Annexure 1. Conflict of Interest Agreement Form for Ethics Committee Members

It is recognized that the potential for conflict of interest will always exist but has faith in the Institutional Ethics Committee, IHBAS (IEC-IHBAS) and its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the IEC-IHBAS that no member may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC-IHBAS for Clinical Studies/research. The Undersigned will immediately disclose to the Chairperson of the IEC-IHBAS any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals. While signing the attendance register, the member documents the proposal for which he/she has Conflict-of-Intertest (COI).

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC-IHBAS review or approval except to provide information requested by the Committee.
Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment

Agreement on Conflict of Interest

Please sign and date this Agreement, if the undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC-IHBAS. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals. I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

_____ _____

Undersigned Signature Date

Name

_____ _____

Chairperson's signature Date

Name Dr. RC Jiloha

Declaration of Conflict of Interest

I, ……., have following proposal(s) with the undersigned as Principal Investigator/Co-investigator or real/potential/perceived competing research program under review by the IEC IHBAS. I shall abstain from any participation in discussions or recommendations in respect of the proposal.

I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

Agenda No. Research Proposal No. Research Proposal Title

_____ _____

Signature Date

Name

Annexure 2. Research Proposal Contents

The protocol should include the following:

1. The face page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary;
3. Background with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research objectives hypothesis, objectives and end points (outcome variables), if applicable);
6. Type of study, and location of the study.
7. Eligibility criteria and participant recruitment procedures (sampling) procedures (including screening in-person or using various digital modes of communication including but not limited to email, phone calls, message services, social media, etc.).
8. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any and a flow chart;
9. Duration of the study;
10. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld justification for the same;
11. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Av recording if applicable; informed consent for stored samples;
12. Audiovisual (AV) recording if applicable; informed consent for future use of stored samples; or a request for waiver of consent.
13. Plan for statistical analysis of the study;
14. Plan to maintain the privacy and confidentiality of the study participants;
15. case record form (or research Performa, screening, or diagnostic tools, etc.), permission to use the licensed or copyrighted material, or plans for payment or commercially available material should also be enclosed wherever required.
16. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period.

17. For research involving more than minimal risk, an account of management of risk or injury;
18. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
19. Provision of ancillary care for unrelated illness during the duration of research;
20. An account of storage and maintenance of all data collected during the trial or research study including physical form and digital form (site, server, country of location of the server, etc. in case of digital storage with duration of storage, the policy for retrieval when required, free or paid.
21. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity. and authorship criteria incase more than one investigator are there and ethical considerations and safeguards for protection of participants.
22. Ethical considerations and safeguards for protection of participants.

Annexure 3. Application Form for Expedited Review

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why expedited review from EC is requested*?

i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples ☐
ii. Involve clinical documentation materials that are non-identifiable (data, documents, records). ☐
iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s) ☐
iv. Revised proposals previously approved through expedited review, full review, or continuing review of approved proposals ☐
v. Minor deviations from originally approved research causing no risk or minimal risk ☐
vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
ix. Any other (please specify) ☐

1. Is waiver of consent being requested ? Yes ☐ No ☐
2. Does the research involve vulnerable person*? Yes ☐ No ☐
   If yes, give details:

Signature of PI: Click here to enter a date.

**Refer to Table 2 as above and for more details National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

Annexure 4. Application Form for Exempted Review

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Choose reasons why exemption from ethics review is requested*?

   i. Research on data in the public domain/ systematic reviews or meta-analyses; ☐
   ii. Observation of public behavior/information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   iii. Quality control and quality assurance audits in the institution ☐
   iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   v. Consumer acceptance studies related to taste and food quality ☐
   vi. Public health programmes by government agencies** ☐
   vii. Any other (please specify in 100 words): ☐

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

**Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to Table 2 of the SOPs and National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

***Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

Annexure 5. Application Form for Initial Review

EC Ref. No. (for office use):

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

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_

Annexure 6. Application Form for Clinical Trials

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number:
   NABH accreditation number EC registration number:

2. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached ☐
   Applied, under process ☐
   Not applied (State reason)

3.

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication or new route of administration	☐
Others (specify) ☐			

Tick all categories that apply to your trial

4. Trial design of the study (May choose more than one)

I.

