DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW
Ph. No. 0522-4918555, 4918504 FAX- 0522-4918506

SOP Version No. V-2; Dt.13.02.2020

STANDARD OPERATING PROCEDURES

(SOP)

Version – V2 , Dated: 13.Feb.2020

DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
INSTITUTIONAL ETHICS COMMITTEE

OFFICE ADDRESS
DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES,
Gomti Nagar, Lucknow, U.P

Written Date: 02/Jan/2020
Review Date:28/Jan/2020
Final Date: 13/Feb/2020

19

DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES,
VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW
Ph. No. 0522-4918555, 4918504 FAX- 0522-4918506

Prepared by:

Name and Position on the IEC	Signature with date
Dr. Pradeep Maurya, Member IEC	
Dr. Manodeep Sen , Member IEC	
Dr. Ritu Karoli Associate Prof. Dep. Medicine RMLIMS	

Reviewed by Institutional Ethics Committee and Subcommitte:

Name and Position on the IEC	Signature with date
Prof. M.K.Mitra , Chairpersion IEC	
Prof. Nuzhat Husain , Member Secretary IEC	
Dr. Pradeep Maurya , Member IEC	
Prof. Arun Chaturvedi, Member IEC	
Dr. Manodeep Sen Member IEC	
Dr. Anil Balapure, Member IEC	
Mr. D.P.Singh , Member IEC	
Mr. Amitabh Mishra, Member IEC	
Adv. Anupras Singh, Member IEC	
Mr. Rajesh Kapoor, Member IEC	
Dr. Saurabh Paliwal, Member IEC	
Hon,ble Justics S.S. Upadhyay, Member IEC	

SOP Version No. V-2; Dt.13.02.2020

Approved by:

Name and Position on the IEC	Signature with date
Prof. M.K.Mitra , Chairperson IEC	M K Mitra

Accepted by:

Name and Position on the IEC	Signature with date
Dr. A.K.Tripathi Director RMLIMS	

Prof. A. K. Tripathi
Director

Abbreviations

CD	Compact disc
CDSCO	Central Drugs Standard Control Organization
Co-I	Co-Investigator
Co-PI	Co-Principal investigator
CRO	Contract Research Organization
CV	Curriculum vitae
DCGI	Drug(s) Controller General of India
DVD	Digital video disc
IB	Investigator brochure
ICD	Informed consent document
ICF	Informed consent form
ICH	International Conference on Harmonization
ICMR	Indian council of medical research
MOHFW	Ministry of Health & Family Welfare
PAN	Permanent account number
PI	Principal investigator
PID	Patient information document

Abbreviations

CD	Compact disc`
AV	Audio Video Consent
CDSCO	Central Drugs Standard Control Organization
Co-I	Co-Investigator
Co-PI	Co-Principal Investigator
CRO	Contract Research Organization
CV	Curriculum vitae
DCGI	Drug(s) Controller General of India
DVD	Digital video disc
IB	Investigator brochure
ICD	Informed consent document
ICF	Informed consent form
ICH	International Conference on Harmonization
ICMR	Indian council of medical research
MOHFW	Ministry of Health & Family Welfare
PAN	Permanent account number
PI	Principal investigator
PID	Patient information document
PIS	Patient information sheet
SAE	Serious adverse event

29

Table of Contents

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

S.No	Annexure
1	Format for submission of Research Proposal Form to be filled by PI Covering letter from HOD Approval of research/scientific committee Undertaking by PI Conflict of Interest by PI Executive Summary Patient information sheet – Hindi/English Informed consent- Hindi/English Request For Waiver Of Consent For Retrospective study / Retrospective Part of The Study English/Hindi Assent form English/Hindi Guidelines for Devising a Participant / Legally Acceptable Guardian Information Document (PID)
2	Conflict of Interest declaration by PI
3	Format for Communication of decision of Dr Ram Manohar Lohia Institute of Medical Sciences-IEC to the Investigator
4	Checklist for contents of the informed consent documents
5	Format for Informed Consent Form (ICF)
6	Letter of the IEC to members for the meeting
7	Undertaking by the Investigator (Schedule-Y)
8	Template for CV of the Investigator
2	Check-list for documents submitted (acknowledgement)
9	Review fees of DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC
10	List of DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC members
11	Definitions of terms used
12	Policy on the Recruitment of Research Subjects
13	Policy on Research Costs to Subjects
14	Guidelines on Compensation for Research Subjects
15	Guidelines and Policy on Informed Consent
16	Policy for Documentation of Informed Consent
17	Health Record Archival
18	Health Record Research
19	Policy on "SITE INSPECTION" by Dr Ram Manohar Lohia Institute of Medical iences -IEC authorized personnel
20	Conflict of Interest Agreement Form for IEC Members
21	Invitation to Attend a Meeting as Independent Consultant
22	Invitation to Attend a Meeting as Observer
23	Confidentiality Document Form for Observer Attendees to IEC, RMLIMS Meetings
24	Onsite Adverse Drug Event Reporting Form
25	**Form to Record Recommendations by IEC**
26	**Off-site Safety Reports Classification Form**
27	**Off Site Safety Reports Log**
28	**Form to Record SAE assessment by SAE monitoring subcommittee**
29	**Monitoring of Audiovisual recording of AV consent Process**
30	**Study Completion Report form**

1. Introduction

Application of scientific methods to the study of health care interventions has been responsible for most of the progress in Medicine. Hence it has become necessary to understand how these newer interventions - including Drugs, Devices and Methods – are discovered and developed. After studying their physical and chemical properties; their physiological and pathological effects; toxicological and teratogenic aspects are studied in animals. However, animal studies have their own limitations. Hence to have valid conclusions, which can be applied to humans, it is essential to evaluate these newer interventions - Drugs, Devices and Methods –in humans and this has to be done ethically. The ethical principles for human research are enshrined in the Declaration of Helsinki.

All the research in human subjects is now guided by the principles laid down by the scientific bodies and regulators at National and International levels. It is essential to follow Good Clinical Practices (GCP) adopted internationally. The Indian Council of Medical Research (ICMR) has also issued ethical guidelines for research on human subjects. Paragraph 2.4.7 of the GCP guideline for India provide that the research subject who suffers physical injury as a result of their participation in the clinical trials are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability, subject to confirmation from Ethics committee. In 2012, CDSCO has issued guidelines for payment of compensation in case of clinical trial related injury or death. All these principles are put into practice through formulation of an Institutional Ethics Committee (IEC).

The International Conference on Harmonization (ICH) adopted the principles for Good Clinical Practices (1996) (ICH-GCP). These are the norms accepted worldwide today. The Indian Council of Medical Research (ICMR) has also developed India specific Ethical Guidelines for Biomedical Research on Human beings in the year 2000, then revised in 2006 and again revised in 2019 . These have formed the basis of the GCP guidelines issued by the Central Drugs Standard Control Organization (CDSCO) of the Ministry of Health & Family Welfare (MOHFW), Government of India.

Under the guiding principles of these guidelines the Independent Ethics Committee is mandated to examine the various research proposals submitted to it for biomedical research on human beings and ensure dignity, rights, safety, and well-being of the present and potential participants of these clinical trials.

With the increasing activity in this field of Clinical Trials coming to India, a need was felt to have an "Institutional Ethics Committee" (IEC) which can provide services to biomedical researchers and subjects who do not have access to get their research protocols reviewed and approved by either institutional ethics committee, independent review boards or other ethics committees. In an attempt to ensure these, an Ethics Committee consistent with the prevalent guidelines of Good Clinical Practices (GCP) issued by the ICMR & ICH is formed in the city of Lucknow with 16 members, each with distinct experience and expertise required for proper functioning of the IEC. A constituent meeting of the Dr Ram Manohar Lohia Institute of Medical Sciences Institutional Ethics Committee, Lucknow was held on **11.01.2016** in which the following principles and policies were adopted and subsequently revised in compliance to the ethical and regulatory requirements.

2. IEC name and functioning

2.1 Name of IEC:

The committee shall be known as Dr Ram Manohar Lohia Institute of Medical Sciences Institutional Ethics Committee, Lucknow. This name will remain unchanged until such a time the committee chooses to change it by a vote of majority of current members of this committee.

