



Dr. Ram Manohar Lohia Institute of Medical Sciences

Vibhuti Khand, Gomti Nagar, Lucknow-226010

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Office Order

In view of concerns raised by IEC in its meeting, the following action points are being formulated for proposals being submitted to IEC for action.


1. Proposal submitted to IEC should be printed in original+2 copies along with PDF of the proposal. Page numbers should be inserted on all the documents and annexure from beginning till the end accurately.
2. All research proposals should be approved by departmental research committee including PG's, Ph.D., M.Sc. work and non-funded research work.
3. **Objective should be clearly defined in the executive summary. A flow chart of methodology is mandatory in every proposal.**
4. Patient information sheet(PIS) should be
 - i. Complete giving adequate and accurate information about the study
 - ii. Specific to the research proposal.
 - iii. English and Hindi PIS should match each other
5. Hindi language of should be very simple and understandable to a lay man.
6. Please note that any Investigations to be done for research purpose will not be charged by the patient.
7. In projects, where a minor is involved or the patient is critically ill/unconscious/ not in the condition to provide written informed consent, consent from Legal guardian has to be attached. In case of children >7 years assent form will also be needed.
8. **Maximum of three clinical trials will be conducted by one PI at one time.**


Only Proposals completed to all aspects will be taken up. Hence PI is requested to fill IEC forms with care.

Contents of Proposals to be submitted for Ethical clearance (As per Standard operating Procedures of IEC)


A complete set in following order includes:


1. Approval letter from the Head of the Department indicating that the proposal has been reviewed and approved by departmental research committee
2. Form to be filled by the PI


Director
Dr. Ram Manohar Lohia
Institute of Medical Sciences
Vibhuti Khand, Gomti Nagar, Lucknow


PROF. NUZHAT HUSAIN
Member Secretary
Institutional Ethics Committee
Dr. RML Institute of Medical Sciences
Lucknow-226010

3. Executive summary of the project (a flow chart of methodology should be included in the Executive summary)
4. Undertaking by the PI
5. Short CV of the PI
6. Patient Information Sheet (each point should be explained properly)
7. रोगीसूचनाप्रपत्र (पूर्णविवरण)
8. Hindi Consent form
9. English Consent form
10. Check list (only with original form)
11. Conditional waiver may be applied for Retrospective study


Prof. NUZHAT HUSAIN
(Prof. Nuzhat Husain)
Member Secretary
Institutional Ethics Committee
Dr. RML Institute of Medical Sciences
Lucknow-226010


(Prof. A.K. Tripathi)
Director RMLIMS
Director
Dr. Rām Manohar Lohia
Institute of Medical Sciences
Vibhuti Khand, Gomti Nagar, Lucknow

Copy to- 1. Research cell, RMLIMS
2. Executive Registrar