Institutional Human Ethical Clearance

COVER SHEET

(for attachment to each copy of the protocol form)

Serial No of IHEC
Management Office:

Proposal Title:

	Name, Designation & Qualifications	***Address Tel & Fax Nos. Email ID***	***Signature***
PI		Department of	
Collaborators	***1.*** ***2.*** ***3.***	***Official Address of collaborators with FAX and email address***	***Signature of collaborator***

Funding Source: …….

1.Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐ Clinical: Single center ☐ Multicentric Behavioral ☐		
2. Status of Review: New ☐ Revised ☐		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :** **i.** Does the study involve use of : Drug ☐ Devices ☐ Vaccines ☐ Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐		
ii. Is it approved and marketed In India ☐ UK & Europe ☐ USA ☐ Other countries, specify		
iii. Does it involve a change in use, dosage, route of administration? **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission :	NO	
iv. Is it an Investigational New Drug? **If yes,** IND No:	NA	
a). Investigator's Brochure submitted	NA	
b). *In vitro* studies data	NA	
c). Preclinical Studies done	NA	
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	NA	
4. Subject selection:		
i. Number of Subjects :		
ii. Duration of study : Years months		
iii. Will subjects from both sexes be recruited	YES	NO
iv. Inclusion / exclusion criteria given	YES	NO
v. Type of subjects Volunteers ☐ Patients		
vi. Vulnerable subjects NONE ☐ ☐ (Tick the appropriate boxes) pregnant women ☐ children ☐ elderly ☐ fetus ☐ illiterate ☐ handicapped ☐ terminally ill ☐ seriously ill ☐ mentally challenged ☐ economically & socially backward ☐ any other ☐		

vii. Special group subjects ☐ ☐ (Tick the appropriate boxes) captives ☐ institutionalized ☐ employees ☐ students ☐ nurses/dependent ☐ armed ☐ any other staff forces		
5. Privacy and confidentiality i. Study involves - Direct Identifiers Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐		
ii. Confidential handling of data by staff	YES	NO
6. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	YES	NO
ii. Use of organs or body fluids	YES	NO
iii. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	YES	NO
iv. Use of pre-existing/stored/left over samples	YES	NO
v. Collection for banking/future research	YES	NO
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?		
vii. Use of Infectious/biohazardous specimens	YES	NO
viii. Proper disposal of material	YES	NO
ix. Will any sample collected from the patients be sent abroad ? **If Yes, justify with details of collaborators**	YES	NO
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	YES	NO

b) Sample will be sent abroad because (Tick appropriate box): NA

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

7. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

8. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)		
9. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?		
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐		
Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
10. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?		
ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐		
iii. Is there a plan for interim analysis of data?		
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?		

11. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:		
12. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐		
13. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**		

Checklist for attached documents:

Protocol form	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

Detailed information of Project

INTRODUCTION

SUMMARY

OBJECTIVES

METHODS

TIME PLAN

Any other information ;

Selection of Samples

Inclusion Criteria: a)

b) Ready to give written consent to be part of the study

Sample number:

Exclusion Criteria:

Annexure 1

PARTICIPANT INFORMATION SHEET (PIS)

Principal Investigator:
Telephone number:
Title of the Study/Project summary/statement describing the aim of study which you will describe to the subject/patient :

You have been invited to take part in a study, which will be helpful in establishing the cause of ……

If you agree to participate, the expected duration of your stay in laboratory will be about …….

Prerequisite for the test ……

All the techniques to be used in the study are non-invasive and safe.

The records of the study will be kept confidential to protect your privacy.

No discomfort or injury is expected at any point of study.

You will be free to withdraw from the study at any stage

Researchers will bear all the costs of the tests.

Your signature on the consent form means that you understand the information given to you about the study. If you sign the form it means that you agree to join the study. You will be provided a copy of this information sheet to keep with records.

For any further information please contact the following:
Name of the investigators with working contact numbers

Annexure 2

PATIENT CONSENT FORM

I have been explained the details of the research study entitled **…….** in my own language. I have read the patient information sheet carefully and all my queries regarding the study have been answered. I hereby agree, of my own will, to participate in this study.

Date:

Patient's signature: _____

Patient's name
and address : _____

Witness's signature:_____

Witness's name
and address: _____

Investigator's signature:_____

Investigator's name
and address _____