



# 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 requested<sup>1</sup>:

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 <sup>2</sup>
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: .....

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

<sup>2</sup>Include telephone/mobile, fax numbers and email id



(b) Is there an external laboratory/outsourcing involved for investigations?<sup>4</sup> 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 .....

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

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

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

If yes, Monetary  Non-monetary  Provide details

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

If yes, Monetary  Non-monetary  Provide details

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

If yes, Monetary  Non-monetary  Provide details Yes  No

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**6. BENEFITS AND RISKS**

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

If yes, categorize the level of risk<sup>5</sup> :

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 study<sup>6</sup> ? Yes  No  NA

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

If Yes, Specify .....

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**7. INFORMED CONSENT**

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes  No

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

<sup>6</sup>The term adverse events in this regard encompass both serious and non-serious adverse events.



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 analyzed<sup>9</sup> and by whom? .....

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

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

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

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SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

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

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.....

(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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<sup>9</sup>For example, a data entry room, a protected computer etc.

## SECTION E: DECLARATION AND CHECKLIST <sup>10</sup>

### 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"/>	<p>I/We have the following conflict of interest (PI/Co-I):</p> <p>1. ....</p> <p>.....</p> <p>2. ....</p> <p>.....</p>
<input type="checkbox"/>	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: .....

Signature: .....

Name of Co-PI: .....

Signature: .....

Name of Guide: .....

Signature: .....

Name of HOD: .....

Signature: .....

<sup>10</sup>These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements  
 Acknowledgement for Receipt of Application (Copy to be provided to PI)

## 12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
<b>ADMINISTRATIVE REQUIREMENTS</b>						
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"/>		
<b>PROPOSAL RELATED</b>						
12	Copy of the detailed protocol <sup>11</sup>	<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"/>		
<b>PERMISSION FROM GOVERNING AUTHORITIES</b>						
	<b>Other permissions</b>	<b>Required</b>	<b>Not required</b>	<b>Received</b>	<b>Applied dd/mm/yy</b>	<b>EC Remarks</b>
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"/>		
<b>ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY</b>						
	<b>Item</b>	<b>YES</b>	<b>NO</b>	<b>NA</b>	<b>Enclosure no.</b>	<b>EC remarks</b>
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

<sup>11</sup>Refer 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

# 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)

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2. Does the study involve pretest and post-test counselling? If yes, please describe.

Yes  No  NA

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

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.....

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)

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.....

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

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.....

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

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.....

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

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.....

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

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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

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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.

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.....

II. Justify reasons if individual harm is overriding societal benefit.

Yes  No  NA

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III. Describe how do societal benefits outweigh individual harm.

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9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception.

Yes  No

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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.

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Signature of PI: .....

dd mm yy