Dr. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCE, LUCKNOW

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal)

Code No. of IEC:

*To be filled by IEC Member Secretary

Proposal Title:

_____

_____

_____

Name & Department, phone no., e mail id of the Applicant (for PG/Ph.D. students)

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	Name, Designation & Qualifications	**Address, Tel & Fax Nos. Email ID**	**Signature**
PI/ Chief Guide			
Co-PI / Co-Guide / Collaborators **1.**			
2.			
3			
4			
5			
6			

Please collect detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at RMLIMS. The investigators should sign their CV. Keep this with you
Sponsor Information :
1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐ b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National ☐ Multinational ☐
4. Contact Address of Sponsor:
Total Budget :

1.Type of Study : Epidemiological ☐ Basic Sciences ☐ Behavioral ☐ Clinical: ☐ Multicentric ☐ Single center ☐		
2. Status of Review: New ☐ Revised ☐		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :**		
i. Does the study involve use of : Drugs ☐ Devices ☐ Vaccines ☐ Indian Systems of Medicines/ 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 attached		
iv. Is it an Investigational New Drug?	Yes ☐	No ☐
If yes,		
a). Investigator's Brochure enclosed	Yes ☐	No ☐
b). Preclinical studies data available(if yes provide summary)	Yes ☐	No ☐
c). Clinical Studies data available(if yes provide summary)	Yes ☐	No ☐

d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). DCGI's permission obtained (if yes, copy of letter enclosed)	Yes	No

4. Brief description of the proposal – Background and brief 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 a) study:	b) subject participation	
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/Dependen	☐	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(if yes provide details)	Yes ☐	No ☐
ii. Use of organs or body fluids(if yes provide details)	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 ionizing radiation/radioisotopes	Yes ☐	No ☐
If yes, has Bhabha 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 ? **If Yes, justify with details and address of collaborators**	Yes ☐	No ☐

a) 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…

b) Has necessary clearance been obtained Yes ☐ No ☐

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Patient Information Sheet attached : (tick the included elements) Yes ☐ No ☐

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 e.g. genetic basis for drug development	☐
Compensation for study related injury	☐		
Translation of information sheet in local language	☐		

ii. If healthy volunteers will be included, information sheet for them attached Yes ☐ No ☐

iii. Consent form in English ☐ local language ☐

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

*If written consent is not obtained, give reasons:

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 ? Yes ☐ No ☐ Direct ☐ Indirect ☐ b) to the 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 ? **If Yes,** reporting is done to : Sponsor ☐ IEC ☐ DSMB ☐	Yes ☐	No ☐
iii. Is there a plan for interim analysis of data?	Yes ☐	No ☐
iv. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long?	Yes ☐	No ☐
12. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes ☐	No ☐
13. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes ☐	No ☐

Checklist for attached documents:

Project proposal	☐
Curriculum Vitae of non RMLIMS Investigators	☐
Brief description of proposal/summary	☐
Copy of the protocol/Project and questionnaire (if any)	☐
Investigator's brochure	☐
Copy of Patient information sheet and consent form in local language	☐
Copy of advertisements/Information brochures	☐
DCGI/DBT/BARC clearance if obtained	☐
Copy of Insurance Policy	☐
Copy of clinical trial agreement	☐
Copy of IEC proforma	☐
Copy of PI undertaking	☐
Copy of Case Report form	☐

Place:
Date:

Signature & Designation of PI/Chief guide/Co-PI/Collaborator