Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Templates for Protocol & other Submissions

SOP Code: 06/V2.2 Dated: 8th November 2024 Page Nos: 50 to 130

6.1. Purpose

This SOP describes how the Principal Investigator should submit the protocol and other documents to the ICMR-NIRRCH Ethics Committee for Human Studies.

6.2. Scope

This SOP applies to the submission of documents and approval from the IEC.

6.3. Responsibility

It is the responsibility of the Principal Investigator to submit the complete documents to be reviewed as per checklist points (Section F), form **AF/1.0/06/V2.2** (see ANNEX 1.01 of SOP 6).

6.4 ANNEX

ANNEX 1	**AF/1.0/06/V2.2**	**Lists of Applications to be attached for Initial Review of project**
ANNEX 1.1	AF/1.1/06/V2.2	Application Form for Initial Review
ANNEX 1.2	AF/1.2/06/V2.2	Format for Technical summary and Detailed Protocol
ANNEX 1.3	AF/1.3/06/V2.2	Guidelines for reviewing PIS and ICD
ANNEX 1.4	AF/1.4/06/V2.2	PIS For Study Participants/Parents of children who would participate in the study
ANNEX 1.5	AF/1.5/06/V2.2	Informed Consent Form (ICF)
ANNEX 1.6	AF/1.6/06/V2.2	Informed Consent Form For permitting to take a photograph
ANNEX 1.7	AF/1.7/06/V2.2	Informed Consent Form For future use of stored samples
ANNEX 1.7A	AF/1.7A/06/V2.2	Informed Consent Form For future use of research data
ANNEX 1.8	AF/1.8/06/V2.2	Assent Information Sheet
ANNEX 1.8A	AF/1.8A/06/V2.2	Oral Assent Information Sheet
ANNEX 1.9	AF/1.9/06/V2.2	Assent Form
ANNEX 1.10	AF/1.10/06/V2.2	Parental/LAR Consent Form
ANNEX 1.11	AF/1.11/06/V2.2	Undertaking format to be submitted by the Principal Investigator/ Research Guide
ANNEX 1.12	AF/1.12/06/V2.2	Undertaking format for using stored samples from other projects
ANNEX 1.13	AF/1.13/06/V2.2	Draft of MoU/ MTA
ANNEX 1.14	AF/1.14/06/V2.2	Format for Curriculum Vitae for Investigators

ANNEX 2	AF/2.0/06/V2.2	Application form for Clinical Trials
ANNEX 2.1	AF/2.1/06/V2.2	Guide to Placebo Justification
ANNEX 3	AF/3/06/V2.2	Application Form for Human Genetics Testing Research
ANNEX 4	AF/4/06/V2.2	Application Form for Socio-Behavioural & Public Health Research
ANNEX 5	AF/5/06/V2.2	Application Form for Exemption from Ethical Review
ANNEX 5.1	AF/5.1/06/V2.2	Undertaking by Principal Investigator along with request for Exemption from Ethical Review *(Check SOP 10 for details)*
ANNEX 6	AF/6/06/V2.2	Application Form for Expedited Review *(Check SOP 11 for details)*
ANNEX 7	AF/7/06/V2.2	Application/Notification form for Amendments *(Check SOP 14 for details)*
ANNEX 8	AF/8/06/V2.2	Continuing Review Report format *(Check SOP 15 for details)*
ANNEX 9	AF/9/06/V2.2	Request for Extension of approved study *(Check SOP 15 for details)*
ANNEX 10	AF/10/06/V2.2	Study Completion/Final report format *(Check SOP 16 for details)*
ANNEX 11	AF/11/06/V2.2	Premature Termination/Suspension/ Discontinuation Report Format *(Check SOP 17 for details)*
ANNEX 12	AF/12/06/V2.2	Information on what to expect after Protocol Submission
ANNEX 13	AF/13/06/V2.2	Document History

ANNEX 1.0 **AF/1.0/06/V2.2**

Title, version no., date, Principal Investigator

List of document for Initial Review Checklist

(Please tick as applicable)

Sr. No.	Items	Yes	No	Not Applicable	Enclosure no./ Page no.	*EC Remarks* (if applicable)
	ADMINISTRATIVE REQUIREMENTS					
	Cover letter					
1	Initial Review Form					
2	Other additional/ related forms (If applicable) a. Form for Exemption from Ethical Review & Undertaking by Principal Investigator b. Form for Expedited Review c. Form for Human Genetics Testing Research d. Form for Socio-Behavioural & Public Health Research e. Form for Amendment f. Form for Clinical Trials with Guide to Placebo Justification					
3	Approval of SAC/ SRC/ IRCT/RAC/ Any other					
4*	EC clearance of other centers					
5*	Draft of agreement between collaborating partners (Memorandum of Understanding-**MoU**)					
6*	Draft of material Transfer Agreement (**MTA**) between collaborating partners					
7	Insurance policy/ certificate					
8	Copy of contract or agreement signed with the sponsor or donor agency					
9*	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						
10	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)}***					
11	Investigators Brochure (If applicable for Drug/ Biologicals/ Device trials)					
12	Participant Information Sheet (PIS)& Participants informed consent form (ICF) (English & translated)					
13	Assent form for minors (12-18 years) (English and Translated)					
14	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)					
15	Advertisement/material to recruit participants (fliers, posters etc.)					
16	Role of Investigators					
17	Brief CV of all Investigators					
18	Research Ethics training/ GCP of Investigators in last 5 years					

PERMISSIONS FROM GOVERNMENT AUTHORITIES						
	Other permissions	**Required**	**NOT Required**	**Received**	**Applied on**	**EC Remarks**
19	CTRI					
20	DCGI					
21	HMSC					
22						
23						
24	RCGM					
25	GEAC					
26	BARC					
27	Tribal Board					
28	CDSCO					
29. 30.	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**Not Applicable**	**Enclosure No./ Page No.**	**EC Remarks**
31.						
32.						

Things the Principal Investigator/ Co- Principal Investigator should be aware about are:

1. Consider the list of appropriate permissions that might be essential for the proposal as given above (page 63 from 19-30)
2. Required copy of all the essential documents, neatly typed, numbered and bound shall be submitted.
3. 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 1 and date.
4. All pages must be serially numbered and put as footer on the right side of the page.
5. Any incomplete proposal will not be considered for the meeting. Any blank left in the study proposal (example: signatures), should be justified.
6. All the PIs are instructed to read the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR, 2017 & other related recent ICMR guidelines before filling the form.

ANNEX 1.1 **AF/1.1/06/V2.2**

Title, version no. date , PI

Application Form for Initial Review
ICMR-NIRRCH Ethics Committee for Human Studies

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 / Amendment/ Final** ● **Duration:**

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization : ICMR- NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(b) Name of Ethics Committee : ICMR- NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH Ethics Committee for Human Studies

(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; 1. research conducted on data available in the public domain for systematic reviews or meta-analysis; 2. observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; 3. quality control and quality assurance audits in the institution;

	4. laboratory validation testing using anonymous or de-identified samples to assess parameters like sensitivity and specificity and is conducted without the intention of research or influencing patient management and does not involve novel or innovative diagnoses or technologies. comparison of instructional techniques, curricula, or classroom management methods; 5. consumer acceptance studies related to taste and food quality; and 6. public health programs by Govt agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers). 7. Any other (please specify in 100 words): …… ……
Expedited Review	Proposals that pose no more than minimal risk may undergo expedited review, for example; 1. research involving non-identifiable specimens and human tissue from sources like blood banks, tissue banks and left-over clinical samples; 2. research involving clinical documentation materials that are non-identifiable (data, documents, records); conducting new experiments as required by journal reviewers for the publication of closed projects, with a short duration and limited sample size; 3. modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); 4. revised proposals previously approved through expedited review, full review or continuing review of approved proposals; 5. minor deviations from originally approved research causing no risk or minimal risk; 6. 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 7. for multicenter 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. 8. 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; 1. research involving vulnerable populations, even if the risk is minimal; 2. research with a minor increase over minimal risk; 3. studies involving deception of participants; 4. 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 5. decision taken by the subcommittee or expedited committee;

	6. amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; 7. major deviations and violations in the protocol; 8. 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; 9. 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; 10. 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) :

i Protocol number (By Ethics Secretariat) :

ii 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 should be submitted for review**

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission:……

Please provide the status of currently approved studies:

Sr. 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 the 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 collaborators/ collaborating institutions: Yes/ No

Sr. 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 <u>with date of proposal submitted to funding agency</u>)* ☐

……..

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 & Director with signature & Date:

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

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 samples	☐
Mixed Method	☐	Epidemiological/Public Health	☐
Any other (*Specify)*	☐……		

4. Objectives:

a. ……
b. ……..
c. ……
d. ……..

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

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

i At site ..... In India..... Globally .....

ii Control group ..... Study group .....

iii Inclusion & exclusion criteria .....

iv 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)

1. Independent external review
2. Review by sponsor/Funder
3. Review within PI's institution Research group SAC/SRC/RAC
4. Review within multi-centre
5. 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:

i Healthy volunteer

ii Patient

iii Vulnerable persons/ Special groups

iv Others (specify) .....

B. Will there be vulnerable persons/ special groups involved ? Yes / No / NA

If yes, type of vulnerable persons/ special groups.

i	Pregnant or lactating women	
ii	Children between 0-7 yrs.	
iii	Children between 7- 12 yrs.	
iv	Children between 12-18 yrs.	
v	Differently abled (Mental/Physical)	
vi	Elderly	
vii	Refugees/Migrants/Homeless	
viii	Institutionalized	
ix	Economically and socially disadvantaged	
x	Terminally ill (stigmatized or rare diseases)	
xi	Employees/Student/Nurses/Staff	
xii	Any other (Specify)	.....

C. Who will do the recruitment?

……

D. Participant recruitment methods used:

i Posters/leaflets/Letters ☐

ii TV/Radio ads/Social media/Institution website ☐

iii Telephone ☐

iv Others (Specify) ☐.....

E. Provide justification for inclusion/exclusion.....

.....

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

.....

.....

.....

G. Mention how safety of participants will be ensured in Emergencies like COVID Pandemic (wherever applicable)

.....

.....

.....

H. Is there any reimbursement to the participants? Yes / No

I. Are there any incentives to the participants? Yes / No

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

.....

J. 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. i. Are adverse events expected in the study ? Yes/ No/ NA

(Include both serious and non-serious adverse events)

ii. 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): .....

B. Version number and date of Informed Consent Form (ICF):.....Type of consent planned for :

i	Signed consent in person	☐
ii	Signed consent using online platforms	☐
iii	Verbal/Oral consent	☐
iv	Waiver of consent	☐
v	Witnessed consent	☐
vi	Audio-Video (AV) Consent	☐
vii	Consent from LAR (If so, specify from whom)	☐
viii	For children<7 yrs. Parental/LAR consent.	☐
ix	Verbal assent from minor (7-12 yrs.) along with parental consent	☐
☒	Assent from minor (age >12-<18 years along with parental consent	☐
xi	Other (Specify)☐:.....	

C. Who will obtain the informed consent ?

i PI/Co-PI □
ii Nurse/Counsellor □
iii Research Staff □
iv Other (Specify) □.....

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

D. Participant Information Sheet (PIS) and Informed Consent Form (ICF).
i English □
ii Local language □
iii Other (specify) □ .....
iv 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)*

i Principal Investigator □
ii Institution □
iii Sponsor □
iv 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

i Sponsor □
ii Institutional/Corpus fund □
iii Project grant □
iv 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):

i Anonymous/Unidentified □

ii Anonymized: Reversibly coded □

iii Irreversibly coded □

iv 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?.....

……

f) Describe the confidentiality protection plan the investigators would make regarding information collected from participants.....

……

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) Describe how these reports will affect the participant's relatives & how this will be handled by the Principal Investigator
Yes / No/ NA
……

(d) Are there any arrangements for the 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)
……
……

(e) Is there any plan for post-research benefit sharing with participants? Yes / No
If yes, *specify* ……
……

(f) Is there any commercial value or a plan for patent/IPR issues? Yes / No
If yes, please provide details. ……

(g) 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	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:…….

ANNEX 1.2 **AF/1.2/06/V2.2**

Format of Technical Summary and Detailed Protocol

Technical summary

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

Detailed Protocol

Introduction and Rationale:
Objectives of the study:
Inclusion & Exclusion Criteria:
Methodology (including Study Duration):
Study Design, Sample Size, Study Setting
Participant Recruitment:

Please provide a flow chart for the participant recruitment process

1. Consent (Who, Where & When)
2. No. of Visits during the study
3. What will be done at each visit
4. Standard of care at where participants are recruited
5. What will be done at NIRRCH & other centers

Vulnerability, management of risk & confidentiality
Lab procedures in brief
Expected Adverse events / Serious adverse events & how they will be managed
Reimbursement & Compensation
Expected Outcome:
References:

Guidelines for Reviewing Participant Information Sheet and Informed Consent Document

The Principal Investigators should train their project staff/ students/ research fellows, who will be dealing with the enrollment of research participants about Good Clinical Practice training or Research Ethics training and should produce an 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

A. Participant Information Sheet Process

1. 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) (ANNEX 1.4, AF/EC/1.4/06/V2.2) and Informed Consent Document (ICD) (ANNEX 1.5, AF/EC/1.5/06/V2.2) should be congruent with the Application and the research study.
2. To see whether the information in the consent form is a reflection of the Investigator's communication with the study participant.
3. Final comprehensive information of the study may also be given to the participants.
4. Information provided in the Participant Information Sheet is in simple language (easily understood by layperson), 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.
5. The consent document is written at the 8th-grade reading level.
6. Because research participants come from a variety of backgrounds and educational levels and are frequently under physical and emotional stress, it is important that the Participant Information Sheet/consent form is easy to understand. If a medical term is essential, lay language definition is included.
7. 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.
8. 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.
9. The investigator, study coordinator, social worker, or any other team member of the research study has to obtain consent from the potential participants.
10. The individual taking the consent should be well-versed, sufficiently trained, and knowledgeable about the study to answer any questions or appropriately refer to questions that may exceed the expertise put forth by the potential study participants.
11. The individual obtaining consent can unintentionally influence a research participant's decision to participate in research, hence every effort should be taken to avoid undue influence.
12. 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.

13. The timing of the consent process may have a negative impact on the potential research participant's ability to make a considered decision.
14. 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 re-consent may be taken.
15. Investigator, study coordinator, 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.

B. Considerations for Assent:

1. There is no need to document assent for children below 7 years of age.
2. For children between 7 and 11 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 has been taken in presence of one of the parents/ LAR in the Parental assent form.
3. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

C. Consent of Parent/LAR

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.

7. 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).

D. 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.

E. Re-consent

The following situations call for re-consent from study participants

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

F. Usage of storage samples/Data

When can one use stored samples/data?

Samples/Data that have been stored after obtaining consent from participants for future use are called stored samples/data. They can be used following the criteria as given below:

1. The consent is within the duration of proposed use
2. If the participant has allowed future use of the sample and/or related data.
3. The primary study in which the participant is enrolled has been completed and completion report is approved by EC
4. If another investigator wishes to use the stored sample/data, a NOC from the PI of the original study is obtained and is approved by Ethics Committee

G. Criteria for Waiver of Consent

The EC may grant consent waiver in the following situations:

1. Research cannot practically be carried out without the waiver and the waiver is scientifically justified;

2. Retrospective studies, where the participants are de-identified or cannot be contacted;
3. Research on anonymized biological samples/data;
4. Certain types of public health studies/surveillance programs/program evaluation studies;
5. research on data available in the public domain; or
6. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempts should be made to obtain the participant's consent at the earliest.

H. Informed Consent Process

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

1. Give the participants significant **information** (Participant Information Sheet- PIS) about the study in the local language with which the participant is well-versed.
2. Make sure the participants have **enough time** to carefully read and consider all options.
3. **Answer all questions** of the participants before making a decision to participate.
4. Explain **risks or concerns** to the participants**.**
5. Make sure that all information is **understood and satisfies the participants**.
6. Make sure the participants understand the study and the consent process.
7. Obtain **voluntary** informed **consent** to participate.
8. Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
9. Consent should be **informally verified on a continuing basis.**
10. **Continue to inform** the participants throughout the study.
11. **Continue to re-affirm** the **consent/assent** to participate throughout the study.
12. **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.
13. 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 AND CHILD HEALTH.
14. 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 participants 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.

15. 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 participants 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:

1. Use short sentences and paragraphs
2. Limit to one thought or topic in a sentence, avoid run-on sentence
3. Use simple words, less syllables in a word.
4. Use common words, remove technical jargon and medical terms.
5. Try to use correct basic grammar and form.
6. Use "gene **transfer**" instead of "gene **therapy**" (less implied effectiveness).
7. Use " **intervention**" instead of "**drug**" or "**medicine** " (less implied effectiveness).
8. Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness and can lead to therapeutic misconception)

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(INDIAN COUNCIL OF MEDICAL RESEARCH)

J. M. Street, Parel, Mumbai 400 012.

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 sponsor 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? (PI should specify the time required if a questionnaire is to be used/ interview is to be undertaken.)
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 they be disposed of? (Make sure to include this statement in the answer that a person can yet participate in the 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:
Obtain more information about the study
Ask a question about the study procedures or treatments

Dr. …….
Scientist.....
Department.....
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR)
J. M. Street
Parel, Mumbai 400 012
Phone: 2419..... , time to contact- anytime/9.00 am to 5.00 pm

Dr.....
Scientist.....
Department.....

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR)
J. M. Street, Parel, Mumbai 400 012
Phone: 2419……, time to contact- anytime/ 9.00am to 5.00 pm

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)

Member- Secretary,
ICMR-NIRRCH Ethics Committtee for Human Studies
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
J.M.Street, Parel. Mumbai 400 012
Tel.No.: Direct- /022-24192147, Board no.- 022-24192000
Email : ethics@nirrch.res.in,
Time to contact- anytime/ 9.00am to 5.00 pm

The Institutional Ethics Committee for Human Studies comprises 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 - NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
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

Title of Project

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(INDIAN COUNCIL OF MEDICAL RESEARCH)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form

I _____ have read/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 the 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 permit these individuals to have 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**

(Impartial **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 Impartial 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**

Title of Project

Informed Consent Form (For permitting to take a photograph)

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(INDIAN COUNCIL OF MEDICAL RESEARCH)

J. M. Street, Parel, Mumbai 400 012.

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 THE 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 the photograph(s) a) will be shown b) will not be shown		
5. I give the project team permission to use my photograph(s) in presentations, printed or electronic material (e.g. reports, publications, leaflets, newspaper articles, news releases) after taking a re-consent for the same.		

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 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**

ANNEX 1.7 **AF/1.7/06/V2.2**

Informed Consent Form (For future use of stored samples)Title of Project

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(INDIAN COUNCIL OF MEDICAL RESEARCH)

J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form

(For future use of stored samples)

PLEASE TICK THE APPROPRIATE OPTION THAT THE PARTICIPANT HAS CONSENTED TO

I---------- have participated in the research study entitled----------

---------.

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

☐ for any biomedical research/future scientific purpose

☐ 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.

Signature/Thumb impression of Study Participant with date Name of the Study Participant

(Impartial **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 Impartial 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**

Informed Consent Form (For future use of stored samples)Title of Project

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

(INDIAN COUNCIL OF MEDICAL RESEARCH)

J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form

(For future use of Research Data)

PLEASE TICK THE APPROPRIATE OPTION THAT PARTICIPANT HAS CONSENTED TO

I---------- have participated in the research study entitled----------

---.

☐ **Agree to allow** my research data to be stored for future use for --------yrs/indefinite period

☐ for any biomedical research/future scientific purpose

☐ for specific diseases such as cancer research

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

Do not wish to allow my research data 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 research data** 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 my data for future use, the investigators will take appropriate permission from the Ethics Committee.

Signature/Thumb impression of Study Participant with date Name of the Study Participant

(Impartial **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 Impartial 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**

Assent Information Sheet

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
(INDIAN COUNCIL OF MEDICAL RESEARCH)
J. M. Street, Parel, Mumbai 400 012.