Randomized	☐	Factorial	☐
Nonrandomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched pair	☐	Non-inferiority trial	☐
Others (specify)	☐	Equivalence trial	☐

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

III. Describe the method of allocation concealment (blinding / masking), if applicable

5. List the primary / secondary outcomes of the trial.

6. Is there a Contract Research Organization (CRO) /Site Management Organization (SMO) / Any Other Agency such as public relation/Human resource? Yes ☐ No ☐

If yes, Name and Contact details:

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others (specify)	☐

Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; If yes, provide regulatory approval details
Yes ☐ No ☐ NA ☐

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details
Yes ☐ No ☐ NA ☐

III. Provide contact details of who prepared and /or is manufacturing the drug(s), device(s) and biologics

IV. Provide details of patent of the drug/s, device/s and biologics.

8. Describe in brief any preparatory work or site preparedness for the protocol?
Yes ☐ No ☐ NA ☐
If yes, (100 words)

9. Is there an initial screening/ use of existing database for participant selection?
Yes ☐ No ☐ NA ☐
If Yes, provide details (*In order to select participants for your protocol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same)*

10. Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address them.
Yes ☐ No ☐ NA ☐

Does the study use a placebo?
If yes, justify the use of the placebo and risks entailed to participants.
Yes ☐ No ☐ NA ☐

Will current standard of care be provided to the control arm in the study?
Yes ☐ No ☐ NA ☐
If no, please justify.

Are there any plans to withdraw standard therapy during the study ?If yes, please justify.
Yes ☐ No ☐ NA ☐

Are there any rules to stop the protocol in case of any adverse events? If yes, please specify.
Yes☐ No☐ NA☐

Does the study have a Data and Safety Monitoring Plan? If no, please justify.

Yes☐ No☐

. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other *(Specify)* ☐

(Certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

List the languages in which translations were done

Justify if translation not done

17. Involvement/consultation of statistician in the study design Yes☐ No☐ NA☐
18. Is there any insurance coverage of the trial? If yes, provide details. Yes☐ No☐

19. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Please provide details.
Yes☐ No☐

20. Is the PI trained in GCP in last 3 years? If yes, please enclose certificate
Yes☐ No☐

Signature of PI: Click here to enter a date.

Annexure 7. Application Form for Human Genetics Testing Research

Title of study: Principal Investigator (Name, Designation and Affiliation)

. Describe the nature of genetic testing research being conducted.
(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Does the study involve pretest and post-test counselling? If yes, please describe.
Yes ☐ No ☐ NA ☐

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent?
Yes ☐ No ☐ NA ☐
If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐
If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

6. What measures are taken to minimize/ mitigate/eliminate conflict of interest?

7. Is there plan for future use of stored sample for research? Yes ☐ No ☐
If yes, has this been addressed in the informed consent. Yes ☐ No ☐

Signature of PI: Click here to enter a date.

Annexure 8. Application Form for Socio-Behavioural and Public Health Research

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Data collection method used in the study

Focus group	☐	Questionnaire/survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/oral history/case studies	☐
Others(Specify)	☐				

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

2. Type of informed consent is used in the study?

Individual consent ☐	Gate-keeper consent ☐	Community consent ☐
Others (specify) ☐		

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing? Yes ☐ No ☐

4. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

5. Are cultural norms and/or social considerations/sensitivities considered while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA

☐

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

III. Describe how do societal benefits outweigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI: Click here to enter a date.

Annexure 9. Format for Curriculum Vitae for Investigators

Name:	
Present affiliation *(Job title, department, and organisation)***:**	
Address *(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Professional registration *(Name of body, registration number and date of registration)***:**	
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations)***:**	

Projects undertaken in the last 5 years:

Relevant research training/experience in the area[25]:
Relevant publications *(Give references to all relevant publications in the last five years)***:**

Signature	**Date:** Click here to enter a date.

[25]*Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

Annexure 10. Undertaking by the investigator in case of a clinical trial

1. Full name, address, and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)

2. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

3. Commitments:

i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the changers) involved are only logistical or administrative in nature.

iii) I agree to personally conduct and/or supervise the clinical trial at my site.

iv) I agree to inform all Subjects; that the intervention/drugs/device are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the OCP guidelines are met.

v) I agree to report to the 'Sponsor all adverse experiences that occur during the investigation(s) in accordance with regulatory and GCP guidelines.

vi) I have read and understood the information in the Investigator's brochure, including

the potential risks and side effects of the drug.

vii) I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority, or their authorized representatives, in accordance with regulatory and OCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix) I agree to promptly report to the Ethics Committee all changes in the methodology/clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

x) I agree to inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

xii) I agree to comply with all other requirements, guidelines, and statutory obligations as applicable to clinical Investigators participating in clinical trials including the provisions contained in National Ethical Guidelines for Biomedical and Health Research involving Human Participant, 2017 by ICMR and The New Drugs and Clinical Trial Act, 2019.

Signature

Name of the PI

Affiliation

Annexure 11. Continuing Review/Annual Report

EC Ref. No. (*for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Validity of approval: Click here to enter a date.
2. Date of Start of study: Click here to enter a date. Proposed date of Completion: Click here to enter a date.

   Period of Continuing Report Click here to enter a date. ---- to ------ Click here to enter a date.
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected No. Screened: No. Enrolled:

   Number Completed: No. on followup: .

