

INDIAN COUNCIL OF MEDICAL RESEARCH
Institutional Ethics Committee (IEC) of ICMR Headquarters Office,
Ramalingaswami Bhawan, New Delhi

Model form to be filled by the Principal Investigator (PI) for
submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)

Proposal Title:

	Name, Designation & Qualifications	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).

Tick appropriately

Sponsor Information :			
1. Indian	a) Government	<input type="checkbox"/>	Central <input type="checkbox"/>
			State <input type="checkbox"/>
			Institutional <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 :			

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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"/>
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 <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 (Tick the appropriate boxes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	captives <input type="checkbox"/>	institutionalized <input type="checkbox"/>	employees <input type="checkbox"/>
	students <input type="checkbox"/>	nurses/dependent <input type="checkbox"/>	armed <input type="checkbox"/>
	any other <input type="checkbox"/>	staff <input type="checkbox"/>	forces <input type="checkbox"/>
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	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	Yes	No
	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	Yes	No
	If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No

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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 ?	Yes	No
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	No
b) Sample will be sent abroad because (Tick appropriate box):		
Facility not available in India <input type="checkbox"/> Facility in India inaccessible <input type="checkbox"/> Facility available but not being accessed <input type="checkbox"/> If so, reasons...		
8. Consent : *Written <input type="checkbox"/> Oral <input type="checkbox"/> Audio-visual <input type="checkbox"/> i. Consent form : (tick the included elements)		
Understandable language <input type="checkbox"/> Statement that study involves research <input type="checkbox"/> Sponsor of study <input type="checkbox"/> Purpose and procedures <input type="checkbox"/> Risks & Discomforts <input type="checkbox"/> Benefits <input type="checkbox"/> Compensation for participation <input type="checkbox"/> Compensation for study related injury <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Alternatives to participation <input type="checkbox"/> Confidentiality of records <input type="checkbox"/> Contact information <input type="checkbox"/> Statement that consent is voluntary <input type="checkbox"/> Right to withdraw <input type="checkbox"/> Consent for future use of biological material <input type="checkbox"/> Benefits if any on future commercialization <input type="checkbox"/> eg. genetic basis for drug development <input type="checkbox"/>
*If written consent is not obtained, give reasons:		
ii. Who will obtain consent ?	PI/Co-PI <input type="checkbox"/> Research staff <input type="checkbox"/>	Nurse/Counsellor <input type="checkbox"/> Any other <input type="checkbox"/>
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 reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>	Yes	No
iii. Is there a benefit a) to the subject ? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		

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11. Data Monitoring	Yes	No
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 <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input type="checkbox"/>	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 <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes	No
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
Checklist for attached documents:		
Project proposal – 12 Copies	<input type="checkbox"/>	
Curriculum Vitae of Investigators	<input type="checkbox"/>	
Brief description of proposal	<input type="checkbox"/>	
Patient information sheet	<input type="checkbox"/>	
Informed Consent form	<input type="checkbox"/>	
Investigator’s brochure for recruiting subjects	<input type="checkbox"/>	
Copy of advertisements/Information brochures	<input type="checkbox"/>	
Copy of clinical trial protocol and/or questionnaire	<input type="checkbox"/>	
HMSC/DCGI/DBT/BARC clearance if obtained	<input type="checkbox"/>	

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator