Covering letter to submit the proposal to ICMR-NIRRCH Ethics Committee for Human Studies:

Date:

Chairperson
ICMR-NIRRCH Ethics Committee for Human Studies
Parel, Mumbai.

Subject: Submission of project proposal entitled, "…….

……..", Version……., Dated …….for Ethical Approval.

Respected Madam,

The details of the project to be put forth for the Ethics Committee meeting to be held on …….. are as follows:

1. Title: ……

……..

2. Name of the PIs:

3. Reason for submission to the Ethics committee (Please tick the appropriate)

a. New Proposal

b. Amendment:

i) Change in the Title

ii) Change in the Collaborators

iii) Change in the Sample size

iv) Any other, please specify

c. Revision as advised by the Ethics Committee

4. Extramural finding obtained:

5. Name of the funding agency:

6. SAC/ SRC approval:

Thanking you,

Yours sincerely,

Principal Investigator

Title, version no., date, PI

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) • Form for Exemption from Ethical Review & Undertaking by Principal Investigator • Form for Expedited Review • Form for Human Genetics Testing Research • Form for Socio-Behavioural & Public Health Research • Form for Amendment • Form for Clinical Trials with Guide to Placebo Justification					
3	Approval of SAC/ SRC/ IRCT/ Any other					
4*	EC clearance of other centers					
5*	Agreement between collaborating partners					
6*	Material Transfer Agreement (**MTA**) between collaborating partners					
7	Insurance policy/ certificate					
8	Copy of contract or agreement (Memorandum of Understanding-**MoU**) 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	NAC-SCRT					
23	ICSCR					
24	RCGM					
25	GEAC					
26	BARC					
27	Tribal Board					
28	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**Not Applicable**	**Enclosure No./ Page No.**	**EC Remarks**
29						
30						

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

1. List of other permissions that might be essential for your project proposal
    - ***CTRI-Clinical Trial Registry-India***
    - ***DCGI-Drug Controller General of India***
    - ***HMSC- Health Ministry's Screening Committee***
    - ***NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy***
    - ***IC-SCR-Institutional committee for Stem Cell Research***
    - ***RCGM- Review Committee on Genetic Manipulation***
    - ***GEAC- Genetic Engineering Approval Committee***
    - ***BARC- Bhabha Atomic Research Centre***
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 recent ICMR guidelines before filling the form.

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/yyyy format	• **Project No.:** • **Date of Receipt:** • **Status: New/ Revision/ Amendment** • **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; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
Expedited Review	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters
Full Board Review	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk ; • studies involving deception of participants; • research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

(g) Title of the study: ……..……..……

……Version……, date…….....

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

a. Protocol number (By Ethics Secretariat):

b. Version number:

(i) Details of Investigators:

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

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

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission: ……

Please provide the status of currently approved studies:

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

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

(k) Duration of the study: ……

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

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

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

No.	Name of the collaborating	Names of the individuals	Designation and	Role in the study	Whether collaborating

	institution	collaborating	Qualifications		institution's EC's approval will be required, Name of the EC

2. FUNDING DETAILS AND BUDGET:

(a) Total estimated budget for site: ……

(b) Self-funding ☐ Institutional funding ☐

Funding agency*(specify*) ☐ …….

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

Forwarded through HOD & 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 sample	☐
Mixed Method	☐	Epidemiological/Public Health	☐

Any other (*Specify)* ☐……

4. OBJECTIVES:

- ……
- ……
- ……
- ……

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

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

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

(b) Is there an external laboratory/outsourcing involved for investigations? (Tick appropriate)

(If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/MoU.) Yes/ No/Not Applicable

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

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

Date of review .....

Comments of scientific committee, if any (100 words)

(Report to be attached) ……

SECTION C : PARTICIPANT RELATED INFORMATION

6. RECRUITMENT AND RESEARCH PARTICIPANTS.

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐

Vulnerable persons/ Special groups ☐

Others (specify) ☐ .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/leaflets/Letters ☐ TV/Radio ads/Social media/Institution website ☐

Telephone ☐ Others (Specify) ☐.....

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

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

Pregnant or lactating women	☐	Children between 0-7 yrs.	☐
Children between 7- 12 yrs.	☐	Children between 12-18 yrs.	☐
Differently abled (Mental/Physical)	☐	Elderly	☐
Refugees/Migrants/Homeless	☐	Institutionalized	☐
Economically and socially disadvantaged	☐		
Terminally ill (stigmatized or rare diseases)	☐		
Employees/Student/Nurses/Staff	☐		
Any other (Specify)	☐.....		

iii. Provide justification for inclusion/exclusion.....

.....

iv. Are there any additional safeguards to protect research participants?
(Principal Investigator should explain about the Special precautions considered for safeguarding the Vulnerable Participants)

.....

.....

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

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

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

.....

……

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution? Yes / No

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

.....

7. BENEFITS AND RISKS

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

If yes, categorize the level of risk:

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

Criteria for risk assessment

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

	diagnostic procedures

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

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

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

.....

.....

.....

(c) Are adverse events expected in the study? Yes/ No/ NA
(Include both serious and non-serious adverse events)

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

If yes, Specify.....

.....

.....

8. INFORMED CONSENT

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

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

(b) Type of consent planned for:

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

Witnessed consent ☐ Audio-Video (AV) Consent ☐

Consent from LAR (If so, specify from whom) ☐

For children<7 yrs. Parental/LAR consent ☐

Verbal assent from minor (7-12 yrs.) along with parental consent ☐
Assent from minor (age >12-<18 years along with parental consent ☐

Other (Specify) ☐:.....

(c) Who will obtain the informed consent?

PI/Co-PI ☐ Nurse/Counsellor ☐
Research Staff ☐ Other (Specify) ☐.....
Any tools to be used while obtaining consent: .....

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

English ☐ Local language ☐
Other (specify) ☐ .....
List the languages in which translations were done / will be done.....
If translation has not been done, please justify .....

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

.....

.....

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

.....

.....

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

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

medical care in case of a study- related injury		study-related injury			

Other (Specify) .....

9. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?
(Enclose undertaking from PI confirming the same)
Principal Investigator ☐ Institution ☐ Sponsor ☐
Other agencies☐(specify)…….....

(b) Is there a provision for free treatment of research related injuries? Yes / No
If yes, then who will provide the treatment? ……

(c) Is there a provision for compensation of research related SAE? Yes / No
If yes, specify
Sponsor ☐ Institutional/Corpus fund ☐
Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes / No
If yes, specify.....…….

10. STORAGE AND CONFIDENTIALITY

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

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐
Irreversibly coded ☐ Identifiable ☐

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

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

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

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

(e) Do you propose to use stored samples/data in future studies? Yes / No/ Maybe
If yes, explain how you might use stored material/data in the future?.....

…….

SECTION D: OTHER ISSUES

11. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

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

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished. Yes/No/Not Applicable
If yes describe in brief (Max 50 words) ……
……

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

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

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

SECTION E: DECLARATION/UNDERTAKING

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.	

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: ……