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB* *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

   Yes ☐ No ☐ NA ☐

   (d) Any other remark

   (e) Have any participants withdrawn from this study since the last approval?

   Yes ☐ No ☐ NA ☐

   If yes, total number withdrawn and reasons:
4. Is the study likely to extend beyond the stated period?
   (Mention problems if encountered) Yes ☐ No ☐

   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period?
If No, skip to item no.6 Yes ☐ No ☐

(a) If yes, date of approval for protocol and ICD : Click here to enter a date.

(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐
If yes, when / how:

6. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes ☐ No ☐
If yes, discuss in detail:

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐
If yes, give details

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief:

(b) Have any SAE's occurred since last review? Yes ☐ No ☐
If yes, number of SAE's : Type of SAE's:

(c) Is the SAE related to the study? Yes ☐ No ☐
Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?
If yes, number of deviations

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

10. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC

    Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? Yes ☐ No ☐
    If yes give details

    Any other comments:

Signature of PI:

Click here to enter a date.

Annexure 12. Application Form for Amendments

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.
2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD[18]

3. Impact on benefit-risk analysis Yes ☐ No ☐ If yes, describe in brief:

4. Is any re-consent necessary? Yes ☐ No ☐
   If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

   Expedited review (No alteration in risk to participants) ☐

   Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/Informed consent document (ICD):

Annexure 13. Protocol Violations/Deviations Reporting

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

   Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

2. Participant ID: Date of occurrence: Click here to enter a date.

3. Total number of deviations /violations reported till date in the study:

4. Deviation/Violation identified by: Principal Investigator/study team ☐
   Sponsor/Monitor ☐ SAE Sub Committee/EC ☐

5. Is the deviation related to (Tick the appropriate box):

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others (*specify*)	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation:

7. Corrective action taken by PI/Co-PI:

8. Impact on (if any): Study participant ☐ Quality of data ☐

9. Are any changes to the study/protocol required? Yes ☐ No ☐
   If yes, give details

Signature of PI: Click here to enter a date.

Annexure 14. Serious Adverse Event Reporting Form (Biomedical Health Research)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

Participant details:

Initials and ID	Age at the time of event	Gender	Weight: (Kg)
		Male ☐ Female ☐	Height: (cm)

Suspected SAE diagnosis:

Date of onset of SAE: Click here to enter a date.

Date of reporting SAE: Click here to enter a date.

Describe the event (*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious)*:

Details of suspected intervention causing SAE (*Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

Report type: Initial ☐ Follow-up ☐ Final ☐
If Follow-up report, state date of Initial report Click here to enter a date.

Have any similar SAE occurred previously in this study? Yes ☐ No ☐
If yes, please provide details.

In case of a multi-centric study, have any of the other study sites reported similar SAEs (Please list number of cases with details if available).

Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hopitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

In case of death, state probable cause of death:

C. No permanent/significant functional/cosmetic impairment ☐
Permanent/significant functional/cosmetic impairment ☐
Not Applicable ☐

Describe the medical management provided for adverse reaction (if any) to the research participants (include the information on who paid, how much was paid and to whom)

Provide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom)

Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Others	☐

Provide any other relevant information that can facilitate assessment of the case such as medical history

Provide details about PI's final assessment of SAE relatedness to research.

Signature of the PI

Date

Annexure 15. Serious Adverse Event Reporting Form (Clinical trials)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Participant details:
   Initials and Case No./Subject ID | Age at the time of event | Gender Male ☐ Female ☐ | Weight: (Kg) Height: (cm)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

   If Follow-up report, state date of Initial report Click here to enter a date.

   What was the assessment of relatedness to the trial in the initial report?

   By PI- Related ☐ Unrelated ☐

   By sponsor - Related ☐ Unrelated ☐

   By EC - Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:

4. Date of onset of SAE: Click here to enter a date. Date of reporting: Click here to enter a date.

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

6. Details of suspected study drug/device/investigational procedure causing SAE:
   I. Suspect study drug (include generic name) device/intervention:
   II. Indication(s) for which suspect study drug was prescribed or tested:

III. Route(s) of administration, daily dose and regimen, dosage form and strength:

IV. Therapy start date: Click here to enter a date. Stop date: Click here to enter a date.

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐
If yes, provide details about the reduced dose.

9. Did the reaction reappear after reintroducing the study drug / procedure?
Yes ☐ No ☐ NA ☐
If yes, provide details about the dose.

10. Concomitant study drugs history and lab investigations:
I. Concomitant study drug (s) and date of administration: Click here to enter a date.

II. Relevant test/laboratory data with dates:Click here to enter a date.

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

11. Have any similar SAE occurred previously in this study? If yes, please provide details.
Yes ☐ No ☐

12. Seriousness of the SAE:

Death	☐	Congenital anomaly	☐
Life threatening	☐	Required intervention to prevent	☐
Hospitalization-initial or prolonged	☐	permanent impairment / damage	
Disability		Others (specify)	☐

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other (specify)	☐

15. Was the research subject continuing the trial? Yes ☐ No ☐ NA ☐

16. Provide the details about PI final assessment of SAE relatedness to trial.

17. Has this information been communicated to sponsor/CRO/regulatory agencies?
Yes ☐ No ☐
Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol?
Yes ☐ No ☐

19. Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)

Signature of PI: Click here to enter a date.

Annexure 16. Premature Termination/ Suspension/ Discontinuation Report Form

Title of study:

Principal Investigator (Name, Designation and Affiliation)

Date of EC Approval: Click here to enter a date. Date of start of study: Click here to enter a date.

Date of Last Progress Report Submitted to EC: Click here to enter a date.
Date of Termination/suspension/discontinuation: Click here to enter a date.
Tick the appropriate
Premature Termination ☐ Suspension ☐ Discontinuation ☐
Reason for Termination/Suspension/Discontinuation:
Action taken Post Termination/ Suspension/Discontinuation:

Plans for post study follow up/withdrawal (if any, *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study):*

Details of study participants:
Total participants to be recruited: Screened: Screen failures:

Enrolled: Consent Withdrawn: Reason(Give details):

Withdrawn by PI: Reason(Give details):

Active on treatment: Completed treatment : Participants on Follow-up:

Participants lost to follow up: Any other: No. of drop outs:

Reasons for each drop-out:

Total Number of SAEs reported till date in the study:
Have any unexpected adverse events or outcomes observed in the study been reported to the EC?

Yes ☐ No ☐

Have there been participant complaints or feedback about the study? Yes ☐ No ☐
If yes, provide details

Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐
If yes, have you implemented that suggestion? Yes ☐ No ☐

Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants): If yes, provide details

Yes ☐ No ☐

Summary of Results (if any):

Signature of PI: Click here to enter a date.

Annexure 17. Study Completion

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date.
2. Date of Start of Study: Click here to enter a date. Date of study completion:Click here to enter a date.
3. Provide details of:
   a) Total no. of study participants approved by the EC for recruitment:
   b) Total no. of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):
   Provide the reasons for withdrawal of participants (*Explanation for the withdrawal of participants whether by self or by the PI)*:
4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)
5. Describe the main Ethical issues encountered in the study (if any)
6. State the number (if any) of Deviations/Violations/Amendments made to the study protocol during the study period

   Deviations: Violation: Amendments:
7. Describe in brief Plans for archival of records / Record Retention:
8. Is there a plan for post study follow-up Yes ☐ No ☐

   If yes, describe in brief:
9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No ☐

   If yes, describe in brief:

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

    If yes, describe in brief:

11. Describe results (summary) with Conclusion (*For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready)*

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC: Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants?

    Yes ☐ No ☐

    If yes, provide details

Signature of PI: Click here to enter a date.

Annexure 18. Reporting of Site Visits by Team from Ongoing Studies Review Sub-committee

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Names of the Team Members

Date of visit Time of visit

Date of EC approval:

Date of start of study: Date of study completion (proposed):

Provide details of:

i. Total number of study participants approved by the EC for recruitment:

ii. Total number of study participants recruited till date:

iii. Total number of participants withdrawn from the study (If any):

Check whether the following are being done according to the method described in the protocol

i.	Sampling process	Yes/No/Remarks
ii.	Consent process	Yes/No/Remarks
iii.	Consent form signatures	Yes/No/Remarks
iv.	Allocation Concealment	Yes/No/Not applicable/Remarks
v.	Randomization	Yes/No/Not applicable/Remarks
vi.	Storage of intervention medicines	Yes/No/Not applicable/Remarks

vii.	Case/Participant Record Form	Yes/No/Remarks
viii.	Data storage & safety	Yes/No/Remarks
ix.	Payment to participants for visits	Yes/No/Not applicable/Remarks
x.	Study Coordinators or Research Officers	Yes/No/Not applicable/Remarks
xi.	Any other (as decided by the team)	
xii.	Remarks on the quality of above processes, their methods and the documentation, etc.	

Ensure that the PI provides the following:

a. List of study participants enrolled in the study (name, age, Sex, CR No./OPD No./Study Registration Number, and contact number).

b. Names, designation, qualifications, research experience and contact details of the Study Coordinators, Research Officers and other study staff.

c. Any other documents as deemed necessary by the Team.

Remarks

a. Findings suggesting deviation from the approved protocol

b. Any suggestion given to the PI

c. Suggestions regarding the process of inspection/site visits

Recommendations, if any.

Name and signatures of the members of the Team

NOTE: Kindly, submit this report to the Convener of Ongoing Projects Sub-Committee and the documents received from PI as early as possible and within 5 days of completion of the visit.