

**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:
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\*To be filled by IEC Member Secretary

**Proposal Title:**

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**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
<b>PI/ Chief Guide</b>			
<b>Co-PI / Co-Guide / Collaborators</b>			
<b>1.</b>			
<b>2.</b>			
<b>3.</b>			
<b>4.</b>			
<b>5.</b>			
<b>6.</b>			

**A. General (For Non- Interventional studies only)**

<b>Project funded</b>	<input type="checkbox"/> No  <input type="checkbox"/> Yes	<b>Funding Agency:</b> <input type="checkbox"/> Non-funded Intramural  <input type="checkbox"/> Funded-Intramural  <input type="checkbox"/> Extramural	Funding agency: .....  Budget: .....
<b>Student project</b>	<input type="checkbox"/> No  <input type="checkbox"/> Yes	MD <input type="checkbox"/> DM <input type="checkbox"/> M.Ch <input type="checkbox"/> M.S. <input type="checkbox"/> MBBS <input type="checkbox"/>  Ph.D <input type="checkbox"/> SRF <input type="checkbox"/> DNB <input type="checkbox"/> Others <input type="checkbox"/>	
<b>Collaborative</b>	<input type="checkbox"/> No  <input type="checkbox"/> Yes	<input type="checkbox"/> National  <input type="checkbox"/> International	<b>Name of Institute /'s:</b> 1..... 2..... 3..... 4.....
<b>Status of Review:</b>	New <input type="checkbox"/>	Revised <input type="checkbox"/>	
<b>Study duration :</b>	Years:	Months:	

**B. Project Details**

<b>I. Study Design</b>	<input type="checkbox"/> Case-Control <input type="checkbox"/> Cohort Study  <input type="checkbox"/> Cross-Sectional <input type="checkbox"/> Retrospective study <input type="checkbox"/> Other		<input type="checkbox"/> Single Centre  <input type="checkbox"/> Multicentre
<b>II. Participants</b>			
1. From RMLIMS	Numbers	Source	Total (if multicentre)
Controls	.....	.....	.....
Patients	.....	.....	.....
2. Gender	<input type="checkbox"/> Both <input type="checkbox"/> Males only <input type="checkbox"/> Females only		
3. Clearly defined inclusion/ exclusion criteria:	<input type="checkbox"/> Yes <input type="checkbox"/> No		
4. Vulnerable subjects	<input type="checkbox"/> No  <input type="checkbox"/> Yes	<input type="checkbox"/> Pregnancy <input type="checkbox"/> Children <input type="checkbox"/> Elderly <input type="checkbox"/> Illiterate  <input type="checkbox"/> Handicapped <input type="checkbox"/> Terminally/seriously ill <input type="checkbox"/> Mentally challenged <input type="checkbox"/> Economically/socially backward <input type="checkbox"/> Others	

<b>III. Risk and Benefits</b>	<p>a. <b>Does this study qualify for</b></p> <p><input type="checkbox"/> Minimal risk</p> <p><input type="checkbox"/> More than minimum risk</p> <p><input type="checkbox"/> High risk</p> <p>b. <b>Is there benefit</b> i) to the subject? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Direct <input type="checkbox"/> Indirect</p> <p>ii) to the society? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<b>IV. Privacy and Confidentiality</b>	<p><b>Study Involves:</b></p> <p><input type="checkbox"/> Direct Identifier (Subject identified by name/ Cr. No)</p> <p><input type="checkbox"/> Indirect identifiers (Patient identified by study ID)</p> <p><input type="checkbox"/> Completely Anonymized (Subject cannot be identified)</p> <p><b>Confidential handling of data by staff:</b></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<b>V. Informed Consent Documents:</b>	<input type="checkbox"/> None (Waiver of consent form)	
<b>a. Participant Information Document (PID)*</b>	<input type="checkbox"/> Written <input type="checkbox"/> Verbal <input type="checkbox"/> Audiovisual	-Language: <input type="checkbox"/> Hindi <input type="checkbox"/> English <input type="checkbox"/> Others -Study includes children: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, Age group .....
<b>b. Informed Consent Forms (ICF's)</b>	<b>PID and ICF for LAR:</b> <input type="checkbox"/> Patient <input type="checkbox"/> Controls/volunteers <input type="checkbox"/> Parents/LAR Legally acceptable/authorized representative/guardian	
	<b>Consent will be taken by:</b> <input type="checkbox"/> PI/Co-PI <input type="checkbox"/> Nurse <input type="checkbox"/> Counselor <input type="checkbox"/> Research Staff <input type="checkbox"/> Student <input type="checkbox"/> Any Other	
	<b>PID and Assent form (children 7-18yrs):</b> <input type="checkbox"/> Child	
<b>VI. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Place:

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

Date: