TAGORE MEDICAL COLLEGE & HOSPITAL

Rathinamangalam, Melakkottaiyur Post, Chennai - 600 127.

PEH-2020-1369

INSTITUTIONAL ETHICS COMMITTEE

Templates for protocol and other submissions

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Annexure I

Application Form For Initial Review

(Tagore Medical College & Hospital - Ethics Committee)

General Instructions	To be filled by EC Office
• Tick one or more as applicable. Mark not applicable wherever Appropriate • Attach additional sheets if required • May select more than one option • Date should be uniformly written in dd/mm/yy format	• **Project No.:** • **Date of Receipt:** • **Status: New / Revision** • **Duration:**

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization : Tagore Medical College & Hospital

(b) Name of Ethics Committee : Tagore Medical College & Hospital - Ethics Committee

(c) Name of Principal Investigator: …….....……

(d) Department/ Division: …….. (e) Date of Submission : …..…...……

(f) Type of review requested (Please tick appropriate) :

i. Exemption from review **ii. Expedited review** **iii. Full committee review**

Exemption from review	Proposals with less than minimal risk where there are no linked identifiers, for example; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
Expedited Review	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • 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; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters

Full Board Review	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk ; • studies involving deception of participants; • research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

(g) Title of the study …….....……

……Version…….....…....date…….....

(h) Acronym/ Short title, (if any) :

a. Protocol number (By Ethics Secretariat) :

b. Version number :

(I) Details of Investigators:

Name	**Designation & Qualification**	**Department and Institution**	**Address for Communication** (include Telephone/Mobile, Fax, email id)
Principal Investigator/ Guide			
*Co-Investigator/ Collaborator/s			
Student/Fellow			

***Principal Investigator should provide Invitation letter to the Co-investigator/ collaborator & acceptance to the invitation from the co-investigator/ collaborator**

(j) Number of studies where applicant is a :

i) Principal Investigator at time of submission:…….....……

Please provide the status of currently approved studies:

No.	**Project No.**	**Title**	**Date of initial approval by the IEC**	**Status** (whether initiated,no. of participants enrolled, etc.)	**Date of approval of continuation and Date of submission of the latest status report**

ii) Co-Principal Investigator at time of submission:…….....……

(k) Duration of the study:…….....……

(l) Whether the study is part of the Fellowship program/ other academic study/-

(m) Whether the study is a regulatory study: Yes/ No

(n) Whether there are collabortors/ collaborating institutions: Yes/ No

No.	Name of the collaborating institution	Names of the individuals collaborating	Designation and Qualifications	Role in the study	Whether collaborating institution's EC's approval will be required, Name of the EC

2. FUNDING DETAILS AND BUDGET:

(a) Total estimated budget for site: ……

(b) Self-funding ☐ Institutional funding ☐ Funding agency*(specify)* ☐ …….

It is certified that the statements made herein are true, complete and accurate to the best of my/our knowledge. I am aware that false, fictitious or fraudulent statements or claims may subject me/us to criminal, civil or administrative penalties. I/we agree to accept responsibility for the scientific conduct of the project and to provide required progress reports if the permission is granted as a result of this application.

Forwarded through HOD & Dean with signature & Date:

	Signature with date & seal
Principal Investigator	
Head of the Department	
Dean	

1. Required copies of all the documents, neatly typed, numbered and bound shall be submitted.
2. Title of the project should be put as a header with the name of Principal Investigator. Versions if any, and date should be incorporated. e.g. all new proposals will bear Version I and date.
3. All pages must be serially numbered and put as footer on the right side of the page.
4. Any incomplete proposal will not be considered for the meeting. Any blank left in the study proposal (example: signatures), should be justified.
5. All the PIs are instructed to read the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR, 2017 before filling the form.

SECTION B - RESEARCH RELATED INFORMATION

Study Title: _____

3. OVERVIEW OF RESEARCH

(a) Lay summary (within 300 words):…….....……

…….....……

…….....……

…….....……

(b) Type of study (Tick appropriate) :

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

Any other (*Specify)* …….....……

4. OBJECTIVES :

- …….....……
- …….....……
- …….....……
- …….....……

5. METHODOLOGY (*not exceeding 2 pages*):

(a) Sample size/ number of participants (as applicable)

- At site ..... In India..... Globally .....
- Control group ..... Study group .....
- Inclusion & exclusion criteria .....
- Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation (attach statistician comment on sample size) …… .....

(b) Is there an external laboratory/outsourcing involved for investigations? (Tick appropriate) *(If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/MoU.)* Yes / ☐ No/ ☐ NA ☐

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

- Independent external review ☐
- Review by sponsor/Funder ☐
- Review within PI's institution Research group SAC/SRC ☐
- Review within multi-centre ☐
- No review ☐

Date of review .....

Comments of scientific committee, if any (100 words) (Report to be attached)…….....……

SECTION C : PARTICIPANT RELATED INFORMATION

6. RECRUITMENT AND RESEARCH PARTICIPANTS.

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ 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 ☐

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.

