INSTITUTIONAL ETHICS COMMITTEE

BASE HOSPITAL & ARMY COLLEGE OF MEDICAL SCIENCES
DELHI CANTT

APPLICATION FOR REVIEW OF RESEARCH PROPOSAL

File No: Date:

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
b) Attach additional sheets if required

1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

(b) Name of the Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of Submission: Click here to enter a date.

(f) Type of review requested[1]:

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(g) Title of the study:

Acronym/ Short title, (If any):

(h) Protocol number(If any): Version number:

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

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

(k) Duration of the study:

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site:

At site In India Globally

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

[2] *Include telephone/mobile, fax numbers and email id*

(b) Self-funding ☐ Institutional funding ☐ Funding agency ☐
(Specify)

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study[3] (within 300 words)

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐			Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

4. METHODOLOGY

(a) Sample size/ No. of Participants (*as applicable)*

At site In India Globally

Control group Study Group

Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for saturation

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

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

Independent external review	☐	Review by Sponsor/Funder	☐	Review within PI's institution	☐
Review within multi-centre research group	☐	No Review	☐		

Date of review: Click here to enter a date.

Comments of Scientific Committee, if any(100 words)

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

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

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

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable person/ Special groups ☐ Others *(Specify)* ☐

Who will do the recruitment?

Participant recruitment methods used:

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

Others*(Specify)* ☐

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

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

Children under 18 yrs ☐ Pregnant or lactating women ☐

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

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally Ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐

iii. Provide justification for inclusion/exclusion

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

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

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

If yes, Monetary ☐ Non-monetary ☐ Provide details

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

If yes, Monetary ☐ Non-monetary ☐ Provide details Yes ☐ No ☐

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

Yes ☐ No ☐

If yes, categorize the level of risk[5]:

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or Low Risk ☐ More than Minimal Risk or High Risk ☐

ii. Describe the risk management strategy:

(b) What are the potential benefits from the study?	Yes	No	If yes, Direct	Indirect
For the participant	☐	☐	☐	☐
For the society/community	☐	☐	☐	☐
For improvement in science	☐	☐	☐	☐

Please describe how the benefits justify the risks

(c) Are Adverse Events expected in the study[6]? Yes ☐ No ☐ NA ☐

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

If Yes, Specify

7. INFORMED CONSENT

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

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

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

(c) Type of consent planned for :

Signed consent ☐	Verbal/ oral consent ☐	Witnessed consent ☐	Audio-Video (A/V) 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 ☐	Written Assent from Minor (13-18 yrs) along with parental consent ☐

Other *(specify)* ☐

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other*(Specify)* ☐

Any tools to be used

(e) Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ other ☐ (*specify*)

List the languages in which translations were done

If translation has not been done, please justify

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1*

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

(f) Provide details of Consent requirement for previously stored samples if used in the study[7]

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

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact	Statement that consent is voluntary
Alternatives to participation ☐	Confidentiality ☐	Commercialization/benefit sharing ☐
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	return of research results ☐	Use of photographs/ identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐

Others*(Specify)* ☐

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8]?

PI ☐ Institution ☐ Sponsor ☐ Other agencies*(specify)* ☐

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

If yes, then who will provide the treatment?

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ NA ☐

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ Insurance ☐

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

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[7]*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017,Page 54 in Section 5.8*

.[8]*Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐

Anonymous/unidentified ☐ Anonymized: reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

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

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

(c) Where will the data be analyzed[9] and by whom?

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

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

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

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

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief *(Max 50 words)* Yes ☐ No ☐ NA ☐

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

(e) Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details
Yes ☐ No ☐ NA ☐

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

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

SECTION E: DECLARATION AND CHECKLIST[0]

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	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 including responsible.
☐	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.

☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	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.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: Signature: Click here to enter a date.

Name of Co-PI: Signature: Click here to enter a date.

Name of Guide: Signature: Click here to enter a date.

Name of HOD: Signature: Click here to enter a date.

12. CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No.	EC Remarks(If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		

4.	Approval of Scientific Committee	☐	☐	☐		
5.	EC clearance of other centers*	☐	☐	☐		
6.	Agreement between collaborating partners*	☐	☐	☐		
7.	MTA between collaborating partners*	☐	☐	☐		
8.	Insurance policy/certificate	☐	☐	☐		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12.	Copy of the detailed protocol[11]	☐	☐	☐		
13.	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
18.	CTRI	☐	☐	☐	Enter date	
19.	DCGI	☐	☐	☐	Enter date	
20.	HMSC	☐	☐	☐	Enter date	
21.	NAC-SCRT	☐	☐	☐	Enter date	
22.	ICSCR	☐	☐	☐	Enter date	
23.	RCGM	☐	☐	☐	Enter date	
24.	GEAC	☐	☐	☐	Enter date	

25.	BARC	☐	☐	☐	Enter date	
26.	Tribal Board	☐	☐	☐	Enter date	
27.	Others (Specify)	☐	☐	☐	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.		☐	☐	☐		
29.		☐	☐	☐		

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

***For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India;HMSC-Health Ministry's Screening Committee;NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy;IC-SCR-Institutional committee for Stem Cell Research;RCGM- Review Committee on Genetic Manipulation;GEAC- Genetic Engineering Approval Committee;BARC-Bhabha Atomic Research Centre*

[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 page no. 35Box 4.4(b)

CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS

Title Page

(a) Full title of the clinical study,

(b) Protocol, Study number, and protocol version number, if any, with date.

(c) The Investigational New Drug (IND) name/number of the investigational drug.

(d) Complete name and address of the Sponsor and contract research organization if any.

(e) List of the investigators who are conducting the study, their respective institutional

affiliations and site locations

(f) Name of clinical laboratories and other departments and/or facilities participating in the study.

Table of Contents

1. Background and introduction

(a) Preclinical experience

(b) Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

2. Study rationale: This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.

3. Study objective (primary as well as secondary) and their logical relation to the study design.

4. Study design–

(a) Overview of the study design: Including a description of the type of study (i.e., double-blind, multicentre, placebo controlled, etc.), a detail of the specific treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

(b) Flow chart of the study

(c) A brief description of the methods and procedures to be used during the study.

(d) Discussion of study design: This discussion details the rationale for the design chosen for this study.

5. Study population: the number of subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the subject population required is also mentioned.

6. Subject eligibility

(a) Inclusion criteria

(b) Exclusion criteria

7. Study assessments – plan, procedures and methods to be described in detail.

8. Study conduct stating the types of study activities that would be included in this section would be: Medical history, type of physical examination, blood/ urine testing, electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.

Each visit should be described separately as Visit 1, Visit 2, etc.

Discontinued subjects*:* Describes the circumstances for Subject withdrawal, dropouts, or other reasons for discontinuation of Subjects. State how drop outs would be managed and if they would be replaced describe the method of handling of protocol waivers, if any. The person who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

Describe how protocol violations will be treated, including conditions where the study will be terminated for noncompliance with the protocol.

9. Study treatment-

(a) Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s),their doses, frequency, and duration of concomitant treatment should be stated.

(b) Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.

(c) Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.

(d) Possible drug interactions

(e) Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a Subject is not allowed to use during parts of or the entire study.

If any washout periods for prohibited medications are needed prior to enrolment, these should be described here.

(f) Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject

(g) Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given

10. Adverse Events:

Description of expected adverse events should be given.

Procedures used to evaluate an adverse event should be described.

11. Ethical considerations: Give the summary of:

(a) Risk/benefit assessment:

(b) Ethics committee review and communications

(c) Informed consent process

(d) Statement of subject confidentiality including ownership of data and coding procedures.

12. Study monitoring and supervision:

A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specific required in filling out the forms Case Record Form correction requirements, including who is authorized to make corrections on the Case Record Form and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

13. Investigational Product Management:

(a) Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study)

(b) The precise dosing required during the study

(c) Method of packaging, labelling, and blinding of study substances

(d) Method of assigning treatments to subjects and the subject identification code numbering system

(e) Storage conditions for study substances

(f) Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed,and returned or destroyed.

(g) Describe policy and procedure for handling unused investigational products.

14. Data Analysis: Provide details of the statistical approach to be followed including **sample size**, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.

Statistical analysis*:* Give complete details of how the results will be analysed and reported along with the description of statistical tests to be used to analyse the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and Subject withdrawals ; rationale and conditions for any interim analysis if planned.

Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

15. Undertaking by the Investigator

16. Appendices: Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.); Case Record Form (CRF) and other data collection forms; a summary of relevant preclinical safety information and any other documents referenced in the clinical protocol.

Part 'A' : PARTICIPANT INFORMATION SHEET (PIS)

Ttile of the study:

_____
_____
_____
_____

1. The following points are mentioned for your (participant's) information and consideration before joining the study:-

(i) It is intimated that this study involves research. The purpose of the study is :

(ii) Expected duration of the participation of subject & Number of participants:

(iii) Description of the procedures to be followed, including all invasive procedures and investigations to be carried out:

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject:

(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this:

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject:

(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records:

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials):

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death (State so if no provision for financial compensation. Compensation is a must for drug trials):

(x) Whom to contact for trial related queries, rights of Subjects and in the event of any injury: (Give name, designation, complete address, mobile number, landline number, fax, email id etc of PI)_____

(xi) The anticipated prorated payment, if any, to the subject for participating in the trial:

(xii) Responsibilities of subject on participation in the trial:

(xiii) It is intimated that your participation is voluntary, you can withdraw from the study at any time and refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled.

(xiv) It is intimated that there is a possibility of failure of investigational product to provide intended therapeutic effect:

(xv) It is intimated that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(xvi) Any other pertinent information:

2. **Additional elements, which may be required:-**

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent:

(b) Additional costs to the subject that may result from participation in the study:

(c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject:

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided:

(e) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable:

(f) Approximate number of Subjects enrolled in the study:

(g) Any alternative procedure or courses of treatment that might be advantageous to the participant as the once to which she/he is going to be subjected:

(h) If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pretest-and post-test counseling:

(j) Insurance coverage if any, for research-related or other adverse events:

(k) Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research. Other specifics are as follows:

(i) Period of storage of the sample/data and probability of the material being used for secondary purpose:

(ii) Whether material is to be shared with others, this should be clearly mentioned:

(iii) Right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research:

(iv) Risk of discovery of biologically sensitive information and provisions to safeguard confidentiality:

(v) Post research plan/benefit sharing, if research on biological material and /or data leads to commercialization:

(l) Responsibility of investigators (esp in occurrence of SAE):

(m) Publication plan, if any, including photographs and pedigree charts:

(Name and sign of PI)

Date:

Part B: Format of informed consent for Subjects participating in a clinical trial / Biomedical research

Study Title:

Study Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject ___

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate).

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death):

(Put tick mark in the given bracket [ ])

(i) I confirm that I have read and understood the information Sheet (PIS) dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

_____

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject/ his or her attendant

INSTITUTIONAL ETHICS COMMITTEE

BASE HOSPITAL & ARMY COLLEGE OF MEDICAL SCIENCES
DELHI CANTT

File No: Date:

Curriculum Vitae of Investigator

Name:	
Present affiliation*(Job title, department, and organisation)***:**	
Address*(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Professional registration *(Name of body, registration number and date of registration)***:**	
Previous and other affiliations*(Include previous affiliations in the last 5 years and other current affiliations)***:**	
Projects undertaken in the last 5 years:	

Relevant research training/experience in the area[25]:

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

Signature	**Date:** Click here to enter a date.

[25]*Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator):

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

2(b) Education , training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications):

3. Name and address of all clinical laboratory facilities to be used in the study:

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study:

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations:

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator:

7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with date.