2.2 Functioning of IEC:

The IEC would function as per the guidelines "ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS" issued by the INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR), NEW DELHI, 2019 published by the Director-General, Indian Council of Medical Research, New DELHI 110 029 (www.icmr.nic.in.).

3. Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Objectives and Activities

3.1 Purpose of the IEC:

The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

MEMBER SECRETARY
IEC
DR. RMLHMS
LUCKNOW

The primary objective of the IEC is to ensure the safety, rights, dignity, and well-being of the actual and potential subjects of the proposed study and to ensure that the proposed study is credible, carried out according to ICH-GCP principles, ICMR guidelines and remains confidential. It would also ensure that the study subjects receive appropriate compensation as per guidelines issued by the Govt. of India in case of any clinical trial related injury.

For the effective functioning of this committee, a standard operating procedure document is drafted and finalized by all the members of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt with by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR.

3.2 Scope of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC:

The Committee shall review research protocols involving human participant or involving data of human participants for the following types:

- Studies involving Pharmaceuticals,
- Studies involving Devices,
- Studies involving herbals, or any other systems of medicines,
- Epidemiological devices,
- Retrospective studies, and
- Disease and drug registries
- Case studies
- In-vitro studies involving human samples

4. Members of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC:

Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will be multi-disciplinary and multi-sectorial in composition.

It shall be an institutional body constituted of medical, scientific, pharmacologist, social sciences, legal experts (non-scientific member) and lay members (non-scientific member).

The committee will consist of a minimum of seven and maximum of 15 members who collectively have the qualifications and experience to review and evaluate the ethical, scientific, medical, and social aspects of any proposed research project.

The committee should have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism. The member should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the researchers at their center/ site/ clinic/ hospital.

4.1 Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- New members will be identified according to the requirement and provided the potential member fulfills the conditions of appointment as per the scope of this SOP.

The following qualities are sought in Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members:

a) Interest and motivation
b) Time and effort
c) Commitment and availability
d) Experience and education
e) Respect for divergent opinions
f) Integrity and diplomacy

The list of committee members, their qualifications and affiliations details shall be maintained with the committee records.

The list of members is enclosed as Appendix (Annexure-X).

26

4.2 Type of Members:

4.2.1 Regular Members:

The regular members at present are a minimum of seven. The number can be increased up to fifteen if it becomes necessary to include members with special skills and background.

4.2.2 Invited members:

Further, as and when required an expert from other medical specialty may be invited as an expert to exert his/her opinion and deliberation.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC on proposed research protocols, when the Chairperson/ Member secretary or the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members determine that a study will involve procedures or information that is not within the area of expertise of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g. genetic disorders, stem cell research etc.) or they may be representatives of communities, patients, or special interest groups.

4.2.3 Invited members for vernacular languages:

Lay persons who are able to read and write the various vernacular languages would be invited to read and understand the informed consent document (ICD), for its complexity and use of technical words in the ICD.

All invited members must sign the confidentiality agreement regarding meeting, deliberations, and related matters. These consultants or subject experts cannot vote for decision.

4.3 Extension and termination/resignation of members:

The tenure of committee-membership will be a continuous period of three years. Extension of membership will be decoded by a vote of two-third of members present in a quorum at a regular committee meeting.

There will be no limit to the number of times that membership can be extended.

If an existing member completes his tenure and does not wish to continue or resigns or a regular member is unable to continue working on committee or fails to perform his/her responsibilities as per the requirement of the IEC and as judged by the Chairperson – a new member will be nominated from the same category as that of the member being replaced.

