

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), PGIMER, Chandigarh

(Five copies of the project to be submitted. This form can be filled using Adobe Acrobat Reader®. A copy of filled up form is to be attached to each copy of the proposal. A soft copy of this form is also required to be submitted either by email (iecpgi@gmail.com) or in a CD)

Serial No of IEC:

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Proposal Title:

	Name, Designation & Qualifications	Address Tel & Fax Nos. Email ID	Signature
PI			
Co-PI / Collaborators			
1.			
2.			
3.			
Please attach short Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

The number of projects and drug trials are being conducted by PI:

The percentage of time the PI would provide in the present project/trial:

Tick(click the box) appropriately

Sponsor Information:

1. Indian a) Government b) Private

If Govt., whether Central State Institutional

2. International Government Private UN agencies

3. Industry National <input type="checkbox"/> Multinational <input type="checkbox"/>
If, multinational, whether through Indian Agency/subsidiary: Yes <input type="checkbox"/> No <input type="checkbox"/>
Contact Address of Sponsor:
Total Budget :

1.Type of Study :		
Epidemiological <input type="checkbox"/>	Basic Sciences <input type="checkbox"/>	Animal studies <input type="checkbox"/> Behavioral <input type="checkbox"/>
Participating centers: Single center <input type="checkbox"/> Multicentric <input type="checkbox"/>		
2. Status of Review: New <input type="checkbox"/> Revised <input type="checkbox"/>		
3. Clinical Trials: Drug /Vaccines/Device/Herbal Remedies:		
i. Does the study involve use of: Drug <input type="checkbox"/> Devices <input type="checkbox"/> Vaccines <input type="checkbox"/> Indian Systems of Medicine <input type="checkbox"/> Any other System of Medicine <input type="checkbox"/> NONE <input type="checkbox"/>		
ii. Is it approved and marketed: In India <input type="checkbox"/> UK & Europe <input type="checkbox"/> USA <input type="checkbox"/> 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:	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Is it an Investigational New Drug? If yes, IND No:	Yes <input type="checkbox"/>	No <input type="checkbox"/>
a). Investigator's Brochure submitted	Yes <input type="checkbox"/>	No <input type="checkbox"/>
b). <i>In vitro</i> studies data	Yes <input type="checkbox"/>	No <input type="checkbox"/>
c). Preclinical Studies done	Yes <input type="checkbox"/>	No <input type="checkbox"/>
d). Clinical Study is: Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/>		
e). Are you aware if this study/similar study is being done elsewhere ? If Yes, attach details	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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 (maximum 500 words):

5. Subject selection:		
i. Number of Subjects :		
ii. Duration of study :		
iii. Will subjects from both sexes be recruited	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Inclusion / exclusion criteria given	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v. Type of subjects	Volunteers <input type="checkbox"/>	Patients <input type="checkbox"/>
vi. Vulnerable subjects Yes <input type="checkbox"/> No <input type="checkbox"/> (If yes, Tick the appropriate boxes)		
Pregnant women <input type="checkbox"/> children <input type="checkbox"/> elderly <input type="checkbox"/> fetus <input type="checkbox"/> illiterate <input type="checkbox"/>		
Handicapped <input type="checkbox"/> Terminally ill <input type="checkbox"/> Seriously ill <input type="checkbox"/> mentally challenged <input type="checkbox"/>		
Economically & socially backward <input type="checkbox"/> any other <input type="checkbox"/>		
vii. Special group subjects Yes <input type="checkbox"/> No <input type="checkbox"/> (If yes, Tick the appropriate boxes)		
captives <input type="checkbox"/> institutionalized <input type="checkbox"/> employees <input type="checkbox"/> students <input type="checkbox"/>		
nurses/dependent <input type="checkbox"/> armed forces <input type="checkbox"/> any other staff <input type="checkbox"/>		
6. Privacy and confidentiality		
i. Participants identity -		
Direct Identifiers <input type="checkbox"/>	Indirect Identifiers/coded <input type="checkbox"/>	
Completely anonymized/ delinked <input type="checkbox"/>		
ii. Confidential handling of data by staff	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7. Use of biological/ hazardous materials		
i. Use of fetal tissue or abortus	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Use of organs or body fluids	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Use of recombinant/gene therapy	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Use of pre-existing/stored/left over samples	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v. Collection for banking/future research	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vi. Use of ionizing radiation/radioisotopes	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vii. Use of Infectious/biohazardous specimens	Yes <input type="checkbox"/>	No <input type="checkbox"/>
viii. Proper disposal of material	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ix. Will any sample collected from the patients be sent abroad ?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

12. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13. Is there compensation for injury? If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other <input type="checkbox"/> company	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Checklist for attached documents:		
1. Project proposal – 5 Copies	<input type="checkbox"/>	
2. Curriculum Vitae of Investigators	<input type="checkbox"/>	
3. Brief description of proposal	<input type="checkbox"/>	
4. Patient information sheet	<input type="checkbox"/>	
5. Informed Consent form	<input type="checkbox"/>	
6. Investigator’s brochure for recruiting subjects	<input type="checkbox"/>	
7. Copy of advertisements/Information brochures	<input type="checkbox"/>	
8. Copy of clinical trial protocol and/or	<input type="checkbox"/>	
9. questionnaire	<input type="checkbox"/>	
10. Institutional Animal Ethics Committee clearance	<input type="checkbox"/>	
11. CPCSEA clearance, if any	<input type="checkbox"/>	
12. HMSC/DCGI/DBT/BARC clearance if obtained	<input type="checkbox"/>	

Place:

Signature PI/Collaborator _____

Date:

Name: