Application Form for Initial Review

(Name of the Institution)

Logo of the Institute **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

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

(b) Name of the Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of Submission: Click here to enter a date.

(f) Type of review requested[1]**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(g) Title of the study:

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-Investigator at time of submission:

(k) Duration of the study:

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site:

At site | In India | Globally

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

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study[3] (within 300 words)

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐			Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
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

(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: Click here to enter a date.

Comments of Scientific Committee, if any(100 words)

[3] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

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

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 ☐

Others*(Specify)* ☐

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

ii. If yes, type of vulnerable person /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

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

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

(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 ☐

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:

(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[6]? Yes ☐ No ☐ NA ☐

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 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	☐

Other *(specify)* ☐

(d) Who will obtain the informed consent?

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

Any tools to be used

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

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

(e) 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[7]

(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[8]?

PI ☐ Institution ☐ Sponsor ☐ Other agencies*(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? If yes, specify. Yes ☐ No ☐ NA ☐

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ 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 ☐ NA ☐

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[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. If Yes, Specify Yes ☐ No ☐ NA ☐

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[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?

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 ☐ NA ☐

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

(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 ☐

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

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

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

[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 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): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: Signature: Click here to enter a date.

Name of Co-PI: Signature: Click here to enter a date.

Name of Guide: Signature: Click here to enter a date.

Name of HOD: Signature: Click here to enter a 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[11]	☐	☐	☐		
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	☐	☐	☐	Enter date	
19.	DCGI	☐	☐	☐	Enter date	
20.	HMSC	☐	☐	☐	Enter date	
21.	NAC-SCRT	☐	☐	☐	Enter date	
22.	ICSCR	☐	☐	☐	Enter date	
23.	RCGM	☐	☐	☐	Enter date	
24.	GEAC	☐	☐	☐	Enter date	
25.	BARC	☐	☐	☐	Enter date	
26.	Tribal Board	☐	☐	☐	Enter date	
27.	Others (Specify)	☐	☐	☐	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

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

[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)

**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*

[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 page no. 35Box 4.4(b)

(Annexure 1)
Application Form for Expedited Review

Logo of the Institute

(Name of the Institution)

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

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

1. Choose reasons why expedited review from EC is requested[12]?
   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) ☐
2. Is waiver of consent being requested ? Yes ☐ No ☐
3. Does the research involve vulnerable person[13]? Yes ☐ No ☐
   If Yes give details:

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

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

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

(Annexure 2)
Application Form for Exemption from Review

Logo of the Institute

(Name of the Institution)

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

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Choose reasons why exemption from ethics review is requested [14]?
   - 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[15] ☐
   - 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.

[14]*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 National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15]*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 3)
Continuing Review/ Annual report format

(*Name of the institute)*

(*Logo of the institute)*

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

The annual report must be duly submitted no later than 30 days before the annual year's completion.

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

1.	EC Reference No.:	
2.	Date of EC Approval: Click here to enter a date.	Duration of Approval months/ years
3.	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.
4.	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[16] 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:	
5.	Is the study likely to extend beyond the stated period[17]? Yes ☐ No ☐ If yes, please provide reasons for the extension	
6.	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? If yes, when / how: Yes ☐ No ☐	

[16]*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.*

[17]*Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

7. 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:

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

9. (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 ☐

10. 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 ☐

11. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC
    Yes ☐ No ☐ NA ☐

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

13. Brief Summary of the Study (up to 500 words) (to briefly describe the status, findings, activities undertaken, any deviations or changes, special mentions etc.)

Signature of PI:

Click here to enter a date.

(Annexure 4)
Application/ Notification form for Amendments

Logo of the Institute

(Name of the Institution)

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

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.

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/ICD:

Signature of PI:

Click here to enter a date.

[18]*Location implies page number in the ICD/protocol where the amendment is proposed.*

(Annexure 5)
Protocol Violation/ Deviation Reporting form (Reporting by case)

Logo of the Institute

(Name of the Institution)

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. 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:

(Annexure 6)
Serious Adverse Event Reporting Format (Biomedical Health Research)

Logo of the Institute

(Name of the Institution)

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

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

1. Participant details :
   Initials and ID | Age at the time of event | Gender Male ☐ Female ☐ | Weight: (Kgs) Height: (cms)
2. Suspected SAE diagnosis:
3. Date of onset of SAE: Click here to enter a date. Describe the event[19]:

   Date of reporting SAE: Click here to enter a date.
4. Details of suspected intervention causing SAE[20]
5. Report type: Initial ☐ Follow-up ☐ Final ☐
   If Follow-up report, state date of Initial report Click here to enter a date.
6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐
7. 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).
8. 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 ☐

[19]*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*
[20]*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)*

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 ☐

9. 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)

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

11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	others(*specify*)	☐

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

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

Signature of PI:

Click here to enter a date.

(Annexure 7)
Premature Termination/ Suspension/ Discontinuation Report Format

Logo of the Institute

(Name of the Institution)

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

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

5. Plans for post study follow up/withdrawal[21] (if any):

6. 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:

7. 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 ☐
8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐
   If yes, provide details

[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

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

10. 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 8)
Application form for Clinical Trials

Logo of the Institute

(Name of the Institution)

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

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. Tick all categories that apply to your trial

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)	☐		

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

   I.

Randomized	☐	Factorial	☐
Non randomized	☐	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 Organisation (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)	☐

7. 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, (100words)

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22]

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 ☐

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

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

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

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

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

16. 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

[22]*In order to select participants for your protcol 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*

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 ☐

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

ii. 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 9)

Serious Adverse Event Reporting Format(Clinical trials)

Logo of the Institute

(Name of the Institution)

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

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	Weight: (Kgs)
		Male ☐ Female ☐	Height: (cms)

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 ☐	By sponsor - Related ☐	By EC - Related ☐
Unrelated ☐	Unrelated ☐	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 permanent impairment / damage	☐
Hospitalization-initial or prolonged	☐		
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 continued on 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 10)
Application Form for Human Genetics Testing Research

Logo of the institute

(Name of the Institution)

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

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

1. 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 11)
Application Form for Socio-Behavioural and Public Health Research

Logo of the Institute

(Name of the Institution)

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

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 taken into account 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 12)
Study completion/ Final report format

Logo of the Institute

(Name of the Institution)

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.

2. Date of Start of Study: Click here to enter a date. Date of study completion: Click here to enter a date.

   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[23]:

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?

   If yes, describe in brief: Yes ☐ No ☐

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[24]:

[23] *Explanation for the withdrawal of participants whether by self or by the PI*

[24] *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 13)
Format for Curriculum Vitae for Investigators

Logo of the Institute

(Name of the Institution)

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

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 14)

Project extension form

Logo of the Institute

(Name of the Institution)

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

****The project extension must be duly submitted no later than 30 days before the approval expires.***
Title of study: Principal Investigator (Name, Designation and Affiliation)

14.	EC Reference No: _____	
15.	Date of EC Approval: Click here to enter a date.	Duration of Approval months/ years
16.	Date of Start of study: Click here to enter a date.	Date of Completion: Click here to enter a date. *(As per the first approval granted)*
	Duration of Extension sought: months/ years	
	Period of Extension sought from Click here to enter a date.	To Click here to enter a date.
17.	Have there been any modifications in the budget for the extension sought? **If No, skip to item no.5** Yes ☐ No ☐ If yes, discuss in detail:	
18.	Does the study involve recruitment of participants? Yes ☐ No ☐ (f) If yes, Total number for study No. (g) Screened: No. Enrolled: No. (h) Number Completed: No. on followup: No. (i) Enrolment status – ongoing / completed/ stopped No. (j) If ongoing , Expected No. (k) Report of DSMB* Yes ☐ No ☐ NA ☐ ** 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.* (l) Any other remark	

	(m) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐ If yes, total number withdrawn and reasons:
19.	Have there been any amendments in the research protocol/informed consent document (ICD) for the extension sought? Yes ☐ No ☐ **If No, skip to item no.7**
	(a) If yes, discuss in detail:
	(b) In case of amendments in the research protocol/ICD, will re-consent be sought from participants? If yes, when / how: Yes ☐ No ☐

20. 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:

21. Have any ethical concerns occurred during the study? Yes ☐ No ☐

If yes, give details

22. (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 ☐

23. Has there been any protocol deviations/violations that occurred during the period of study?

If yes, number of deviations

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

24. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC Yes ☐ No ☐ NA ☐

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

26. Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.)

Signature of PI:

Click here to enter a date.