Annexure 1

Application Form for Initial Review

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. .....

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

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

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

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

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission ..... ii) Co Principal Investigator at time of submission: .....

(k) Duration of the study: .....

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

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SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

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(b) 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)*	☐		

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4. METHODOLOGY

(a) Sample size/ number 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 .....

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[3]*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?[4] 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: dd mm yy

Comments of scientific committee, if any (100 words)

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SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable persons/ 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 ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

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

Children under 18 yrs ☐ 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)*: ☐ .....

iii. Provide justification for inclusion/exclusion .....

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

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

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

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(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

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

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

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6. BENEFITS AND RISKS

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

If yes, categorize the level of risk[5] :

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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(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 .....

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(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

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

If Yes, Specify .....

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7. INFORMED CONSENT

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

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

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(b) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Waiver of consent ☐ Witnessed consent ☐

Consent from LAR ☐ (If so, specify from whom) ..... For children<7 yrs ☐ parental/LAR consent Verbal assent from ☐ minor (7-12 yrs) along with parental consent Written assent from ☐ minor (13-18 yrs) along with parental consent

Audio-Video (AV) ☐ consent Other ☐ *(specify)* .....

(c) Who will obtain the informed consent?

PI/Co-PI ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* .....

Any tools to be used .....

(d) 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 .....

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(e) Are you seeking waiver of consent? If yes, what are the reasons. Yes ☐ No ☐

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(f) Provide details of consent requirements for previously stored samples if used in the study[7]

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(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	☐	Sponsor contact information	☐
Others(Specify)	☐				

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8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

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

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

If yes, then who will provide the treatment? .....

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

Sponsor ☐ Institutional/Corpus fund ☐ 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? If yes, specify. Yes ☐ No ☐

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[7] *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.*

[8] *Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

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

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

(c) Where will the data be analyzed[9] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

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

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SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

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(b) Will you inform participants about the results of the study? Yes ☐ No ☐

(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) Yes ☐ No ☐ NA ☐

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(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐

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(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐

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(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 details. Yes ☐ No ☐

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[9]*For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST [10]

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.
☐	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.
☐	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 confidentiality of 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): 1. .... 2. ....

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

[10] *These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

Acknowledgement for Receipt of Application (Copy to be provided to PI)

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 Participant 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 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
¶Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)