

INDEPENDENT ETHICS COMMITTEE, MUMBAI

Annex 1
AF/01/01-SOP05/01

Project Submission Application Form for Initial Review

Serial No of IEC

Proposal Title:

	Name, Designation & Qualifications	Contact Address Tel & Fax Nos. Email ID	Signature
PI			
Co-PI / Collaborators			
1.			
2.			
3.			

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). If additional collaborators attach details on a separate page.

Sponsor Information :			
1. Indian	a) Government	<input type="checkbox"/>	Central <input type="checkbox"/> State <input type="checkbox"/>
	b) Private	<input type="checkbox"/>	
2. International	Government	<input type="checkbox"/>	Private <input type="checkbox"/> UN agencies <input type="checkbox"/>
3. Industry	National	<input type="checkbox"/>	Multinational <input type="checkbox"/>
Contact Address of Sponsor:			
Total Budget :			
Type of Study : Epidemiological <input type="checkbox"/> Basic Sciences <input type="checkbox"/> Animal studies <input type="checkbox"/>			

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Behavioral Clinical: Single center Multicentric		
Name and Address of the Centers : _____ (Attach the details on a separate sheet)		
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/ Alternate System of Medicine <input type="checkbox"/>	Any other <input type="checkbox"/>	NA <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 <input type="checkbox"/>		
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). <i>In vitro</i> studies data		Yes No
c). Preclinical Studies done		Yes No
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 else where ?		Yes No
If Yes, attach details		
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 (Attach sheet with maximum 500 words):		
5. Subject selection:		
i. Number of Subjects :		
ii. Duration of study :		
iii. Will subjects from both sexes be recruited		Yes No
iv. Inclusion / exclusion criteria given		Yes No
v. Type of subjects Volunteers <input type="checkbox"/>		Patients <input type="checkbox"/>

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vi.	Vulnerable subjects (Tick the appropriate boxes)	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	pregnant women	<input type="checkbox"/>	children	<input type="checkbox"/>	elderly
	fetus	<input type="checkbox"/>	illiterate	<input type="checkbox"/>	handicapped
	terminally ill	<input type="checkbox"/>	seriously ill	<input type="checkbox"/>	mentally challenged
	economically & socially backward	<input type="checkbox"/>	any other	<input type="checkbox"/>	
vii.	Special group subjects (Tick the appropriate boxes)	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	captives	<input type="checkbox"/>	institutionalized	<input type="checkbox"/>	employees
	students	<input type="checkbox"/>	nurses/dependent	<input type="checkbox"/>	armed
	any other	<input type="checkbox"/>	staff	<input type="checkbox"/>	forces
6. Privacy and confidentiality					
i.	Study involves -	Direct Identifiers	<input type="checkbox"/>	Indirect Identifiers/coded	<input type="checkbox"/>
		Completely anonymised/ 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 DNA 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 ionising 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"/>

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vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long?	Yes	No
<input type="checkbox"/>	Yes	No
12. Is there compensation for participation If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:		
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	No
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No

Place:

Date:

Signature & Designation of PI

Address for communication:-
Administrative Officer
Independent Ethics Committee
Dept of Clinical Pharmacology
G Bldg, 4th floor, old RMO Bldg,
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