

Application Form for Initial Review

Logo of the Institute

(Name of the Institution)

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 requested¹:
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 2017 on 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 study³ (within 300 words)

(b) Type of study:

Basic Sciences

Retrospective

Prospective

Qualitative

Quantitative

Mixed Method

Clinical

Epidemiological/ Public Health

Socio-behavioural

Biological samples/Data

Any others (Specify)

Cross Sectional

Case Control

Cohort

Systematic Review

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)

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

⁴If 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 risk⁵:

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 | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| For the society/community | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| For improvement in science | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| Please describe how the benefits justify the risks | | | | | |

- (c) Are Adverse Events expected in the study⁶? 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

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

⁶The 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 study⁷
- (g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

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

8. PAYMENT/COMPENSATION

- (a) Who will bear the costs related to participation and procedures⁸?
 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

⁷Information 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

⁸Enclose 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: Irreversibly Identifiable
reversibly coded coded
- 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 analyzed⁹ 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 the application, which is not included elsewhere in the form? If yes, provide the details. Yes No

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

SECTION E: DECLARATION AND CHECKLIST¹⁰

11. DECLARATION (Please tick as applicable)

<input type="checkbox"/>	I/We certify that the information provided in this application is complete and correct.
<input type="checkbox"/>	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
<input type="checkbox"/>	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
<input type="checkbox"/>	I/We declare that the expenditure in case of injury related to the study will be taken care of.
<input type="checkbox"/>	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
<input type="checkbox"/>	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.
<input type="checkbox"/>	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
<input type="checkbox"/>	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
<input type="checkbox"/>	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.
<input type="checkbox"/>	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
<input type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Approval of Scientific Committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	EC clearance of other centers*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	Agreement between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	MTA between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8.	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PROPOSAL RELATED						
12.	Copy of the detailed protocol ¹¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13.	Investigators Brochure (If applicable for drug/biologicals/device trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

15.	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17.	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

PERMISSION FROM GOVERNING AUTHORITIES

	Other Registration/permissions	Required	Not required	Received	Applied dd/mm/yy	EC Remarks
18.	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
19.	DCGI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
20.	HMSC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
21.	NAC-SCRT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
22.	ICSCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
23.	RCGM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
24.	GEAC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
25.	BARC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
26.	Tribal Board	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
27.	Others (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
29.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

¹⁰These 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

¹¹Refer 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

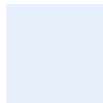
(Name of the Institution)

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

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

1. Choose reasons why expedited review from EC is requested¹²?
- 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 person¹³? Yes No
- If Yes give details:

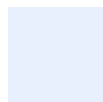
Signature of PI:



[Click here to enter a date.](#)

Comments of EC Secretariat:

Signature of Member Secretary:



[Click here to enter a date.](#)

¹²Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2

¹³For 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):*

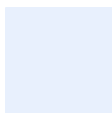
Title of study:

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):

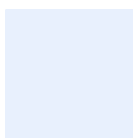
Signature of PI:



Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary:

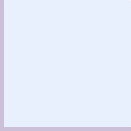


Click here to enter a date.

¹⁴Select 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.

¹⁵Such 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



(Logo of the institute)

(Name 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: <small>Click here to enter a date.</small>	Duration of Approval months/ years
3.	Date of Start of study: <small>Click here to enter a date.</small>	Proposed date of Completion: <small>Click here to enter a date.</small>
	Period of Continuing Report <small>Click here to enter a date.</small>	To <small>Click here to enter a date.</small>
4.	Does the study involve recruitment of participants? Yes <input type="checkbox"/> No <input type="checkbox"/> (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 <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> (d) Any other remark	
	(e) Have any participants withdrawn from this study since the last approval? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> If yes, total number withdrawn and reasons:	
5.	Is the study likely to extend beyond the stated period ¹⁷ ? Yes <input type="checkbox"/> No <input type="checkbox"/> 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? Yes <input type="checkbox"/> No <input type="checkbox"/> If No, skip to item no.6	
	(a) If yes, date of approval for protocol and ICD : <small>Click here to enter a date.</small>	
	(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? If yes, when / how: Yes <input type="checkbox"/> No <input type="checkbox"/>	

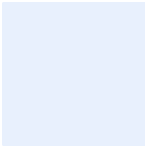
¹⁶In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.

¹⁷Problems 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

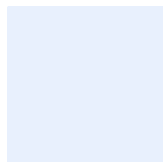
3. Impact on benefit-risk analysis Yes No
If yes, describe in brief:

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.](#)

¹⁸Location 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)

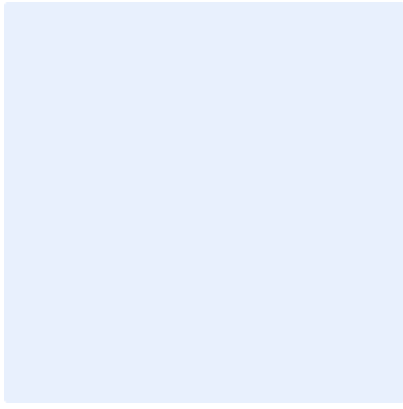
EC Ref. No. (for office use):

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.](#)
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 | <input type="checkbox"/> | Source documentation | <input type="checkbox"/> |
| Enrollment | <input type="checkbox"/> | Staff | <input type="checkbox"/> |
| Laboratory assessment | <input type="checkbox"/> | Participant non-compliance | <input type="checkbox"/> |
| Investigational Product | <input type="checkbox"/> | Others (specify) | <input type="checkbox"/> |
| Safety Reporting | <input type="checkbox"/> | | |
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 event¹⁹:

Date of reporting SAE: [Click here to enter a date.](#)

4. Details of suspected intervention causing SAE²⁰

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

¹⁹Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

²⁰Refers 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.

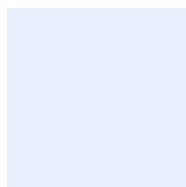
- | | | | | | | | |
|---|--------------------------|---|--------------------------|----------------------------------|--------------------------|---------------------------------|--------------------------|
| Hopitalization | <input type="checkbox"/> | Increased Hospital Stay | <input type="checkbox"/> | Death | <input type="checkbox"/> | Congenital anomaly/birth defect | <input type="checkbox"/> |
| Persistent or significant disability/incapacity | <input type="checkbox"/> | Event requiring intervention (surgical or medical) to prevent SAE | <input type="checkbox"/> | Event which poses threat to life | <input type="checkbox"/> | Others | <input type="checkbox"/> |

In case of death, state probable cause of death:

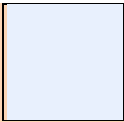
- C. No permanent/significant functional/cosmetic impairment
- Permanent/significant functional/cosmetic impairment
- Not Applicable

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. Provide 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 | <input type="checkbox"/> | Recovered | <input type="checkbox"/> |
| Continuing | <input type="checkbox"/> | Unknown | <input type="checkbox"/> |
| Recovering | <input type="checkbox"/> | others(<i>specify</i>) | <input type="checkbox"/> |
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/withdrawal²¹ (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
9. Have there been any suggestions from the SAE Sub Committee? Yes No
If yes, have you implemented that suggestion? Yes No

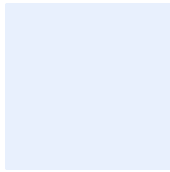
²¹ Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

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

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

I.

Randomized
 Non randomized
 Parallel
 Cross-over
 Cluster

Factorial
 Stratified
 Adaptive
 Comparison trial
 Superiority trial

Matched-pair
Others (specify)

Non-inferiority trial
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	<input type="checkbox"/>	Clinical and medical monitoring	<input type="checkbox"/>
Regulatory affairs	<input type="checkbox"/>	Data management	<input type="checkbox"/>
Statistical support	<input type="checkbox"/>	Medical writing	<input type="checkbox"/>
Site management	<input type="checkbox"/>	Audits, quality control, quality assurance	<input type="checkbox"/>
Finance management	<input type="checkbox"/>	Recruitment and training	<input type="checkbox"/>
Administrative support	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>

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 details²²

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? If no, please justify. Yes No NA

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

²²In 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

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 <input type="checkbox"/>	Height: (cms)
		Female <input type="checkbox"/>	

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 <input type="checkbox"/>	By sponsor - Related <input type="checkbox"/>	By EC - Related <input type="checkbox"/>
Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>

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	<input type="checkbox"/>	Congenital anomaly	<input type="checkbox"/>
Life threatening	<input type="checkbox"/>	Required intervention to prevent permanent impairment / damage	<input type="checkbox"/>
Hospitalization-initial or prolonged	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>
Disability			

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	<input type="checkbox"/>	Recovered	<input type="checkbox"/>
Continuing	<input type="checkbox"/>	Unknown	<input type="checkbox"/>
Recovering	<input type="checkbox"/>	Other (specify)	<input type="checkbox"/>

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

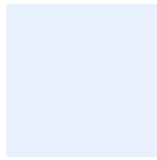
Provide details if communicated (including date)

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)

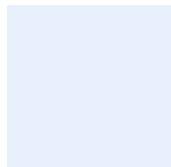
EC Ref. No. (for office use):

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.

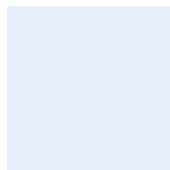
II. Justify reasons if individual harm is overriding societal benefit. Yes No NA

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 participants²³:
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 Conclusion²⁴:

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:

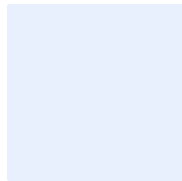
Yes No

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 area²⁵:

Relevant publications *(Give references to all relevant publications in the last five years):*

Signature 

Date: [Click here to enter a date.](#)

²⁵Details 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)

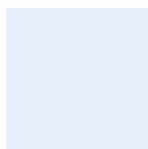
14.	EC Reference No: _____	
15.	Date of EC Approval: Click here to enter a date.	Duration of Approval months/ years
16.	Date of Start of study: Click here to enter a date.	Date of Completion: Click here to enter a date. <i>(As per the first approval granted)</i>
	Duration of Extension sought: months/ 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 <input type="checkbox"/> No <input type="checkbox"/> If yes, discuss in detail:	
18.	Does the study involve recruitment of participants? Yes <input type="checkbox"/> No <input type="checkbox"/> (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 <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> <i>* 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.</i> (l) Any other remark	

	(m) Have any participants withdrawn from this study since the last approval? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/>

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.](#)