Pregnant or lactating women	☐	Children between 0-7 yrs.	☐
Children between 7- 12 yrs.	☐	Children between 12-18 yrs.	☐
Differently abled (Mental/Physical)	☐	Elderly	☐
Refugees/Migrants/Homeless	☐	Institutionalized	☐
Economically and socially disadvantaged	☐		
Terminally ill (stigmatized or rare diseases)	☐		
Employees/Student/Nurses/Staff	☐		
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 participants? Yes / No

(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? Yes / No

If yes, Monetary ☐ Non-monetary ☐ Provide details ☐

.....

……

7. 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 :

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: .....

.....

CRITERIA FOR RISK ASSESSMENT

Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

(b) What are the potential benefits from the study?

Potential benefits	Yes	No	If yes	
			Direct	Indirect
For the participant				
For the society/community				
For improvement in science				

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study ? Yes/ No/ NA

(Include both serious and non-serious adverse events)

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

If yes, Specify .....

.....

.....

8. INFORMED CONSENT

(a) Version number and date of Participant Information Sheet (PIS) : .....

Version number and date of Informed Consent Form (ICF) : .....

(b) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Waiver of consent ☐

Witnessed consent ☐ Audio-Video (AV) 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 ☐

Assent from minor (age >12-<18 years along with parental consent ☐

Other (Soecity) ☐ :.....

(c) Who will obtain the informed consent ?

PI/Co-PI ☐ Nurse/Counsellor ☐

Research Staff ☐ Other (Specify) ☐ .....

Any tools to be used while obtaining consent: .....

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

English ☐ Local language ☐ Other (specify) ☐ .....

List the languages in which translations were done / will be done.....

If translation has not been done, please justify .....

(e) Are you seeking waiver of consent? If yes, what are the reasons. Yes / No

.....

.....

(f) Provide details of consent requirements for previously stored samples if used in the study *(Information on re-consent requirements in ICMR 2017 Guidelines , Pg. 54, Section 5.8)*

.....

.....

(g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF) (Mark appropriate option)

Simple language		Data/Sample sharing		Compensation for study related injury	
Risks and discomforts		Need to re-contact		Statement that consent is voluntary	
Alternatives to participation		Confidentiality		Commercialization / Benefit sharing	
Voluntariness and Right to withdraw		Storage of samples		Statement that study involves research	
Benefits and risks involved		Return of research results		Use of photographs/ Identifying data	
Purpose and procedure and what the participant is expected to do		Payment for participation		Research team and Ethics Committee contact information	
Provision for providing free medical care in case of a study- related injury		Provision for compensation for study-related injury			

Other (Specify) .....

9. PAYMENT / COMPENSATION

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

(Enclose undertaking from PI confirming the same)

Principal Investigator ☐ Institution ☐ Sponsor

Other agencies ☐ (specify)…….....

(b) Is there a provision for free treatment of research related injuries? Yes / No

If yes, then who will provide the treatment?

….....…….....

(c) Is there a provision for compensation of research related SAE? Yes / No

If yes, specify

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? Yes / No

If yes, specify.....…….

10. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data (specify):

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐

Irreversibly coded ☐ Identifiable ☐

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

.....

.....

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

…….....

(c) Where will the data be analyzed and by whom? For example, a data entry room, a protected computer etc. …….....

(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

11. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? Yes / No

If yes, specify.…….....……

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

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished. Yes /No/NA

If yes describe in brief (Max 50 words)

.....

.....

(d) Is there any plan for post research benefit sharing with participants? Yes / No

If yes, *specify* .....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? Yes / No

If yes, please provide details.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes / No

If yes, provide details .....

SECTION E: DECLARATION

12. DECLARATION/UNDERTAKING (Please tick as applicable) 1

1	I/We certify that the information provided in this application is complete and correct.	
2	I/We confirm that all investigators have approved the submitted version of proposal/related documents.	
3	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	
4	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.	
5	I/We will comply with all policies and guidelines of the institute and the Ethics Committee and affiliated/ collaborating institutions where this study will be conducted.	
6	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.	
7	I/We declare that the expenditure in case of injury related to the study will be taken care of.	
8	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.	
9	I/We confirm that we will maintain accurate and complete records of all aspects of the study.	
10	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.	
11	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/ Personal/ Professional) with the sponsor(s) and outcome of study.	

12. I/We have the following conflict of interest (PI/Co-PI/ Collaborator)(if applicable):

1.....

2.....

Name and signature of Principal Investigator with date:.....

Name and signature of Co-Principal Investigator with date:.....

Name and signature of Collaborator with date:.....

SECTION F: CHECKLIST

13. Checklist (Please tick as applicable)

Sr. No.	Items	Yes	No	NA	Enelosure No.	EC Remarks (if Applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter					
2	Approval of SAC/ SRC/ IRCT					
3*	EC clearance of other centres					
4*	Agreement between collaborating partners					
5*	Material Transfer Agreement (MTA) between collaborating partners					
6	Insurance policy/ certificate					
7	Copy of contract or agreement (Memorandum of Understanding-MoU) signed with the sponsor or donor agency					
8	Provide all significant previous decisions by the other ECs/ Regulatory authorities for proposed study (whether in same location or elsewhere)& modification(s) to protocol					
*** Applicable in case of Multicentric Study Proposals**						
PROPOSAL RELATED						
9	Copy of the Detailed Protocol {Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)}					
10	Investigators Brochure (If applicable for Drug/ Biologicals/ Device trials)					
11	Participant Information Sheet (PIS)& Participants informed consent form (ICF) (English & translated)					
12	Assent form for minors (12-18 years) (English and Translated)					
13	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)					
14	Role of Investigator					
15	Advertisement/material to recruit participants (fliers, posters etc.)					
16	Brief CV of all Investigators					
17	Research Ethics training/ GCP of Investigators in last 5 years					

PERMISSIONS FROM GOVERNMENT AUTHORITIES						
	Other Permissions	Required	NOT Required	*Received*	Applied on	EC Remarks
18	CTRI					
19	DCGI					
20	HMSC					
21	NAC-SCRT					
22	RCGM					
23	GEAC					
24	BARC					
25	Tribal Board					
26	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

Sr. No.	Items	Yes	No	NA	Enclosure No.	EC Remarks (if Applicable)

- ***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***
- ***RCGM- Review Committee on Genetic Manipulation***
- ***GEAC- Genetic Engineering Approval Committee***
- ***BARC- Bhabha Atomic Research Centre***

Annexure II

Format of Technical summary and Detailed Protocol

Technical summary

PI should provide one page summary including technical details about the protocol.

Detailed Protocol

Introduction and Rationale:

Objectives of the study:

Overall and Specific:

Participants enrolled for this study:

Exclusion criteria:

Methodology (including Study Duration):

Study Design, Sample Size, Study Setting

Expected Outcome:

References:

Annexure III

Guidelines for reviewing Participant Information Sheet and Informed Consent Document

The Principal Investigators should train their project staffs/ students/ research fellows, who will be dealing with enrollment of research participants about the Good Clinical Practice training or Research Ethics training and should produce undertaking that they have trained their staff regarding Research Ethics.

The following points should be considered while reviewing the Participant Information Sheet and Informed Consent Document

1) Participant Information Sheet Process

- The EC members should check whether the Participant Information Sheet and Informed Consent Document are as per the template provided to the Principal Investigator. The Participant Information Sheet (PIS) and Informed Consent Document (ICD) should be congruent with the Application and the research study.
- To see whether the information in the consent form is a reflection of Investigator's communication with the study participant.
- Final comprehensive information of the study may also be given to the participants.
- Information provided in Participant Information Sheet is in simple language (easily understood by lay person), with no scientific jargon and yet complete and updated. Informed consent documents should be written using language at the reading level and technical level of the participant.
- Consent document is written at the 8th grade reading level.
- Because research participants come from a variety of backgrounds and educational levels and are frequently under physical and emotional stress, it is important that Participant Information Sheet/consent form is easy to understand. If a medical term is essential, lay language definition is included .
- As studies have shown that the "understanding" may decrease with the length of the text, it would be appreciated that the consent form be concisely written.
- No informed consent, whether oral or written, may include any language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- Investigator, study co-ordinator, social worker or any other team member of the research study has to obtain consent from the potential participants.

- The individual taking the consent should be well versed, sufficiently trained and knowledgeable about the study to answer any questions or appropriately refer questions that may exceed their expertise put forth by the potential study participants.
- The individual obtaining consent can unintentionally influence a research participants decision to participate in research, hence every effort should be taken to avoid undue influence.
- Maintaining privacy and the place/setting in which the consent is obtained is of paramount importance. The consent process should be conducted individually and in areas where the discussion is not overheard, there is no peer pressure and or/inattention and no unwanted stress or anxiety.
- The timing of the consent process may have a negative impact on the potential research participant's ability to make a considered decision.
- All research participants must be given the Participant Information Sheet and the Informed Consent Document to take it home to discuss it with their family members, doctor and friends. Allowing the research participants sufficient time may improve the quality of the informed consent process. In case of studies pertaining to delivery/labor, informed consent should be obtained in the prenatal visit and reconsent may be taken.
- Investigator, study co-ordinator, social worker or any other team member of the research study should sit face-to-face with the potential participant read/discuss the Participant Information Sheet/Informed Consent Document

Considerations for Assent:

- There is no need to document assent for children below 7 years of age.
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded. Principal Investigator can mention that the verbal/ oral consent of a child is been taken in presence of one of the parent/ LAR in the Parental assent form.
- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

Consent of Parent/LAR

- The EC should determine if consent of one or both parents would be required before a child could be enrolled.
- Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.
- Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.

- Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.
- When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.
- Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.
- Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

2) Telephonic/ online surveys and interview

- Verbal or online consent need to be sought with due approval stating details about how the information will be collected and how confidentiality will be maintained.

3) Reconsent

The following situations call for a re-consent from study participants

- New information pertaining to the study becomes available which has implications for participant or which changes the benefit-risk ratio
- A research participant who is unconscious regains consciousness or who had suffered loss of insight regains mental competence and is able to understand the implications of the research
- A child becomes an adult during the course of the study
- Research requires a long-term follow-up or requires extension
- There is change in treatment modality, procedures, site visits, data collection methods or tenure of participation which may impact participants descion to continue in the research
- Therwe is possibility of disclosure of identity through data presentation or photographs (this should be camouflaged adequately) in an upcoming publication
- The partner/ Spouse may also be required to give additional re-consent in some of the above cases
- Use of biological samples for purpose other than previously consented

4) Criteria for Waiver of Consent

The EC may grant consent waiver in the following situations:

- Research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- Retrospective studies, where the participants are de-identified or cannot be contacted;
- Research on anonymized biological samples/data;
- Certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

Informed Consent Process

The actual **process of informed consent** should:

- Give the participants significant **information** (Participant Information Sheet- PIS) about the study in the local language with which the participant is well-versed.
- Make sure the participants have **enough time** to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain **risks or concerns** to the participants**.**
- Make sure that all information is **understood and satisfies the participants**.
- Make sure the participants understand the study and the consent process.
- Obtain **voluntary** informed **consent** to participate.
- Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
- Consent should be **informally verified on a continuing basis.**
- **Continue to inform** the participants throughout the study.
- **Continue to re -affirm** the **consent/assent** to participate throughout the study.
- **Procedures or methods** used in the informed consent process for recruitment of study participants may include details about the study or research topic could be provided through Brochures, Pamphlets, Internet information, Audio-visual presentations etc.
- Consent forms must be presented on letterhead or must state in the first paragraph that the project is being conducted by the National Institute for Research in Reproductive Health.

- Describe how personal information will remain confidential. In the case where the data collected contains identifying information (e.g., interview tapes, contact information for follow up studies, clinical history with age and name and other identifiable information), describe with whom, for how long, how the data will be stored, and that when the data is no longer required the data will be appropriately destroyed. If the data are anonymous, this statement may be omitted.

All records identifying the participants will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. The study doctor and research team will use personal information about the participant to conduct this study. This may include their name, address, medical history and information from their study visits. However, this personal information is not included in the study data that will be forwarded to the sponsor or sponsor representatives. They will be identified by a coded number in any reports of publications produced from this study (study data).

This is important in studies like in Reproductive tract infections, gene studies etc.

- Describe who has access to the data, where the data is and how it will be stored securely.

To confirm that the study data collected about the participant is correct and related to them, selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to their personal information at the study site. These persons are required to maintain the confidentiality of their information. **By signing this document, they are authorizing such access.**

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words, remove technical jargon and medical terms.
- Try to use correct basic grammar and form.
- Use "gene **transfer**" instead of "gene **therapy**" (less implied effectiveness).
- Use"**agent**" instead of "**drug**" or "**medicine** " (less implied effectiveness).

Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness)

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Annexure IV

Participant Information Sheet
(For Study Participants/Parents of children who would participate in the study)

Title of Project:_____

Principal Investigator : Name,

Designation,

Contact details_____

Co- Investigator(s) : Name,

Designation,

Contact details_____

Collaborators : Name,

Designation,

Contact details_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research study about?
2. Who is the sponsorer for this study?
3. What information is known about this type of research study?
4. Why is this research study being done?
5. How will the research study be done?
6. Who can take part in this research study?
7. How many participants will be included for this research study (total and at this site)?
8. What do you have to do if you agree to take part in the research study?
9. What are the possible benefits to you by being in the research study?
10. What are the possible risks and inconveniences that you may face by being in the research study?
11. What are the tests that will be performed on the participant/ biological sample?
12. How long will you be in the research study?
13. How long the biological samples will be stored and how will it be disposed? (Make sure to include this statement in the answer that a person can yet participate in current study even if they refuse to store their biological sample)
14. Under what conditions will your Participation in the study be terminated?
15. What happens if you are injured since you took part in this research study?
16. What will happen if you change your mind about participation in this research study?
17. How will your privacy and confidentiality be maintained?
18. Will you have to bear any Expenses or Costs by participating in the research study?
19. Whom do you call if you have questions or problems?
    a. Research related
    b. Regarding rights as a Participant

Please contact the researchers listed below to:

Obtain more information about the study

Ask a question about the study procedures or treatments

Dr. …….

Scientist.....

Department.....

Dr.....

Scientist.....

Department.....

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

Dr. ……..

Member- Secretary,

The Institutional Ethics Committee comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

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Annexure V

Informed Consent Form

I_____have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

Name of the Study Participant

Signature/Thumb impression of Study Participant with date

(Witness of the consent procedure if the participants is illiterate)

I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions

Name of the Witness

Signature of Impartial witness with date

Name of the Person administering the Consent

Signature of Person administering the consent with date

Name of the Principal Investigator/collaborator

Signature of Principal Investigator/ Collaborator with date

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Annexure VI

Informed Consent Form (For permitting to take a photograph)

I.....have agreed to participate in the research study entitled..... I understand that photographs of certain medical conditions would be used to explain/highlight the research findings.

PLEASE TICK THE APPROPRIATE OPTION THAT PARTICIPANT HAS CONSENTED TO

Please tick mark the options you choose	YES	NO
1. I agree to have my photograph taken.		
2. I understand that my questionnaire responses will not be linked to the photograph(s).		
3. I understand that my name will not be linked to the photograph(s).		
4. I understand that my face in photograph(s) - will be shown - will not be shown		
5. I give the project team permission to:		
- use my photograph(s) in printed or electronic material (e.g. reports, publication, leaflets, newspaper articles, news releases)		
- use my photograph(s) in presentations (e.g. at conferences or seminars)		

Name of the Study Participant

Signature/Thumb impression of Study Participant with date

(**Witness of the consent procedure if the participants is illiterate**)

I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions.

Name of the Witness

Signature of Impartial witness with date

Name of the Person administering the Consent

Signature of Person administering the consent with date

Name of the Principal Investigator/collaborator

Signature of Principal Investigator/ Collaborator with date

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Annexure VII

Informed Consent Form
(For future use of stored samples)

PLEASE TICK THE APPROPRIATE OPTION THAT PARTICIPANT HAS CONSENTED TO

I_____

☐ **Agree to allow** my sample/ biological specimen to be stored for future use for ..... yrs/indefinite period

☐ for any biomedical research

☐ for specific disease such as cancer research

☐ for other pre-specified diseases such as Diabetes/Heart Disease

☐ **Do not wish to allow** my sample/ biological specimen to be stored for future use which is beyond the scope of the research study that I have already consented for, unless researchers re-contact me to seek my permission

☐ **Do not wish to allow my sample**/ biological specimen to be stored for future research . I do not want researchers to contact me about future studies.

I wish to be informed/not to be informed about results of my investigation. In this case, I agree to take the responsibility to inform the Principal Investigator of the research study if there is a change in my contact details i.e address or contact number.

I understand that if I have permitted use of my samples for future storage, the investigators will take appropriate permission of the Ethics Committee.

Name of the Study Participant

Signature/Thumb impression of Study Participant with date

(**Witness of the consent procedure if the participants is illiterate**)

I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions.

Name of the Witness

Signature of Impartial witness with date

Name of the Person administering the Consent

Signature of Person administering the consent with date

Name of the Principal Investigator/collaborator

Signature of Principal Investigator/ Collaborator with date

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Annexure VIII

Assent Information Sheet (for children from 12 years to 18 years)

Title of Project:_____

Principal Investigator: Name,

Designation,

Contact details_____

Co- Investigator(s): Name,

Designation,

Contact details_____

Collaborators: Name,

Designation,

Contact details_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Assent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the study about and how it might help?
2. What do you have to do if you take part in the study?
3. What discomfort there might be and what will be done to minimize it?
4. Who will answer the child's questions during the study? (Please make a mension that the child can tell the research staff and parents if something disturbs him/ her, etc.)

5. Whether an option to say "no" exists?

6. Whom do you call if you have questions or problems?

   a. Research related

   b. Regarding rights as a Participant

Please contact the researchers listed below to:

Obtain more information about the study

Ask a question about the study procedures or treatments

Dr. …….

Scientist.....

Department.....

Dr.....

Scientist.....

Department.....

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office.

Dr. ……..

Member Secretary

The Institutional Ethics Committee comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

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Annexure IX

Assent Form (for children from 12 years to 18 years)

I …….....……have read /have had read the participant information sheet version no. ……..dated……..bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my assent willingly to participate in this research study.

(If age between 12 -18 years)
Name of the Study Participant

Signature/Thumb impression of Study Participant with date

(<u>Witness of the consent procedure if the participants is illiterate</u>)

I have witnessed the assent procedure of the study participant and the individual has had the opportunity to ask questions.

Name of the Witness

Signature of Impartial witness with date

Name of the Person administering the Consent

Signature of Person administering the consent with date

Name of the Principal Investigator/collaborator

Signature of Principal Investigator/ Collaborator with date

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Annexure X

Parental/LAR Consent Form

I_____have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled "……".

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my child's role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I am willing to give relevant information about my child/ allow clinical examination of my child / collection of biological samples from my child.

I understand that my child's participation is voluntary and that he/she has the right to withdraw from the study at any time without giving any reasons for the same. This will not affect his/her further medical care or any legal right.

I understand that the information collected about my child during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine his/her medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my child's records.

I hereby give my consent willingly to participation of my child in this research study. I am informed that I will not be given any compensation/ reimbursement for participation in the study.

