recruit participants (fliers, posters etc.)					

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm /yy**	**EC Remarks**
18.	CTRI					
19.	DCGI					
20.	HMSC					
21.	NAC-SCRT					
22.	ICSCR					
23.	RCGM					

24.	GEAC					
25.	BARC					
26.	Tribal Board					
27.	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.						
29.						

**For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre*