Indian Institute of Technology - Kanpur
Institutional Ethics Committee (IEC)
Application for approval by the IEC

Title of the proposal:

	Name & Designation	**Address, Telephone, Email ID**	**Signature**
PI/Student			
Co-PI / Collaborators /Thesis supervisor 1.			
2.			
3.			
4.			
5.			
6.			

- Applications that involve clinical investigations should have clinical collaborators.
- Proposal involving clinical investigations should be cleared first by the ethics committee of the participating medical centre, and a copy of the approval letter should be submitted.
- Each collaborator/Co-PI should either sign this application on the first page or provide a signed consent letter on the letterhead expressing willingness to participate in the study.
- A sample questionnaire should be submitted along with the application if the proposal involves survey.
- A sample form for the "informed consent" should be submitted (in English and its translation in the local language as applicable).
- Declaration at the end of the application, in addition to the first page, must be signed by the PI.
- Full application, including the Annexure and enclosures, must be submitted as a single PDF file by email to the Member Secretary, IEC.

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Cover page

All sections should be "ticked" [✔] appropriately. No field should be left empty (write "NA" if a field is not applicable).

Sponsor Information :			
1. Indian	a) Government:	Central [ ] State [ ]	Institutional [ ]
	b) Private [ ]		
2. International	Government [ ]	Private [ ]	UN agencies [ ]
3. Industry	National [ ]	Multinational [ ]	
Contact Address of Sponsor:			
Total Budget :			

1.Type of Study :	Epidemiological [ ]	Basic Sciences[ ]	Animal studies [ ]
Clinical:	Single center [ ]	Multicentric [ ]	Behavioral [ ]
2. Status of Review:	New [ ]		Revised [ ]
If revised, please mention the previously allotted IEC serial number:			
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?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		

a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
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	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (See Annexure - I):

5. Subject selection:

i. Number of Subjects (*a specific upper limit must be mentioned*):

ii. Duration of study (*a specific upper limit in months must be mentioned*):
The actual duration should not exceed the duration specified here.

iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion and exclusion criteria given	Yes	No

v. Type of subjects Volunteers [ ] Patients [ ]

vi. Vulnerable subjects Yes [ ] No [ ]
(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 Yes [ ] No [ ]
(Tick the appropriate boxes)

captives [ ]	institutionalized [ ]	employees [ ]
students [ ]	nurses/dependent [ ]	armed forces [ ]
any other [ ]	staff [ ]	

6. Privacy and confidentiality

i. Study involves - Direct Identifiers [ ]
Indirect Identifiers/coded [ ]
Completely anonymised/ delinked [ ]

ii.	Confidential handling of data by staff	Yes	No

7. 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 Yes	No No
iv. Use of pre-existing/stored/leftover samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
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): Facility not available in India [ ] Facility in India inaccessible [ ] Facility available but not being accessed. [ ] If so, reasons…		

8. 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 [ ]
Benefits if any on future commercialization eg. genetic basis for drug development [ ]	

*If written consent is not obtained, give reasons:

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

9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk lower than the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk [ ] More than minimum risk [ ] High risk [ ]	Yes	No
Iii.Is there a benefit a) to the subject? Direct [ ] Indirect [ ] b) Benefit to society [ ]		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor [ ] Ethics Committee [ ] DSMB [ ]	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary [ ] In kind [ ] Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor [ ] by Investigator [ ] by insurance [ ] by any other [ ] company	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

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Checklist for attached documents:

[ ] Project proposal
[ ] Curriculum Vitae of Investigators
[ ] Brief description of proposal
[ ] 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 Ethics Committee clearance
[ ] Institutional Animal Ethics Committee clearance
[ ] CPCSEA clearance, if any
[ ] HMSC/DCGI/DBT/BARC clearance if obtained

Declaration: I confirm that the information provided above is correct to the best of my knowledge.

Place: **Signature & Designation of the applicant**
Date:

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Annexure - I
INSTITUTE HUMAN ETHICS COMMITTEE PROTOCOL FORM

1. **General Information:**
   Principal Investigator:
   Title:

2. **Abstract:** It must be written in non-technical language for the lay reader and address, as appropriate, the following points:
   - A brief description of the background and/or scientific context of the study.
   - The hypotheses being tested.
   - A brief description of the experimental design, how the study will be conducted, and human subject involvement and duration.
   - Anticipated results.

3. **Purpose, Methods and Procedures:** Describe in detail the purpose, research methods and procedures of the study.

4. **Details of Drug and/or Therapy:** Describe in detail the safety of proposed intervention and any drug or vaccine to be tested, including results of relevant animal and human research conducted. A description of plans for withdrawal of drugs or any therapies in the course of research. For research involving more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to overdosage should be included.

5. **Subject Selection:** Indicate how many subjects will be included in the study, how they will be recruited, from where recruited, and when. When vulnerable populations are involved, describe why they are necessary. Must provide **inclusion criteria** and **exclusion criteria** for potential subjects. Also provide justification for the exclusion of any groups on the basis of age, sex, ethnicity, social or economic or any other factors.

6. **Risks:** Describe any potential physical, psychological, social or legal risks to subjects. Assess the likelihood and seriousness of those risks. If the methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

7. **Benefits:** Describe the anticipated benefits of the research to the individual subjects, to the particular group or class from which the subject population is drawn. If there is no direct benefit to the subject, state so. Describe what, if any, societal/scientific benefits can be expected from the study.

8. **Risk-Benefit Ratio:** Assess the relative weights of the study's risks and benefits.

9. **Compensation or Costs to Subjects**: If the investigation involves the possibility of added expense to the subject or to a third party, such as an insurer (e.g., longer hospitalization, extra laboratory tests, travel) indicate how this is justified. If there is compensation for unpleasant or risky procedures, provide details of that compensation. For research carrying more than minimal risk, provide information regarding what, if any, medical treatment, or compensation will be available to the subject if s/he is injured as a result of participating this study.

10. **Disclosure of Personal and Financial Interest in the Research Study and/or Sponsor:** The investigator must disclose any personal and financial interests in the research as well as the extent of personal and financial interest in the sponsor.

11. **Obtaining Informed Consent:** Describe the setting in which the consent process will take place. Include a complete list of individuals (include title) who will obtain written informed consent. Any person designated to obtain consent must be fully knowledgeable of all details of the protocol and be able to answer any questions from subjects, such as risks or alternative treatments and therapies. Whenever the study involves persons below 18 years of age, the informed consent should be signed by their parents/guardians. If the investigator is requesting a waiver from obtaining informed consent, or any of the required elements of informed consent, justification must be provided.

12. **Research Personnel:** Include a complete list of all key research personnel involved in the conduct of this study.

13. **Statistical Analysis**:

14. **Storage and Maintenance of Data**:

15. **Maintenance of Confidentiality**: Address procedures for maintaining privacy and confidentiality during the recruitment and study period, as well as after the study has been completed.

16. **Sources of Funding**:

17. **Other Ethical Issues***:*

List of enclosures:

	Write "Yes" or "NA"
Consent letter from collaborators (necessary if the application is not signed by them)	
Consent letter from participating medical/health centre if the application does not involve clinical collaborators.	
Approval of study protocol by the IEC of the participating medical centre	

Sample questionnaire (in English and its translation in local language as applicable)	
Template of the informed consent form (in English and its translation in local language as applicable)	
Please attach any other documents as required	