INDIAN COUNCIL OF MEDICAL RESEARCH

Model form to be filled by the Principal Investigator (PI) for submission to the Institutional Animal Ethics Committee (IAEC)

(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 a detailed Curriculum Vitae of all Investigators (with subject-specific publications limited to the previous 5 years).			

INDIAN COUNCIL OF MEDICAL RESEARCH

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, or 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? **If Yes**, attach details	Yes	No
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 (Tick the appropriate boxes)	Yes ☐	No ☐	
	pregnant women, fetus	children ☐	elderly ☐	
	terminally ill	illiterate ☐ , seriously ill ☐	handicapped ☐	
	economically & socially backward ☐	any other ☐	mentally challenged ☐	
vii.	Special group subjects (Tick the appropriate boxes)	Yes ☐	No ☐	
	captives	institutionalized ☐	employees ☐	
	students	nurses/dependent ☐	armed ☐	
	any other	staff	forces	

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 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
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collect 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 the study involves research Sponsor of study ☐	Confidentiality of records ☐
Purpose and procedures ☐	Contact information ☐
Risks & Discomforts ☐	Statement that consent is voluntary ☐
Benefits ☐	Right to withdraw ☐
Compensation for participation ☐	Consent for future use of biological material ☐
Compensation for study related injury ☐	Benefits if any on future commercialization eg. genetic basis for drug development ☐

*If written consent is not obtained, give reasons:

ii. Who will obtain consent? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects ?
(posters, flyers, brochure, websites – if so kindly attach a copy)

10. Risks & Benefits:

i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?

ii. Is there physical / social / psychological risk / discomfort? ☐

If Yes, Minimal or no risk ☐
More than minimum risk ☐
High risk ☐

iii. Is there a benefit a) to the subject ?

Direct

b) Bene

fit to society Yes No

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 ? Yes No

If Yes, reporting is done to : Sponsor Ethics Committee DSMB

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 Animal Ethics Committee (IAEC), VU

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 ☐

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