

**INDEPENDENT ETHICS COMMITTEE, MUMBAI**

**Annex 1**  
AF/01/01-SOP05/01

**Project Submission Application Form for Initial Review**

<b>Serial No of IEC</b>
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**Proposal Title:**

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

**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.**

<b>Sponsor Information :</b>			
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"/>
<b>Contact Address of Sponsor:</b>			
<b>Total Budget :</b>			
<b>Type of Study :</b>			
	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)	
<b>2. Status of Review:</b>	New <input type="checkbox"/> Revised <input type="checkbox"/>
<b>3. Clinical Trials:</b>	
<b>Drug /Vaccines/Device/Herbal Remedies :</b>	
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 <input type="checkbox"/> No <input type="checkbox"/>
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, Date of permission :	
iv. Is it an Investigational New Drug?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, IND No:	
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 else where ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If Yes, attach details	
<b>4. Brief description of the proposal</b> – 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):	
<b>5. Subject selection:</b>	
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"/>

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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
<b>6. Privacy and confidentiality</b>					
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"/>
<b>7. Use of biological/ hazardous materials</b>					
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"/>
	<b>If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?</b>	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"/>
	<b>If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?</b>	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"/>
<b>If Yes, justify with details of collaborators</b>					
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"/>