Name of the Parent / LAR

Signature/Thumb impression of Parent / LAR with date

(Witness of the consent procedure if the Parent/ LAR is illiterate)

I have witnessed the consent procedure of the parent/ LAR and the individual has had the opportunity to ask questions.

Name of the Witness

Signature of Impartial witness with date

Name of the Person administering the Consent

Signature of Person administering the consent with date

Name of the Principal Investigator/collaborator

Signature of Principal Investigator/ Collaborator with date

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Annexure XI

Format for Curriculum Vitae for Investigators

Institutional Ethics Committee

Name:

Present affiliation *(Job title, department, and Organisation)*:

Address (Full work address):

Contact 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
(*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 researchduring last 5 years. Give the date of the training)*

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

Signature with date:

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Annexure XII
Application form for Clinical Trials
Institutional Ethics Committee

Please mark/circle appropriate answers

Project No…… Duration of the study:……

Title of study: ……

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): ……

……

1. Type of clinical trial: Regulatory trial/ Academic trial
   CTRI registration number : …… NABH accreditation number: .....
2. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached / Applied, under process / Not applied (State reason)
   ……..
3. Tick all categories that apply to your trial

Phase- I	☐	Phase- II	☐
Phase -IV or Post Marketing Surveillance	☐	Phase- III	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Bioavailability / Bioequivalence studies	☐	Drug/device combination	☐
Repurposing an existing intervention	☐	Non-drug intervention	☐
Indian system of medicine (AYUSH)	☐	Others (specify) ……	

4. Trial design of the study.

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

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

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

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

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes / No

If yes, Name and Contact details:
.....
.....
.....

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

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

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

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

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

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, describe in brief (100 words) …….....
…….....
…….....
…….....

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

If yes, provide details …….....……
...…….....

10. Provide details of anticipated incidence, frequency and duration of adverse events related to the intervention. Yes/ No/ NA
If yes, what are the arrangements made to address them? .....….....
……
…….....

11. 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. Justify any plans to withdraw standard therapy during the study. Yes/ No/ NA
…….....……
…….....……....
…….....……

14. Describe the rules to stop the protocol in case of any adverse events. Yes/ No/ NA
…….....……
…….....……....

15. Provide details of Data and Safety Monitoring Plan. Yes/ No/ NA
…….....……
…….....……....

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 can be easily understood by the participants)

Other*(Specify)* …….....……

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. Provide details of insurance coverage of trial. Yes/ No/ NA

…….....……

…….....……

I. Medical Council of India (MCI) or the State Medical Council registration details of Principal Investigator. Yes/ No

…….....……

…….....……

II. GCP training in last 3 years by investigators. Please enclose PI certificate. Yes/ No

Signature of PI with date: ……

Annexure XIII

Guide to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease Board decision.

I. Benefits of standard treatment

1) Is there a standard of care/ standard treatment? If yes, what is the standard treatment/ standard of care?
2) Is the standard treatment/standard of care widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answer of (1) to (6) are "yes", placebo is not recommended.

If any one or more answers are "no", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?
   If yes, placebo is not acceptable.
2) Is the use of placebo instead of treatment likely to lead to permanant damage?
   If yes, placebo is not acceptable
3) Is the risk of using palcebo instead of treatment likely to cause irreversible disease progression?
   If yes, placebo is not acceptable.
4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

If the answer of (4) to (6) are"yes", placebo is not acceptable unless risk management is adequate.

III. Risk management

1) Is there benefit in the overall management of the subject?
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

2) Will the discontinuation of provious treatment put the participant in danger of acute relapse when transferred to placebo?
   - ☐ No, consider placebo
   - ☐ Yes, placebo not recommend.

3) Are subjects at high risk for the use of placebo excluded?
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

4) Is the duration of the study the minimum necessary in relation to the action of the drug?
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

5) Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

6) Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?
   - ☐ Not applicable.
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

7) Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?
   - ☐ Not applicable.
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?
   - ☐ Not applicable.
   - ☐ Yes, consider placebo
   - ☐ No, placebo not recommend.

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

- ☐ Not applicable.
- ☐ Yes, consider placebo
- ☐ No, placebo not recommend.

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?

- ☐ Yes, consider placebo.

2) Are the risks of the test drug disclosed?

- ☐ Yes, consider placebo.

3) Are the advantages of alternative treatments explained?

- ☐ Yes, consider placebo.

Conclusions:

1. The use of placebo is ethically acceptable because:
   Subjects are not exposed to severe or permanent harm by the use of placebo
   Subjects under placebo will benefit from the overall treatment of the disease.
   Risks of the use of placebo are minimized
   Risks are adquately disclosed in the consent form.

2. The use of placebo in this study could be reconsidered if the following conditions are met:
   ……
   ……
   ……
   ……

3. The use of placebo in this study is ethically unacceptable because:
   - ☐ subjects are exposed to severe or permanent harm by the use of placebo instead of active treatment.
   - ☐ Due to the nature of the disease, the risks of placebo can not be minimized

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Annexure XIV
Application Form for Human Genetics Testing Research

Please mark/circle appropriate answers

Project No. ……..……. Duration of the study:…….....……

Title of study: …….....

