



Application Form for Initial Review

.....
(Name of the Institution)

EC Ref. No. (For office use):

- General Instructions : a) Tick one or more options 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 Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of submission:

dd	mm	yy
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(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:

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

²Include 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 summary³ (within 300 words):
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(b) Type of study:

- | | | |
|---|--|--|
| Basic Sciences <input type="checkbox"/> | Clinical <input type="checkbox"/> | Cross Sectional <input type="checkbox"/> |
| Retrospective <input type="checkbox"/> | Epidemiological/
Public Health <input type="checkbox"/> | Case Control <input type="checkbox"/> |
| Prospective <input type="checkbox"/> | Socio-behavioural <input type="checkbox"/> | Cohort <input type="checkbox"/> |
| Qualitative <input type="checkbox"/> | Biological samples/ Data <input type="checkbox"/> | Systematic Review <input type="checkbox"/> |
| Quantitative <input type="checkbox"/> | Any others (Specify) <input type="checkbox"/> | |
| Mixed Method <input type="checkbox"/> | | |

4. METHODOLOGY

- (a) Sample size/ number of participants (as applicable)
At site..... In India..... Globally
- Control group..... Study group
- Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation
.....
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.....
.....
.....

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

(b) Is there an external laboratory/outsourcing involved for investigations?⁴ Yes No NA

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

Independent external review Review by sponsor/Funder Review within PI's institution

Review within multi-centre research group No review

Date of review:

dd	mm	yy
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Comments of scientific committee, if any (100 words)

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.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers Patients Vulnerable persons/ Special groups

Others (Specify)

Who will do the recruitment?

Participant recruitment methods used:

Posters/leaflets/Letters TV/Radio ads/Social media/Institution website Patients / Family/ Friends visiting hospitals Telephone

Others (Specify)

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

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

Children under 18 yrs Pregnant or lactating women

Differently abled (Mental/Physical) Employees/Students/Nurses/Staff

Elderly Institutionalized

Economically and socially disadvantaged Refugees/Migrants/Homeless

Terminally ill (stigmatized or rare diseases)

Any other (Specify):

iii. Provide justification for inclusion/exclusion

.....

.....

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

.....

.....

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

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

If yes, Monetary Non-monetary Provide details

.....
.....

(d) Are there any incentives to the participants? 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

For the society/community

For improvement in science

Please describe how the benefits justify the risks

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.....
.....

(c) Are adverse events expected in the 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 item no. 8 Yes No

.....
.....

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

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

- (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 | <input type="checkbox"/> | Verbal/Oral consent | <input type="checkbox"/> | Witnessed consent | <input type="checkbox"/> | Audio-Video (AV) consent | <input type="checkbox"/> | |
| Consent from LAR
(If so, specify from whom) | <input type="checkbox"/> | For children<7 yrs
parental/LAR consent | <input type="checkbox"/> | Verbal assent from
minor (7-12 yrs) along
with parental consent | <input type="checkbox"/> | Written assent from
minor (13-18 yrs) along
with parental consent | <input type="checkbox"/> | |
| Other | <input type="checkbox"/> | | | | | | | |
- (specify)
- (d) Who will obtain the informed consent?
- PI/Co-I Nurse/Counselor Research Staff Other (Specify)
- Any tools to be used
- (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 requirements 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 | <input type="checkbox"/> | Statement that consent is voluntary | <input type="checkbox"/> | |
| 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 | <input type="checkbox"/> | |
| Others(Specify) | <input type="checkbox"/> | | | | Secretary of EC | |
-

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 N/A
- If yes, then who will provide the treatment?
- (c) Is there a provision for compensation of research related SAE? If yes, specify. Yes No N/A
- Sponsor Institutional/Corpus fund Project grant Insurance
- (d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes No N/A
-
- (e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes No N/A

⁷Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and 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: Reversibly coded Irreversibly coded Identifiable

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

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.....
.....

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

(c) Where will the data be 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

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.....

(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 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 details. Yes No

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.....

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

SECTION E: DECLARATION AND CHECKLIST ¹⁰

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.
<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"/>	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 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 confidentiality of 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-I): 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: dd mm yy

Name of Co-PI:

Signature: dd mm yy

Name of Guide:

Signature: dd mm yy

Name of HOD:

Signature: dd mm yy

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)

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

*For multicentre 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. 35 Box 4.4(b)

Version 2.0

08

Annexure

Logo of the
Institute

Application Form for Expedited Review

.....
(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. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
- ii. Involves 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 proposal previously approved through expedited review, full review or continuing review of approved proposal.
- v. Minor deviation from originally approved research causing no risk or minimal risk.
- vi. Progress/annual report 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 modifications 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 persons¹³ ? Yes No

If Yes give details:
.....
.....

Signature of PI:

Comments of EC Secretariat:

Signature of Member Secretary:

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

Logo of the
Institute

Application Form for Exemption from Review

.....
(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 requested¹⁴?

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 agencies¹⁵

vii. Any other (please specify in 100 words):

.....

.....

.....

.....

Signature of PI:

dd	mm	yy
----	----	----

Comments of EC Secretariat:

Signature of Member Secretary:

dd	mm	yy
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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)

Continuing Review / Annual 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: Validity of approval:

2. Date of Start of study: Proposed date of Completion:

Period of Continuing Report: ---- to -----

3. Does the study involve recruitment of participants? Yes No

(a) If yes, Total number expected..... Number Screened: Number Enrolled:
Number Completed:..... Number on followup:.....

(b) Enrolment status - ongoing / completed/ stopped

(c) Report of DSMB¹⁶ Yes No NA

(d) Any other remark.....

(e) Have any participants withdrawn from this study since the last approval? Yes No NA

If yes, total number withdrawn and reasons:

4. Is the study likely to extend beyond the stated period ?¹⁷ Yes No

If yes, please provide reasons for the extension.

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

If No, skip to item no. 6 Yes No

(a) If yes, date of approval for protocol and ICD :

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

If yes, when / how:

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

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes No

If yes, discuss in detail:
.....
.....

7. Have any ethical concerns occurred during this period? Yes No

If yes, give details:.....
.....

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

Describe in brief:
.....
.....

(b) Have any SAE's occurred since last review? Yes No

If yes, number of SAE's :..... Type of SAE's:
.....
.....

(c) Is the SAE related to the study? Yes No

Have you reported the SAE to EC? If no, state reasons Yes No
.....
.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations
Have you reported the deviations to EC? If no, state reasons Yes No
.....
.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes No NA

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

.....
.....

Any other comments:.....
.....

Signature of PI:

dd	mm	yy
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Logo of the
Institute

Application/Notification form for Amendments

.....
(Name of the Institution)

EC Ref. No. (For office use):

Title of study:
.....
.....

Principal Investigator (Name, Designation and Affiliation):
.....
.....

1. Date of EC approval:

Date of start of study

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 reconsent 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:

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

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 Date of start of study

2. Participant ID: Date of occurrence

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-I:

.....

.....

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:

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	Weight:.....(Kgs)
.....	Male <input type="checkbox"/> Female <input type="checkbox"/>	Height:.....(cms)
.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE:	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>	Describe the event ¹⁹ :
Date of reporting SAE:	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>	

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4. Details of suspected intervention causing SAE ²⁰

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.....

5. Report type: Initial Follow-up Final
If Follow-up report, state date of Initial report

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

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.....

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)

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

B.
Hospitalization 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 participant. (Include information on who paid, how much was paid and to whom).

.....
.....

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

.....

11. Outcome of SAE

Fatal Recovered
Continuing Unknown
Recovering Other (specify)

.....

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

.....
.....
.....

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

.....
.....
.....

Signature of PI:

Premature Termination/Suspension/ Discontinuation Report Format

.....
(Name of the Institution)

EC Ref. No. (For office use):

Title of study:
.....
.....

Principal Investigator (Name, Designation and Affiliation):
.....
.....

1. Date of EC approval:

Date of start of study:

2. Date of last progress report submitted to EC:

3. Date of termination/suspension/discontinuation:

4. Tick the appropriate

Premature Termination Suspension Discontinuation

Reason for Termination/Suspension/Discontinuation:
.....
.....

Action taken post Termination/ Suspension/Discontinuation (if any):
.....
.....

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):

.....

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

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

Participants lost to follow up: Any other: Number 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

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes No

(e.g., making arrangements for medical care of research participants): If Yes, provide details

.....

.....

Summary of results (if any):

.....

.....

.....

.....

.....

Signature of PI:

dd mm yy

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 | |
| Others (specify) | <input type="checkbox"/> | or new route of administration | <input type="checkbox"/> |

4. Trial design of the study

- | | | | |
|------------------|--------------------------|-----------------------|--------------------------|
| I. Randomized | <input type="checkbox"/> | Factorial | <input type="checkbox"/> |
| Non randomized | <input type="checkbox"/> | Stratified | <input type="checkbox"/> |
| Parallel | <input type="checkbox"/> | Adaptive | <input type="checkbox"/> |
| Cross-over | <input type="checkbox"/> | Comparison trial | <input type="checkbox"/> |
| Cluster | <input type="checkbox"/> | Superiority trial | <input type="checkbox"/> |
| Matched-pair | <input type="checkbox"/> | Non-inferiority trial | <input type="checkbox"/> |
| Others (specify) | <input type="checkbox"/> | Equivalence trial | <input type="checkbox"/> |

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 (<i>specify</i>) | <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, provide details (100words).....
.....
.....
.....
.....

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

If Yes, provide details²².....
.....
.....
.....

10. Is 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

.....
.....
.....

²² In order to select participants for your protocol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same

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

English Local language
(certified that local version (s) is/are a true translation of the English version and
Other(Specify) can be easily understood by the participants)

.....
List the languages in which translations were done

Justify if translation not done.....
.....

17. Involvement/consultation of statistician in the study design Yes No NA

18. Is there any insurance coverage of the trial? If yes, provide details. Yes No

.....
.....
.....

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:

dd	mm	yy
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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./ Age at the time of event Gender Weight:.....(Kgs)

Subject ID Male Height:.....(cms)

..... Female

.....

2. Report type: Initial Follow-up Final

If Follow-up report, state date of Initial report

dd	mm	yy
----	----	----

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:

dd	mm	yy
----	----	----

Date of reporting:

dd	mm	yy
----	----	----

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:

dd	mm	yy
----	----	----

Stop date:

dd	mm	yy
----	----	----

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 drugs history and lab investigations:

I. Concomitant drug (s) and date of administration:

.....
.....

II. Relevant test/laboratory data with dates:

.....
.....

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 | |
| Hospitalization-initial or prolonged | <input type="checkbox"/> | permanent impairment / damage | <input type="checkbox"/> |
| Disability | <input type="checkbox"/> | Others (<i>specify</i>) | <input type="checkbox"/> |

.....

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 (<i>specify</i>) | <input type="checkbox"/> |

.....

15. Was the research participant continued on the trial? Yes No NA

16. Provide details about PI's 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:

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

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

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 a plan for future use of stored samples for research? Yes No

Yes No

If yes, has this been addressed in the informed consent ?

Yes No

Signature of PI:

dd mm yy

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 | <input type="checkbox"/> | Questionnaire/Survey | <input type="checkbox"/> | Observation | <input type="checkbox"/> |
| Interviews | <input type="checkbox"/> | Documents and records | <input type="checkbox"/> | Ethnographies/Oral | <input type="checkbox"/> |
| Others (Specify) | <input type="checkbox"/> | | | history/Case studies | |

.....
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 used in the study.

- | | | | | | |
|--------------------|--------------------------|---------------------|--------------------------|-------------------|--------------------------|
| Individual consent | <input type="checkbox"/> | Gate-keeper consent | <input type="checkbox"/> | Community consent | <input type="checkbox"/> |
| Others | <input type="checkbox"/> | (specify)..... | | | |

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

.....
.....
.....

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

.....
.....
.....

5. Are cultural norms/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

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.....
.....

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:

dd	mm	yy
----	----	----

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:

2. Date of start of study:

Date of study completion:

3. Provide details of:

a) Total number of study participants approved by the EC for recruitment:

b) Total number 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:.....

.....

.....

.....

.....

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

8. Is there a plan for post study follow-up?

Yes No

If yes, describe in brief:
.....
.....
.....
.....

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

Yes No

If yes, describe in brief:
.....
.....
.....
.....

10. Is there a plan for post study benefit sharing with the study participants?

Yes No

If yes, describe in brief:
.....
.....
.....
.....

11. Describe results (summary) with Conclusion ²⁴ :

.....
.....
.....
.....

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:

dd	mm	yy
----	----	----

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.

Logo of the
Institute

Format for Curriculum Vitae for Investigators

.....
(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:

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