Title of Project

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. What are the possible benefits of participating in the study?
5. Who will answer the child's questions during the study? (Please make a mention that the child can tell the research staff and parents if something disturbs her/him etc.)
6. Whether an option to say "no" exists?
7. 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:
Obtain more information about the study
Ask a question about the study procedures or treatments

Dr. …….
Scientist.....
Department.....
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR)
J. M. Street
Parel, Mumbai 400 012
Phone: 2419..... , time to contact- anytime/9.00 am to 5.00 pm

Dr.....
Scientist.....
Department.....
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR)
J. M. Street, Parel, Mumbai 400 012
Phone: 2419……, time to contact- anytime/ 9.00am to 5.00 pm

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 studies like HIV)

Member Secretary
ICMR-NIRRCH Ethics Committee for Human Studies
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
J.M.Street, Parel. Mumbai 400 012
Tel.No.: Direct- 022-24192147, Board no.- 022-24192000
Email : ethics@nirrch.res.in,

Time to contact: time to contact- anytime/ 9.00 a.m. to 5.00 p.m.

The Institutional Ethics Committee for Human Studies comprises a group of people like doctors, researchers, and community people (non-scientific) who work towards safeguarding the rights of study participants like you who take part in research studies undertaken at the Institute - NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

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

ANNEX 1.8A **AF/1.8A/06/V2.2**

Oral Assent Information Sheet

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
(INDIAN COUNCIL OF MEDICAL RESEARCH)
J. M. Street, Parel, Mumbai 400 012.

Oral Assent Information Sheet (for children from 7 years to below 12 years)

Title of Project:_____

Principal Investigator: Name,
Designation,
Contact details_____

Co-Investigator(s): Name,
Designation,
Contact details_____

Collaborators: Name,
Designation,
Contact details_____

We are here to invite you to take part in this research study. Routine care for illness & Research are different from each other. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. But the main goal of research studies is to gain knowledge that may help future patients.

This information about the study will describe the purpose of the study and the risks and possible benefits of participating in the study.

Please try to understand the information carefully & also feel free to ask for an explanation of any words/ part of conversation you do not understand. After you have understood the purpose of this study, you are free to talk to the doctors/researchers/ your parents or guide/ teacher about the study and ask them any questions you have. You can discuss the information even 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 given a copy of the information you have heard from the researcher team. The respective person from the team will also inform about the study to one/ both of your parents or legally authorized representative (LAR) & Parental consent also will be obtained.

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.

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.

PI should note that the type and amount of information given needs to be simplified as per the child's cognitive and developmental level.
The information should be as simple as it can and also should be age-appropriate.
The basic information that needs to be provided includes the points given below:

1. What the study is about and how it might help
   We want to see whether a new medicine will or won't help children like you who have skin rashes"
   "We want to understand why children get tummy aches, like you do"

2. What will happen and when
   "You will have to come to the hospital in the morning with an empty stomach. We will insert a needle and take a teaspoonful of blood"

3. What discomfort there might be and what will be done to minimize it
   "It will hurt as much as a pin prick, but the pain will last only 5 minutes. The area may look red for some time" (if the blood is withdrawn during the study)

4. Who will answer the child's questions during the study
   If you have any questions at any time, you can ask Dr _____.

5. Whether an option to say "no" exists
   "You can say "no" if you don't wish to take part in the study. No one will be angry with you."
   "If you say "yes" and then change your mind later, it will be fine. No one will scold you".

6. What are the possible benefits of participating in the study?
   "You may get the answer related to your trouble you are facing currently"
   "You may not get any benefit but your friends/ other children of your age might get solution for their Health trouble"

7. Whom do you call if you have questions or problems?
   a. Research related

Dr. …….
Scientist.....
Department.....
ICMR-NIRRCH
J. M. Street
Parel, Mumbai 400 012
Phone: 2419.....
time to contact- anytime/9.00 am to 5.00 pm

b. Regarding rights as a participant

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)

Member Secretary
ICMR-NIRRCH Ethics Committee for Human Studies
NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
J.M.Street, Parel. Mumbai 400 012
Tel.No.: Direct- 022-24192147, Board no.- 022-24192000
Email : ethics@nirrh.res.in
Time to contact: time to contact- anytime/ 9.00 a.m. to 5.00 p.m.

ANNEX 1.9 **AF/1.9/06/V2.2**

Assent Form

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
(INDIAN COUNCIL OF MEDICAL RESEARCH)
J. M. Street, Parel, Mumbai 400 012.
Title of Project
Assent Form (for children from 12 years to below 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 permit these individuals to have access to my records.

I hereby give my assent and am willing to participate in this research study.

(If age between 12 -18 years) **Signature/Thumb impression of**
Name of the Study Participant **Study Participant with date**

Name of Parent/LAR **Signature /Thumb impression of LAR/Parent**

(Impartial **Witness of the consent procedure if the participants is illiterate**)
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 assent **Signature of Person administering the assent with date**

Name of the Principal Investigator/collaborator **Signature of Principal Investigator/ Collaborator with date**

ANNEX 1.10 **AF/1.10/06/V2.2**

Parental/LAR Consent Form

NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH
(INDIAN COUNCIL OF MEDICAL RESEARCH)
J. M. Street, Parel, Mumbai 400 012.
Title of Project
Parental/LAR Consent Form

I_____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/ward's role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I am willing to give relevant information about my **Name of child/Ward**…… I allow clinical examination of my child /ward and collection of biological samples from my child.

I understand that my child's participation is voluntary and that she/ he 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 her/his 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 the 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**

(Impartial **Witness of the consent procedure if the Parent/ LAR is also illiterate**)
I have witnessed the consent procedure of the parent/ LAR and the individual has had the opportunity to ask questions.

Name of the Impartial Witness	**Signature of Impartial witness with date**
Name of the Person administering consent with date	**Signature of Person administering consent with date**
Name of the Principal Investigator/collaborator	**Signature of Principal Investigator/ Collaborator with date**

Undertaking format to be submitted by the Principal Investigator/ Research Guide

(For projects submitted by Ph. D. Students)

I, Dr. ----------, _____ (designation) hereby certify that Mr./ Ms. _____ (Student name) is working on the project entitled " _____

_____

_____ "

under my guidance from----------(date). She/ he has submitted the said project to the Mumbai University as her/his dissertation/ thesis topic. The said project is a part of the EC approved study entitled "_____

_____" Project No. ----------

initially approved by the ICMR-NIRRCH Ethics Committee on----------(date). The project was amended (if applicable) on ---------- and the amendment was approved by the EC on

I confirm that the thesis project's objectives and methodology are a part of the objectives and methodology of the larger Project No. ---------- and no new/ additional objectives or no new/ additional procedures or methodological aspects have been added to the thesis project. The sample size required for the thesis project will be from within the sample size approved for the larger project (Project No. --------) approved by the EC.

(If the study is retrospective study of de-identified data Guide will have to certify additionally that de-identification will be done by a third person or by a software system)

Guide's signature with date:

Guide name:

Designation:

Undertaking for use of stored samples

Date:

Principal Investigator handing over the samples: _____
Project No. _____
Title: _____
_____

Principal Investigator taking over the samples:_____
Project No. _____
Title: _____
_____

Both the Principal Investigator should retain a copy in their concerned files

I, hereby agree to the use of anonymized stored samples of my project no._____Entitled_____ by the Principal Investigator _____ for the project no. _____, entitled _____ where participants consent for storage of sample is available.

The duration of sample storage signed by participants is _____ years as per ICD (if applicable).

(Mark the appropriate)

1. My study is ongoing/ completed.
2. I have completed the use of my samples (Yes/No)
3. I will not be requiring the stored samples for validation or repeat testing/ I will be given the sample if I require any repeat or validation for my study

I will hand over the samples only after EC approval and its copy is given to me for my records.

Signature of the Principal Investigator handing over the samples	
Signature of the Principal Investigator taking over the samples	
Signature of Director with seal	

Draft MoU/ MTA

MEMORANDUM OF UNDERSTANDING/Material Transfer Agreement

THIS MEMORANDUM OF UNDERSTANDING/Material Transfer Agreement **(**MOU/MTA**)** is made on day of month, year by and between **ICMR-NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH (ICMR-NIRRCH)**, a research institute formed and registered having their place of work at J**.**M**.** Street, Parel, Mumbai, Maharashtra- 400012 through **……., Director, and ……., Principal Investigator, ……** at ICMR-NIRRCH, J**.**M**.** Street, Parel, Mumbai, Maharashtra- 400012

AND

……., ……., a Hospital/ Institute formed and registered having their place of work at …….. through **……., ……., Director, and ……., Collaborator,** ……., working at …… **.**

SCOPE OF AGREEMENT:

1. **The ICMR-NIRRCH, research institute is desirous to conduct research in the area of …….. and execute a research project entitled "……". This project is funded by …….. The proposed study is a multi-center study and ……. is one of the Collaborating centers.**
2. **The …… through the Department …….. is also desirous to participate in this research project and would be involved to the extent as laid down in this MOU/MTA.**
3. **The purpose of the project is …… ……. The study is expected to generate …… The results of this study would be useful for ……..**

NOW IT IS AGREED BETWEEN THE PARTIES AS FOLLOWS:

1. **OBJECTIVE OF THE RESEARCH PROJECT**

1.1 The objective of the study:

2. **OBLIGATIONS OF THE INSTITUTES**

2.1 It is agreed and understood that ICMR-NIRRCH shall do the laboratory analysis of clinical samples (blood samples) collected from ……., shall be responsible for the …….. analysis, scientific reports and publications in peer reviewed journals.

2.2 It is agreed and understood that collaborator at ……will screen the study participants, obtain the informed consent and recruit the cases and controls as per the inclusion and exclusion criteria of the study protocol. The data will be collected from cases

and controls ……., …… ml of the blood sample from cases and controls will be collected only once during the entire study period of …… years.

2.3 It is agreed that the parties associate exclusively for the purpose of this project within the region specified.

2.4 Each party agrees and undertakes that they will not enter into or in any way seek an award of any contract for the project or any part thereof other than in accordance with this MOU without the written informed consent of the other party hereto.

2.5 The parties hereto ICMR-NIRRCH and ……. shall have no objection to the use of the data collected under the project for research purposes as is required under the project.

3. ROLES AND REPONSIBILITIES

3.1 ……., Principal Investigator (PI) will be responsible for obtaining all mandatory approvals before initiation of the study. PI will coordinate with the collaborator at ……. and provide the required training to the project staff and collaborator for data collection as per ……. PI will ensure the data quality controls as per the International protocols.

3.2 ……., Director, ICMR-NIRRCH and supervisor for the study will provide all the administrative and laboratory support required for the study.

3.3 ……., ……., ……., …….. will recruit the study participants …….. at …….. and collect the …… as per the study protocol. The Collaborator shall counsel the study participants and obtain the written informed consent. The collaborator will collect the needed information ……. and the project staff will collect the data …… and Case record form as per the study protocol. The collaborator will supervise the data collection process and ensure the quality control measures as per the protocol.

3.4 PI and research team at ICMR-NIRRCH shall be responsible for co-ordination of the study, transportation of the ……samples and conducting the laboratory experimental work at PI's laboratory in ICMR-NIRRCH.

3.5 PI and research team (Project staff and Collaborator at ICMR-NIRRCH) are responsible for the proper collection, handling, packing, transportation of the ……. samples from ……in a sealed and marked ice-bucket with all necessary precautions so that there is no tampering or spillage of the …… samples. The standard operating procedures (SOPs) ……. will be followed. At ICMR-NIRRCH, ……. samples of …….. cases and ……controls will be processed and will be stored at ……ºC, at ICMR-NIRRCH. PI's ……. has adequate space for storage of the copies of the consent forms, completed data collection forms and other project related documents. ICMR-NIRRCH has …… facilities in a proper working condition.

4. CONFIDENTIALITY

4.1 The parties and the persons responsible and working on the project shall keep confidential all the information relating to the project that is confidential in nature, including the participant's name and any other information related to identity of study participants. Confidentiality of participants shall be maintained in all publications of the study too.

The samples for the study would be anonymized (removing personal identifiers) by the Collaborator at ……. and the anonymized samples with the code numbers only will be sent to ICMR-NIRRCH. Each sample will get a unique code assigned by the Collaborator, records of which will be maintained by the Collaborator at ..... (Linked anonymization). Any additional information regarding the participant would be routed through the Collaborator at ……, ……..

4.**2 No confidential information shall be revealed to any third person without the express written consent of the party or participant whose information is confidential in nature.**

4.3 Use of confidential information for any purpose other than the said purpose of the project shall not be allowed, unless all parties agree and give written consent for the same.

4.5 Parties shall confirm to the guidelines for research, good clinical practice and medical ethics and shall not breach the same. All study participants will be consented for the study and it will be conducted under the ICMR National Ethical Guidelines for Biomedical and Health Research involving human participants, 2017.

5. CONSIDERATION

5.1 There is no financial consideration to be paid by either of the parties signing this MOU**. The funding to be received for this project ……** which shall be received by ICMR-NIRRCH/ …….. and utilized for carrying out the research as detailed in the project proposal and accounts for the same shall be submitted to the funding agency after due audit**.**

5.2 **Monetary compensation will be provided to the study participants for participation in the study. The amount of compensation will be as per the decision of Ethics Committee of ……. Funds have been allocated for meeting the expenses towards the compensation to the participants in the project grant. ICMR-NIRRCH will bear the expenses for compensation. ……, ……. shall bear no expenses for the study.**

5.3 **Compensation for adverse or serious adverse event associated with ……. sample collection shall be paid by ICMR-NIRRCH.**

6. PUBLICATIONS, INTELECTUAL PROPERTY RIGHTS

6.1 It is agreed that the ownership and credit for the research project shall be

shared by all the parties involved in the project handling, execution and analysis of the same. Any publication arising out of the research project would include, but not be limited to, all the investigators as listed in the project proposal and Collaborator from ……., ……..

6.2 Ethical review of the research project shall be done and all rules and regulations shall be followed strictly by all parties.

6.3 The Intellectual Property and commercial activities will be dealt as per the …….

7. Ethical review of the research project shall be done and all rules and regulations shall be followed strictly by all parties including the **safety and wellbeing of the study participants** as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving human participants, 2017.

8. The governing law shall be the law applicable in India for the time being in force**.** If there is a dispute or difference on the ownership or credentials of the project, or any other aspect of the project or as to the rights and responsibilities and obligations of the parties hereto, the same shall be referred to the common Arbitrator, as agreed upon by both parties, for resolving the dispute and the decision of the said arbitrator shall be final and binding on all parties**.** The agreement of the arbitrator shall be governed under the Indian Arbitration and Conciliation Act, 1996 for the time being in force**.** The venue for such arbitration shall be Mumbai, India**.**

9. Any notice under this MOU or change of persons in charge or responsible for the projects, shall be sent to the other party in writing by either post, email, facsimile or delivered by hand. The notice to the party should be sent at the address mentioned in this MOU.

10. The MOU shall be terminated at the completion of the project. In case for some reason it is stopped or terminated prior to completion by either party, reasons for the same would have to be given in writing and approval from the Ethics Committee and any other concerned authority for the same would have to be taken. Decision on the impact of such termination on the participants would also have to be assessed and appropriate compensation would have to be paid by the party terminating the project prior to its completion.

11. The entire MOU constitutes the final and concluded agreement between the parties. It replaces all other, if any, MOUs or agreements signed for the above said project, whether in oral or in writing.

The parties have set their hands to this MOU voluntarily on the day and year first mentioned herein

Signed and executed by

Collaborator at:

Principal Investigator at:

ICMR-NIRRCH,
PAREL, MUMBAI

Dr. .....
Affiliation and Address
Date**:**

Signed for and on behalf of

Dr. ……
Affiliation and Address
ICMR-NIRRCH, Parel, Mumbai
Date**:**

Signed for and on behalf of
ICMR-NIRRCH,
PAREL, MUMBAI

Dr**.** .....
Director
Affiliation and Address
Date:
Seal:

Dr**.** ……
Director
ICMR-NIRRCH, Parel, Mumbai, 400012
Date:
Seal:

Witnesses:

1. Name and signature
2. Name and signature

ANNEX 1.14 **AF/1.14/06/V2.2**

Format for Curriculum Vitae for Investigators

ICMR-NIRRCH Ethics Committee for Human Studies

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 research during 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:

Application form for Clinical Trials

Application form for Clinical Trials
ICMR-NIRRCH Ethics Committee for Human Studies

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

i	Phase- I	☐
ii	Phase- II	☐
iii	Phase- III	☐
iv	Phase -IV or Post Marketing Surveillance	☐
v	Investigational medicinal products	☐
vi	Investigational New drug	☐
vii	Medical devices	☐
viii	New innovative procedure	☐
ix	Bioavailability/Bioequivalence studies	☐
x	Drug/device combination	☐
xi	Repurposing an existing intervention	☐
xii	Non-drug intervention	☐
xiii	Indian system of medicine (AYUSH)	☐
xiv	Others (specify) ……	

4. Trial design of the study.

i	Randomized	☐
ii	Factorial	☐
iii	Non randomized	☐
iv	Stratified	☐
v	Parallel Cross-	☐
vi	Adaptive	☐

vii Cross-over ☐
viii Comparison trial ☐
ix Cluster ☐
x Superiority trial ☐
xi Matched-pair ☐
xii Non-inferiority trial ☐
xiii Equivalence trial ☐
xiv Others (specify) ……

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

b) 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)

i Project management ☐
ii Clinical and medical monitoring ☐
iii Regulatory affairs ☐
iv Data management ☐
v Statistical support ☐
vi Medical writing ☐
vii Site management ☐
viii Audits, quality control, quality assurance ☐
ix Finance management ☐
x Recruitment and training ☐
xi Administrative support ☐
xii Others *(specify)* ……..

7. Please provide the following details about the intervention being used in the protocol.
   a. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details.
   Yes / No/ NA
   b. …….....…….
   ……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……
   …….....

c. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics……..
……..
……..

d. 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

……

……

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

……

……

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

Signature of PI with date: ……

Guide to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using a placebo, risk management, and disclosure should be considered. The following are some guides to ease the Board's 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 the 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 a placebo instead of treatment life-threatening?
   If yes, a placebo is not acceptable.
2) Is the use of placebo instead of treatment likely to lead to permanent damage?
   If yes, placebo is not acceptable
3) Is the risk of using a placebo 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 participant?
   □ Yes, consider placebo
   □ No, placebo not recommend.
2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?
   □No, consider placebo
   □ Yes, placebo not recommend.
3) Are participant 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 participant 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 participant experience severe consequences?
 Not applicable.
 Yes, consider placebo
 No, placebo not recommend.

7) Are there clearly defined stopping rules to withdraw the participant 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 recommended.

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:
 Participants are not exposed to severe or permanent harm by the use of placebo.
 Participants under placebo will benefit from the overall treatment of the disease.
 Risks of the use of placebo are minimized.

 Risks are adequately 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:
   - Participants 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 cannot be minimized.

