INDIAN COUNCIL OF MEDICAL RESEARCH

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)

Serial No of IEC Management Office:

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	☐	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 ☐		
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 ?				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 ☐ 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		Yes	No
i.	Use of fetal tissue or abortus		
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
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 ☐
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	☐
Compensation for participation	☐	Benefits if any on future commercialization eg. genetic basis for drug development	☐
Compensation for study related injury	☐		

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Research staff ☐ Nurse/Counsellor ☐ 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 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 ☐ 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 company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

Checklist for attached documents:

Project proposal – 20 Copies	☐
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	☐

Place: Signature & Designation of PI/Co-PI/Collaborator
Date:

INDIAN COUNCIL OF MEDICAL RESEARCH

Institutional Ethics Committee

Model Form to be filled by Reviewers

Serial No of IEC Management Office:

Proposal Title:

Principal Investigator: **Co-investigator:** 1.
2.
3.

Supporting Agency: ICMR/ non ICMR

If non ICMR, name of agency:

Project Status: New ☐ Revised ☐

Review: Regular ☐ Interim ☐

Date of Review:

1. Research Design

i.	Scientifically sound enough to expose subjects to risk	Yes ☐	No ☐
ii.	Relevant to contribute to further knowledge	Yes ☐	No ☐
iii	Of national importance	Yes ☐	No ☐

2 Risks

a. Is there physical/social/psychological risk/discomfort?	Yes ☐	No ☐
b. Is the overall risk/benefit ratio	Acceptable ☐	Unacceptable ☐

3 Benefits

Direct: Reasonable ☐ Undue ☐ None ☐

Indirect: Improvement in science/knowledge ☐ Any other ☐

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4 Subject selection :

i	Inclusion / exclusion criteria addressed?	Yes ☐	No ☐
ii	Vulnerable subjects (woman, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected ?	Yes ☐	No ☐
iii.	Special group subjects (captives, students, nurses & dependant staff) adequately protected?	Yes ☐	No ☐

5 Privacy & Confidentiality maintained? Yes ☐ No ☐

6 Patient Information Sheet: Adequate ☐ Inadequate ☐

7. **Consent form components addressed adequately?** Yes ☐ No ☐

8. Compensation, (if applicable) addressed adequately? Yes ☐ No ☐

9. Is there a Conflict of Interest? Yes ☐ No ☐

If yes, Acceptable ☐ Unacceptable ☐

10. Budget: Appropriate ☐ Inappropriate ☐

11. Decision of review

Recommended ☐ Recommended with suggestions ☐

Revision ☐ Rejected ☐

Any other remarks/suggestions:

Reviewer's name and Signature

INDIAN COUNCIL OF MEDICAL RESEARCH

Communication of Decision of the Institutional Ethics Committee(IEC)/ Institutional Review Board(IRB)

IEC/IRB No:

Protocol title:
Principal Investigator:
Name & Address of Institution:
☐ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC/ IRB: ☐ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Please note *

- **Inform IEC/IRB immediately in case of any Adverse events and Serious adverse events.**
- **Inform IEC/IRB in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC/IRB.**
- **Members of IEC/IRB have right to monitor the trial with prior intimation.**

Signature of Member Secretary
IEC/IRB