……

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

Co-PIs/Collaborators (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. Explain the additional safeguards provided to maintain confidentiality of data generated.
   ……
   ……
3. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes/ No/ NA
4. If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counselling).
   ……
   ……
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 a plan for future use of stored samples for research? Yes / No
   If yes, has this been addressed in the informed consent? Yes / No
8. Is the study a gene therapy trial? If yes, is there approval from local EC and Department of Bio Technology? Yes / No / NA

Signature of PI with date: ……

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Annexure XV
Application Form for Socio - Behavioural & Public Health Research

Please mark/circle appropriate answers

Project No. …… Duration of the study:……

Title of study: ……

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): ……

1. Data collection method used in the study.

   Focus group Questionnaire / Survey

   Observation Interviews

   Ethnographies/Oral history/Case studies Documents and records

   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 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.

   ……

   ……

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

   ……

   ……

   ……
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 with date: ……

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Annexure XVI
Application Form for Exemption from Ethical Review

Project No. ……Duration of the study:……..

Title of study:…….....……

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): ……..

…….....

1. Choose reasons why exemption from ethics review is requested? Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research *Involving Human Participants 2017, Page 51 Table 4.2.*	
I Research on data in the public domain/ systematic reviews or meta-analyses.	
ii. Observation of public behaviour/ 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 programs by government agencies*Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*	
vii. Any other (please specify in 100 words): ……..……..... ……..... …….....	

Signature of PI with date : …….....……

Comments of EC Secretariat: …….....……

Signature of Member Secretary with date: …….....……

Encl. : 1. Initial Review form
2. Detailed protocol

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Annexure XVII
Undertaking by Principal Investigator along with Request for Exemption from Ethical Review

1. I undertake that no changes would be made to the Approved Protocol without the knowledge of Ethics Committee.
2. If any changes are required to be made to the protocol, I will submit the revised draft version of the protocol to the Ethics Committee.
3. I undertake that amendment to the protocol and Amended protocol will not be implemented or given effect to till the Ethics Committee approves the amended project.
4. I understand that the Ethics Committee will determine if the amended protocol justifies exempt from Ethical review.

Signature of PI with date : ……

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Annexure XVIII
Application Form for Expedited Review

Project No. ……

Title of study:……

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): ……..

……

1. Choose reasons why expedited review from EC is requested?
   Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2
   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 among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
   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 persons *(For details, refer to application for initial review, Section-C, 5(b))*? Yes/ No

If Yes give details……..……

Signature of PI with date : ……

Comments of EC Secretariat: ……

Signature of Member Secretary with date: …….....

Application form for Initial review & Detailed protocol should be submitted along with this form

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Annexure XIX

Application/Notification form for Amendments

Project No. ……..

Title of study:……

……Version……date……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): ……

……

Duration of the study: .....

1. Presented to EC – date:.....
2. Date of EC approval: ……..…… Date of start of study: ……
3. Previous Amendments: 1. No ..... 2. Yes.....

   If yes, date/s of approval given for the Amendment/s:.....
4. a. Describe types of amendment(s): …….....……..……

1.	Change in Title:	
2.	Change in the Collaborator:	
3.	Change in the sample size:	
4.	Change in the study protocol:	
5.	Any other: (Please specify)	

b. Details of amendment(s):

Sr. No.	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ ICD *(page number in the ICD/protocol where the amendment is proposed)*

5. Impact of Amendment on study: .....

6. Financial Status:.....

7. Impact on benefit-risk analysis. Yes/ No
   If yes, discuss in brief:….....…….....……
   …….....……
8. Is any re-consent necessary? Yes/ No
   If yes, have necessary changes been made in the informed consent? Yes/ No
9. 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)
10. Outcome and Implications of the Study:.....
11. Publications (If any):.....
12. Presentations (If any):.....
13. Version number of amended Protocol/Investigator's brochure/ICD:…….....……

Signature of PI with date: ……

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Annexure XX

Continuing Review Report format

Please mark/circle appropriate answers

Project No. …… Duration of the study:……

Title of study: …….....……...……...

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): .....……

……

1. Date of initial EC Approval:…….....
2. If Any amendment, approval date of the amendment…….....……..
3. Validity of approval: …….....…….....
4. Date of Start of study: ……..... Proposed date of Completion:…….....

   Details of Continuing Review Report submitted till date:

Serial No.	Period for CRR ---- to ------	CRR due on	CRR submitted on

5. Does the study involve recruitment of participants? Yes / No
   (a) If yes, Total number expected:…… Number Screened: ….....……
   Number Enrolled: …….....
   Number Completed:……...….....…… Number on follow up ……...…..……
   (b) Enrolment status – ongoing / completed/ stopped.
   (c) Report of DSMB *(In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.)* Yes / No / NA
   (d) Any other remark: ……...……..……
   ……...……....……

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

If yes, total number withdrawn and reasons: ……...……

……...……....……

6. Is the study likely to extend beyond the stated period ? Yes / No

(State if any p*roblems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*)

If yes, please provide reasons for the extension: ……...……

…….....

.....

7. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past period? Yes / No

If No, skip to item no. 6

(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: :…….....……

8. 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:……

…….....

.....

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

If yes, give details:

.....……

10. (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

……...….....

……...….....

11. Has there been any protocol deviations/violations that occurred during this period? Yes / No
    If yes, number of deviations …….....……
    Have you reported the deviations to EC? If no, state reasons Yes / No
    .....
    .....
12. In case of multi-centric trials, have reports of off-site SAEs been submitted to the EC? Yes / No / NA
13. Are there any publication or presentations during this period? If yes give details. Yes / No
    …….....……
    …….....……
14. Any other comments: ……

Signature of PI with date: ……

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Annexure XXI

Request for Extension of the Approved Study

Protocol No.: Principal Investigator:

Protocol Title:

Date of Initial EC Approval: Approved duration of study

Date of Initiation of study:

Details of Amendment:

Date of last Recent Amendment approval:

Phone number:

E-mail address :

Sponsor's /Funding Agencies Name

Address:

Phone : E-mail :

Current Funding/ Finantial Status:

No. of Study Arms (If any):

Number of participants in each of the Study Arms:

Study dose(s):

Reasons for extension of the study protocol:

Signature of P.I.: Date:

*Principal Investigator should clearly mention in the covering letter that there is no change in the protocol & Risk- benefit ratio do not alter.

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Annexure XXII

Study Completion/Final report format

Please mark/circle appropriate answers

Project No. …… Duration of the study:……

Title of study: …….....……...……...

……

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

Co-PIs/Collaborators (Name, Designation and Affiliation): .....……

……

1. Date of EC approval : ……
2. Date of start of study:…… Date of study completion:…….....……
3. Sponsor's/Funding Agencies details (Name, Address, Phone, Email ID): .....
   …….....……
4. (a) Objectives:.....
   .....
   (b) Methodology: .....
   .....
5. Provide details of:
   a) Details of study site(s): .....
   b) Total number of study participants as each site approved by the EC for recruitment
   c) Total number of study participants recruited
   d) Total number of participants withdrawn from the study (if any) }

Provide the reasons for withdrawal of participants (*Explanation for the withdrawal of participants whether by self or by the PI)*……...……

……

6. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared):…….....……
   …….....
   …….....
7. Describe the main ethical issues encountered in the study (if any): ……....……..
   …….....……
   …….....

8. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period.
   Deviations: …….....
   Violation: …….....…….
   Amendments: …….....……

9. Describe in brief plans for archival of records / record retention:…….…….....
   …….....
   …….....
   …….....

10. Is there a plan for post study follow-up? Yes / No
    If yes, describe in brief:…….....……
    …….....
    …….....
    …….....

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

12. Is there a plan for post study benefit sharing with the study participants? Yes / No
    If yes, describe in brief: …….....……
    …….....……
    …….....

13. Describe results (summary) with Conclusion: ….....……
    .....

14. No. of Study Arms (If any):..... Study dose (s):.....

15. Number of AE/SAEs that occurred in the study: …….....…

16. Change in risk benefit ratio:.....

17. Have all AE/SAEs been intimated to the EC? Yes/ No

18. Is medical management or compensation for SAE provided to the participants? Yes/ No
    If yes, provide details…….....……
    …….....
    …….....

19. Outcome and Implications of the Study: .....

20. Publications (If any):.....

21. Presentations (If any): .....

Signature of PI with date: ……

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Annexure XXIII

Information on what to expect after Protocol Submission

I Prior to approval of a research study

- The Secretariat will ensure completeness of the proposal submitted by the PI to EC.
- Primary reviewers will be assigned and the secretariat will send the copies at least 8 days in advance of the full board meeting to the primary reviewers and EC members.
- The project will be reviewed at the IEC meeting.
- An investigator is expected to be present at the time of full board meeting and will be invited (telephonically) to the IEC meeting to discuss issues related to the study proposal, if needed.
- After the full board, the minutes will be given within 15 days.
- An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 21 days to maximum 90 days of date of receipt of the letter as per template below:

Serial No.	Reviewer's comment	Response to comment	Changes made (addition in **Bold** & deletion in strike out text)	Pg. No.

- In the absence of any response, the project will be declared closed for the IEC office records.

II Once approval for a study is granted

- An approval will be granted for usually one year study period.
- It is the responsibility of the principal investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within one month's time span of the due date mentioned on the approval letter i.e. in the 10 month from the date of approval).

III Once a study is over

Submission of Study Completion Report

- For studies which are completed within the IEC approval period, a study completion report as per the format should be submitted to the IEC, by the investigator.
- The study completion report is expected for review within 2 months of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from the sponsor.

IV In case a study is not initiated or terminated,

The same should be communicated to the IEC stating reasons for the same. The report of premature termination of the study should be given as per format.