Application Form for Human Genetics Testing Research

icmr NIRRCH INDIAN COUNCIL OF MEDICAL RESEARCH NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH	**Application Form for Human Genetic Testing Research** ICMR-NIRRCH Ethics Committee for Human Studies

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: ……

Application Form for Socio-Behavioral & Public Health Research

icmr NIRRCH	**Application Form for Socio-Behavioral & Public Health Research** ICMR-NIRRCH Ethics Committee for Human Studies

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.
    a. Focus group
    b. Questionnaire/Survey
    c. Observation
    d. Interviews
    e. Ethnographies/Oral history/Case studies
    f. Documents and records
    g. 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.
    a. Individual consent
    b. Gate-keeper consent
    c. Community consent
    d. 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 behavior 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.
   a. Invasive
   b. Potentially harmful
   c. Emotionally disturbing
   d. Involving disclosure

   ii. Describe the risk minimization strategies. ……
   ……

   iii. Justify reasons if individual harm is overriding societal benefit. Yes/ No/ NA
   ……
   ……

   iv. 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: ……

ANNEX 5 **AF/5/06/V2.2**

Application Form for Exemption from Ethical Review

	Application Form for Exemption from Ethical Review ICMR-NIRRCH Ethics Committee for Human Studies

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 behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person	
iii. Quality control and quality assurance audits in the institution.	
iv. Laboratory validation testing using anonymous or de-identified samples to assess parameters like sensitivity and specificity, etc is conducted without the intention of research or influencing patient management and does not involve novel or innovative diagnoses or technologies.	
v. Comparison among instructional techniques, curricula, or classroom management methods	
vi. Consumer acceptance studies related to taste and food quality	
vii. 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)*	
viii. Any other (please specify in 100 words): ……	

Forwarded through Director with signature & Date:

	Signature with name, date & seal
Principal Investigator	
Head of the department	
Director	

Principal Investigator should also provide one page brief write-up about their study plan:

Comments of EC Secretariat: ……
……
.....
Signature of Member Secretary with date: ……

ANNEX 5.1 **AF/5.1/06/V2.2**

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 : ……

ANNEX 6 **AF/6/06/V2.2**

Application Form for Expedited Review

icmr NIRRCH INDIAN COUNCIL OF MEDICAL RESEARCH NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH	**Application Form for Expedited Review** ICMR-NIRRCH Ethics Committee for Human Studies

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 specimens 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. Involves conducting new experiments as required by journal reviewers for the publication of closed projects, with a short duration and limited sample size.
   iv. Modification or amendment to the approved protocol (administrative changes/correction of typographical errors and change in researcher (s).
   v. Revised proposal previously approved through expedited review, full review, or continuing review of approved proposal.
   vi. Minor deviation from originally approved research causing no risk or minimal risk.
   vii. Progress/annual report where there is no additional risk, for example, activity limited to data analysis. An expedited review of SAEs/ unexpected AEs will be conducted by SAE subcommittee.
   viii. For multicenter 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.
   ix. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).
   x. Any other (please specify): ……..
   xi. ……
2. Is a waiver of consent being requested? Yes/ No
3. Does the research involve vulnerable persons *(For details, refer to the 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

Application/Notification form for Amendments

icmr NIRRCH INDIAN COUNCIL OF MEDICAL RESEARCH NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH	**Application/Notification form for Amendments** ICMR-NIRRCH Ethics Committee for Human Studies

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: a. No ..... b. 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: ……

	Continuing Review Report (CRR) format ICMR-NIRRCH Ethics Committee for Human Studies

Please mark/circle appropriate answers

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

Title of study:……

……

Principal Investigator (Name, Designation, Affiliation, Phone No. & Email ID): ……

Co-PIs/Collaborators (Name, Designation, Affiliation, Phone No. & Email ID):……..

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 to date:

Serial no.	Period for CRR _____to_____	CRR due on	CRR submitted on

5. Financial status: Self-funding/ Institutional funding/ Funding agency

   (specify):……
6. Objectives:……

   ……
7. Does the study involve recruitment of participants? Yes / No/ NA

   (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, the total number withdrawn and reasons:

……

8. Summary of the work done (preferably in 1-2 paragraphs):

……

……

9. Number on study/ follow-up: ……

10. 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:……

……

……

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

If No, skip to item no. 6 Yes / No

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

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

If yes, when / how: :…….

……

12. 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: ……..

……

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

If yes, give details: ……

……

14. (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, the 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

……

……

15. Have there been any protocol deviations/violations/ non-compliance that occurred during this period? Yes / No

If yes, number of deviations/violations/non-compliance

……..

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

……

16. In case of multi-centric trials, have reports of off-site SAEs been submitted to the EC ? Yes / No / NA

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

……

……

18. Attach a copy of approvals from collaborating centers/ MoU/ MTA/ Agreement copy.

……

19. Any other comments: ……..

Signature of PI with date : ……

ANNEX 9 **AF/9/06/V2.2**

Request for Extension of the Approved Study

	**Request for Extension of the Approved Study** ICMR-NIRRCH Ethics Committee for Human Studies

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/ Financial 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:

Duration required for extension:

Signature of P.I.: Date:

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

Study Completion/Final report format

	Study Completion/Final report format ICMR-NIRRCH Ethics Committee for Human Studies

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:

Details of study site(s):	
Total number of study participants as each site approved by the EC for recruitment	
Total number of study participants recruited	
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: ……

Premature Termination/ Suspension/ Discontinuation Report Format

icmr NIRRCH	Premature Termination/ Suspension/ Discontinuation Report Format ICMR-NIRRCH Ethics Committee for Human Studies

Project No. …… Duration of the Project: ……
Title of study:……
……
Principal Investigator (Name, Designation and Affiliation): ……..
Co-PIs/Collaborators (Name, Designation and Affiliation): ……..
……..

1. Date of EC approval: …… Date of start of study: ……
2. Date of last progress report submitted to EC:……
3. Date of termination/suspension/discontinuation:…… ……..
4. Sponsor's/Funding Agencies Name, Address, Phone No., e-mail details:……
   ……
5. Study site(s):…… No. of Participants as each site:……
6. Study Design & Sample Size:……
7. Objectives:……
8. Methodology:……
9. No. of Study Arms (If any):……

   Number of participants in each of the Study Arms:……
10. Study dose(s)…… ……..
11. Tick the appropriate: Premature Termination/ Suspension / Discontinuation
    a. Reason for Termination/Suspension/Discontinuation: ……
       ……
    b. Change in risk benefit ratio:……
    c. Action taken post Termination/ Suspension/Discontinuation (if any):
       ……
       ……
       ……
12. Plans for post study follow up/withdrawal (if any):……
    ……
13. Details of study participants:

a. Total participants to be recruited: ……..……

b. Screened: ……..…..

c. Screen failures:……..……

d. Enrolled:……..……..……

e. Consent Withdrawn:……..……

f. Reason (Give details): ……..…… ……..……..……

g. Withdrawn by PI:……..……..……..

h. Reason(Give details): ……

i. Active on treatment: ……..……

j. Completed treatment : ……..…..

k. Participants on follow-up: ……..……

l. Participants lost to follow up: ……..

m. Any other: ……..…..

n. Number of drop outs:……..……..

o. Reasons for each drop-out:……

14. Total number of SAEs reported till date in the study: ……..……

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes/ No

15. Have there been participant complaints or feedback about the study? Yes/ No

If yes, provide details:……

16. Have there been any suggestions from the SAE Sub Committee? Yes/ No

If yes, have you implemented that suggestion? Yes/ No

Risk benefit ratio:……

Whether the study samples are being retained for future use:……

17. Outcome & Implications of the study:……

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

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

……..

19. Summary of results (if any): ……

20. Publications (If any):……

21. Presentations (If any):……

Signature of PI with date : ……

Information on what to expect after Protocol Submission

The IEC is currently following the version 7; dated 8th November 2024 of the Standard Operating Procedures (SOPs), which are individual activity-based and are 27 in number.

The SOPs are available on the institutional LAN and the institute website.

The templates and forms are available on the Institute LAN for submission to the Ethics Committee

I. Prior to approval of a research study

1. PIs are requested to submit projects at least one month before the IEC meeting date.
2. The Secretariat will ensure the completeness of the proposal submitted by the PI to EC.
3. Primary reviewers will be assigned and the secretariat will send copies at least three weeks in advance of the full board meeting to the assigned primary reviewers and EC members with a request to reviewers to provide feedback within two weeks of the receipt of the projects
4. In case the review highlights major concerns, the compiled comments will be shared in advance ahead of the full board meeting with the principal investigator of the project, at the discretion of the member secretary/joint member secretary, to enable him/her to prepare responses ahead of the discussion of the project during the full board meeting.
5. In case of the above scenario, the PIs of new projects (version 1), revised and re-submitted projects (Version 2) for which major concerns are indicated during the review, will be requested to make a brief presentation of the projects followed by a provision for of responses/clarifications to the comments of the reviewers. Comments, suggestions for which PI needs to provide additional information, clarification, make changes in the protocol and participant information sheet should be documented and included in the minutes.
6. In order to facilitate timely review of projects, preparation of minutes etc., for new projects, at least one IEC-affiliated member, including the member secretary and joined member secretary (if member secretary has a conflict of interest), will review the submissions. The affiliated reviewing member will compile and finalize comments with the assistance of IEC secretariat staff, adhering to the established review timelines.
7. After the full board, the minutes will be given within 15 days.
8. The revised version of projects, whether to be reviewed by circulation among reviewers or presented at the full board meeting, should be submitted by the PIs within two weeks of receiving the minutes and no later than 60 days. Investigators are expected to respond to the IEC's letter of recommendation or queries within 60 days of receiving the letter, using the template provided below.

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

9. Revised projects received after 60 days can be considered and submitted for full board review even if they have been initially permitted to be reviewed by circulation following full board review. In the absence of any response, the project will be declared closed by the IEC office and filed in the archives for the specified period for completed projects.

10. To ensure timely review of revised projects, reviewers are requested to submit their comments or suggestions within two weeks of receiving the projects via email. **The IEC secretariat's email should specify that if no comments are received within this timeframe, it will be assumed that the reviewers are satisfied with the revised project and the responses to their previous comments.**

II. Once approval for a study is granted

1. Approval will be granted for usually a one-year study period.

2. It is the responsibility of the principal investigator for studies that 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 months from the date of approval). For example, for a study that was approved on 1st January 2019, the application for continuation of ethical approval (along with the Status report) should be received in the office of the IEC on or before 31st October 2019. If the application is received by this due date, the study can be continued unless a communication from the Ethics Committee 'not approving the continuation' is received. If the application is not submitted on or before the due date, the PI will be required to stop the study on or before 31st December 2019, unless a written communication informing about the continuation of ethical approval is obtained on or before 31st December 2019.

3. Study-related documents (protocol amendments, SAE reports, continuing review reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above-stated study-related documents needs to be submitted for the IEC review as per the format.

   No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants.

A cover letter should be submitted and the template for it is available on the LAN.

III. Once a study is over

Submission of Study Completion Report

1. For studies that are completed within the IEC approval period, a study completion report as per the format should be submitted to the IEC, by the investigator.

2. 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 centers 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.

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ANNEX 13 **AF/13/06/V2.2**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	20th March 2013	First approved Copy
Dr. Ragini Kulkarni	Version 1.1	3rd June 2013	Inclusion of the sentences: " I give/ do not give permission to preserve my samples to be used for any extension or modification of this study that may be decided in the future with the appropriate permission of the Ethics Committee" in Informed Consent Form
Dr. Ragini Kulkarni	Version 1.2	24th September 2014	• Removed bullet 5.2 - Invite internal members to review the project on page no.4 • Minor correction in bullet 5.3, 5.4, 5.5 and 5.6 from page 4 to page 6 • Inclusion of the following Annexures : Annex 7: Assent form template, page no.21 Annex 9 : Guidance of Protocol Submission, page no.25 Annex 10 : Approval letter, page no.27
Dr. Ragini Kulkarni	Version 1.3	12th January 2015	Inclusion in the face sheet "Duration of the study" and addition of the sentence in Informed Consent form "I am informed that I will be/will not be given any compensation/reimbursement for participation in the study."
Dr. Ragini Kulkarni	Version 1.4	15th April 2015	Addition of the sentence in the approval letter "Due date for submission of Continuing review/Completion Report: …" and addition of the point in Enclosure list "GCP Training Certificate of Principal Investigator/Co-Investigators/Collaborators". Changes in the name of the members of the Ethics Committee in Approval letter
Dr. Ragini Kulkarni	Version 1.5	4th March 2016	Addition of the words 'wherever relevant' after the words 'Legal Authorised Representative' in Informed Consent Form Insertion of Annex 7: Informed Consent form for future use of stores samples on page 21
Dr. Ragini Kulkarni	Version 1.6	24th September 2016	Pg.6, Time for responding to comments changed to '90 days' instead of '180 days' Pg.20,21- deletion of the word 'Collaborator' from Informed Consent Form.
Dr. Ragini Kulkarni	Version 1.7	7th November 2017	Extensive revision of the SOP has been done as per SIDCER/FERCAP recommendations and the ICMR guidelines 2017.

Dr. Beena Joshi	Version 2.0	1st May 2019	Revision of the SOP has been done as per the ICMR guidelines 2017 & ICMR common forms for Ethical Review 2018
Dr. Beena Joshi	Version 2.1	26th February 2021	Inclusion of study title in the informed consent for future storage form (Annex 1.7)
Dr. Vikrant Bhor	Version 2.2	8th November 2024	All bullets are numbered. ● Changes in initial review form Section 'A' regarding exemption from review and expedited review as per ICMR guidelines ● Initial review form Q.No.2(b) details about the proposal submitted to the funding agency and the approval date ● Assent form is changed from 12to 18 years to 12 to below 18 years (Annexure 1.8) ● Written assent for 12 to 18 years question about benefits of the study is added ● Oral assent format added for children between 7 to 12 yearsAssent form (Annexure 1.9) Parent/LAR signature is added ● Parental/LAR Consent form (Annexure 1.10) Name of child is added ● Form for future use of research data is added Annexure 12 The time for responding to comments changed to '60 days' instead of '90 days The timelines subject to submission and review have been modified. The review process has been modified PI is allowed to give a brief presentation with clarification to EC comments