

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

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

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). DCGI's permission obtained (if yes, copy of letter enclosed)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <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"/>
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 Forces <input type="checkbox"/>
Any Other <input type="checkbox"/>	Staff <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 <input type="checkbox"/>	No <input type="checkbox"/>
7. Use of biological/ hazardous materials		
i. Use of fetal tissue or abortus(if yes provide details)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Use of organs or body fluids(if yes provide details)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Use of recombinant/gene therapy	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	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 ionizing radiation/radioisotopes	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, has Bhabha Atomic Research Centre (BARC) Approval for Radioactive Isotopes been obtained?	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 ? If Yes, justify with details and address of collaborators	Yes <input type="checkbox"/>	No <input type="checkbox"/>
a) 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...		
b) Has necessary clearance been obtained	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8. Consent : *Written <input type="checkbox"/> Oral <input type="checkbox"/> Audio-visual <input type="checkbox"/>		
i. Patient Information Sheet attached : (tick the included elements)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Understandable language	<input type="checkbox"/>	Alternatives to participation <input type="checkbox"/>
Statement that study involves research	<input type="checkbox"/>	Confidentiality of records <input type="checkbox"/>
Sponsor of study	<input type="checkbox"/>	Contact information <input type="checkbox"/>
Purpose and procedures	<input type="checkbox"/>	Statement that consent is voluntary <input type="checkbox"/>
Risks & Discomforts	<input type="checkbox"/>	Right to withdraw <input type="checkbox"/>
Benefits	<input type="checkbox"/>	Consent for future use of biological material <input type="checkbox"/>
Compensation for participation	<input type="checkbox"/>	Benefits if any on future commercialization <input type="checkbox"/>
Compensation for study related injury	<input type="checkbox"/>	e.g. genetic basis for drug development <input type="checkbox"/>
Translation of information sheet in local language	<input type="checkbox"/>	
ii. If healthy volunteers will be included, information sheet for them attached	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Consent form in English	<input type="checkbox"/>	local language <input type="checkbox"/>
iv. Who will obtain consent ?	PI/Co-PI <input type="checkbox"/>	Nurse/Counsellor <input type="checkbox"/>
	Research staff <input type="checkbox"/>	Any other <input type="checkbox"/>
*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 <input type="checkbox"/>	No <input type="checkbox"/>
10. Risks & Benefits:		
i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Is there physical / social / psychological risk / discomfort?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Yes, Minimal or no risk	<input type="checkbox"/>	
More than minimum risk	<input type="checkbox"/>	
High risk	<input type="checkbox"/>	

lli. Is there a benefit a) to the subject ? <table style="display: inline-table; vertical-align: middle;"> <tr> <td>Yes</td> <td><input type="checkbox"/></td> <td>No</td> <td><input type="checkbox"/></td> </tr> </table> Direct <input type="checkbox"/> Indirect <input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	
b) to the society <table style="display: inline-table; vertical-align: middle;"> <tr> <td>Yes</td> <td><input type="checkbox"/></td> <td>No</td> <td><input type="checkbox"/></td> </tr> </table>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	

11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor <input type="checkbox"/> IEC <input type="checkbox"/> DSMB <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Is there a plan for interim analysis of data?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Are there plans for storage and maintenance of all trial database? If Yes, for how long?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12. 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 company <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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

Place:
Date:

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