Any member can resign at any time from the IEC, by giving 10 days prior notice of his/her intention to do so and reasons, if any, for doing so. Provided that any member shall stand disqualified and his/her membership revoked with immediate effect, if:

- He/she is held to be declares him, insolvent.
- He/she is convicted for moral turpitude or imprisoned.
- He/she is guilty of any professional malpractice.
- He/she does not act in good faith and in bonafide discharge of their function, as a member of the IEC.
- He/she continuously abstains from attending the meeting of the IEC.
- He/she has willingly suppress, withheld or concealed any information available or known to him/her. With regard to any application for approval pending before the IEC and/or of his/her personal or conflict of interest in any such trial.
- Similarly, if internal faculty member proceeds on leave for more than 6 months, the Director may replace with another faculty member in consultation with the Dean

4.4 Roles and responsibilities of members

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
- Participate in the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC meeting.
- Review & discuss research proposals submitted for evaluation.
- Review progress reports and monitor ongoing studies.
- Monitor SAEs and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC meetings.
- Declare conflict of interest, if any.
- To carry out work delegated by Chairperson, Co-Chairperson & Member Secretary.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

27

- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC secretariat

5. Office bearers:

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will have the following office bearers who have the expertise and professional qualifications to review what comes in.

5.1 Chairperson:

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC chairperson should be fully capable of managing the IEC and the matters brought before it with fairness and impartiality. The task of making the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will fall primarily on the shoulders of this individual. The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC must be perceived to be fair and impartial, immune from pressure by the investigators whose protocols are brought before it, or other professional and non-professional sources.

5.1.1 Roles and responsibilities the Chairperson

- He/she will be responsible for conducting all committee meetings and he will lead all discussions and deliberations pertinent to all research proposals.
- Will preside over all the administrative matters pertinent to the Committee's functions.
- In case of anticipated absence, the chairperson will nominate a Committee member as acting chairperson. The acting chairperson will have all the powers of chairpersons for that meeting.

5.2 Member-secretary:

The Member Secretary will be appointed member of DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC, committed to the task of coordinating and managing the activities of the committee. He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.

5.2.1 Co- Member-secretary

The Co-Member Secretary will be appointed member of DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC, committed to the task of coordinating and managing the activities of the committee. If the member secretary not present in the meeting then He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.

5.3 Secretariat:

Secretariat is composed of Member Secretary, DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC and the administrative supporting staff. The supporting staff consists of staff appointed by the Chairperson/Member Secretary.

The secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Organizing DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC meetings regularly
- Preparation of agenda and minutes of the meetings
- Maintaining DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC documentation and archive
- Communicating with DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC members and PIs
- Arrangement of training for personnel and DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC members
- Providing necessary administrative support for DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC related activities to the Members and Chairperson, DR RAM MANOHAR LOHIA INSTITUTE

- To receive processing fees and issue official receipts for the same
- Receiving all research proposals
- Forwarding all materials for review by committee members, with covering letter
- Establishing time limits for receipt of reviewers' comments,
- Inviting scientific experts from relevant therapeutic area to the scheduled meetings, if required.
- To notify the review outcome to concerned Principal Investigator of the research proposal, Preparation and circulation of minutes of meetings,
- Retention and safe-keeping of all documents and records,
- Member secretary shall assign a unique code or number to each proposal and check for its completeness
- In case a critical part of the study is missing, the member secretary will inform the investigator and request for it in writing. If this is done by fax phone or email, it shall be documented.

5.4 Scientific Advisory Committee:

Chairperson and Member-Secretary in consultation with the members may form a separate panel of experts, if necessary, as Scientific Advisory Committee, who will be experts in their respective fields, and who will give their opinion and assessment on the proposal. However, they will not vote on the specific Research Proposal. The IEC will formulate norms to pay honoraria to them.

The Chairperson, as appropriate, will decide the need for participation of special invitees who will participate in discussion and deliberation but will not vote on research proposals.

5.5 IEC subcommittees

Subcommittees of IEC may be formed as when required for expedited review of new or revised proposal where major changes not required and SAE reporting. The decisions of all the subcommittees will be reported to the next meeting of IEC by the Member Secretary.

5.5.1 Expedite review committee

It will consist of the Member secretary and two members designated by the chairperson. At least one member should be from outside the Institute. The subcommittee should report to the main IEC. The approval granted through expedited review must be ratified at the next Full committee meeting.

5.5.2 Three -member subcommittee

The subcommittee will consist of the Member Secretary (convener) and two outside IEC members designated by the chairperson. It will take decisions regarding revised proposals/clarifications in proposals where major changes are not required. The subcommittee should report to the IEC.

5.5.3 SAE subcommittee

The subcommittee will consist of the Member Secretary, one senior faculty member of the Institute (Chairman of SAE subcommittee) and 3-4 other members from inside the Institute. The SAE subcommittee will review SAE reports with assessment of causality, compensation and regulatory compliance. The decisions of the SAE subcommittee must be approved at the next Full committee meeting.

5.6 Training of members:

Dr. Ram Manohar Lohia Institute of Medical Sciences -IEC members have a need for initial and continued education regarding the ethics and science of biomedical research.

All members must be conversant with ICMR Guidelines for Research involving Human Subjects 2017, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

All members will receive training material (electronic form) in research bioethics and functioning of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC and will be exposed to ongoing opportunities for enhancing

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

their capacity for ethical review.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members will be encouraged to receive ongoing training by attending workshop at least once every year.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will conduct training sessions from time to time (preferably six monthly) to impart training to the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members and invited members (on case to case basis).

6. Elements of review by the committee

- Review qualifications of all investigators participating in the proposed research study.
- Scientific design and conduct of the study.
- Approval of appropriate scientific review committees.
- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
- Management of research related injuries, adverse events.
- Compensation in case of trial related injury.

- Justification for placebo in control arm, if any.
- Availability of products after the study, if applicable.
- Patient information sheet and informed consent form in vernacular (local) language.
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure of study sites.
- Criteria for withdrawal of patients, suspending or terminating the study.
- Ensure compliance with the norms of ICH-GCP guidelines and ICMR guidelines for ethical research in human beings.
- Vulnerable population
    - Individuals may be considered to be vulnerable if they are:
    - socially, economically or politically disadvantaged and therefore susceptible to being exploited;
    - incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;

      able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
    - unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.
    - When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them.
    - Researchers must justify the inclusion of a vulnerable population in the research. ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.
    - The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.(see annexure 1.13,1.14,1.15…)

7. Standard Operating Procedures:

7.1 Procedures for Submission of Proposal

1. The committee will require the submission the following documents from the investigator/investigator appointed personnel.

S.No	*Document*	*No. of Copies*
1.	A covering letter addressed to the Chairperson and/or Member Secretary (Annexure 1)	2
2.	Current CV of the Principal Investigator (signed and dated)	03
3.	Undertaking by the Principal Investigator in Schedule-Y format (Annexure 5)	03
4.	Study-protocol synopsis	03
5.	Full Version of the Study Protocol and latest amendments, if any, to it	03
6.	Case Report Form (CRF)	03
7.	Patient Information Sheet / Document (PIS/PID) in English and other languages (Hindi) languages.	03
8.	Informed consent form (ICF) in English and other languages (Hindi) as with back translations if appropriate.	03
9.	Investigator's Brochure (IB) for new products / Official prescribing information for products which are marketed in India/other countries / Scientific literature of the drug substance or product supporting the use of the drug in the said indication	03
10.	Regulatory status of the new drug in India and developed countries.	03
11.	Permission from appropriate applicable regulatory authorities for study or study related activities.	03
12.	If it is a new drug, approval of DCGI (Drug Controller General of India) permitting the trial.	03
13.	Subject Recruitment Procedure, whenever applicable.	03
14.	Available safety information and procedure for reporting any adverse reactions.	03
15.	Details of research grant (if any).	03
16.	Information about payment and compensation/ insurance/ indemnity to subjects / investigator team for participation including healthy volunteers.	03
17.	Any other document	03

2. All submissions to be made in **PRINT** copies and **ELECTRONIC** copies of above documents at the office of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC between **10:00 hrs. to 17:00 hrs.** on **Monday to Friday** (except public declared holidays). The paper submission front cover transparent with spiral roll binding, Along with paper copies, submission of documents in electronic form as either ".doc / .docx" or "pdf" files is also required to be sent at **researchcellrmlims@gmail.com**
3. The electronic submissions (.doc, .docx, .pdf, or .xls wherever applicable) to be done in the form of 'CD / DVD/ flash drive' and by mail to E-mail I.D, (data less then 10Mb.)
4. For CV of the investigator, the template can be used as in Annexure 8.
5. All submissions to be made at the office of the "Dr Ram Manohar Lohia Institute of Medical Sciences – **Independent Ethics Committee**" located at the address below:

Research Cell Office
Room No.35, 2nd floor Administrative Block
RMLIMS
Contact No. 0522-4918504
Extension No. 2016
E mail: researchcellrmlims@gmail.com

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

6. The submission should accompany payment against the charges for processing of research protocol as per the scheduled fees in form of **Online / D.D. (D.D. valid 03 months at the time of submission) to be drawn in favor of "M/S Research Cell RMLIMS Lucknow"**
7. **Account No. 6193000100001869 IFSC Code- PUNB0619300 payable at Lucknow**
8. Permanent Account Number (PAN) of Dr Ram Manohar Lohia Institute of Medical Sciences-IEC is '**AAATD9802F**' and GST number is **09AAATD9802F2ZRO**
9. The trust is registered under the **NAME**: Dr Ram Manohar Lohia Institute of Medical Sciences, Gomti Nagar, Lucknow (**Reg. no.: 1982, 2006-2007 dt.** 04.11.2006).
10. The approval if provided would be for a period of one year from date of approval.
11. The investigator would be given an acknowledgement of the submission in the CHECK-LIST as per the Annexure 2.
12. If required, the Dr. Ram Manohar Lohia Institute of Medical Sciences -IEC would request the investigator or his/her representative to be present for the discussion and presentation of the study protocol and procedures in person at the Dr. Ram Manohar Lohia Institute of Medical Sciences -IEC, Lucknow office.

7.2 Review Meetings:

1. The committee will hold regular meeting once in every two weeks and less frequently if there are no research proposals to review – but not less than once every six months.
2. The meetings would be conducted at the convenience of all members, preferably on the second and fourth Saturday of each month.
3. All the regular members will receive notification of meeting schedules at least 2 days in advance.
4. Only those members who are independent of the clinical trial or sponsor would vote / opine for the matters related to the study.
5. Hierarchy: The Chairperson will be the head of the committee and Member- Secretary will be the guardian of all the documents and funds in the committee's possession. All members will be regular committee members with equal ranking.
6. The proceeding of all meetings will be recorded in English in the form of minutes. The member secretary will be responsible for coordination, recording and circulation of minutes of the meeting.

7.3 Quorum Requirements

A minimum of five (5) members are required to form the quorum without which a decision regarding the project should not be taken. The quorum requirements of DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES - IEC should have the following representation:

a. Basic medical scientists (preferably one pharmacologist)
b. Clinicians
c. Legal expert
d. Social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
e. Lay person from the community

In any case, the ethics committee must include at least one member whose primary area of interest/ specialization is nonscientific and at least one member who is independent of the institution / trial site. Besides, there should be appropriate gender representation on the **DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES** -IEC.

No quorum should consist entirely of members of one profession or one gender. In absence of the Chairperson, Co-Chairperson will chair the meeting.

7.4 Review Procedures

7.4.1 <u>Review process in general</u>

a) All communications will be in writing or mail.
b) Whenever required each member, before receiving review material, will sign a confidentiality agreement with the Sponsor and/or Principal Investigator to maintain confidentiality of review material and committee records, copy of which will be with the committee as well as with the sponsor.

32

c) Every attempt shall be made to reach a consensus on each proposal reviewed. A majority vote for approval, disapproval, and request for alteration, information, suspension or termination of ongoing research study will be defined as a minimum of one half of the members in attendance at the review. All voting members present at the review will vote while absent members cannot vote. Further, any member participating in the research project under discussion will opt out from all deliberations. However he or any other Investigator / Co- investigator may be called in to provide clarification on the Study Protocol. In case there is a tie, the chairperson may either cast a deciding vote or postpone the decision to next meeting pending further inquiry into the merits of the proposal and an attempt is made to reach consensus.

d) Outcome Of Review: The committee will document its views on the following-
   - Approval,
   - Request for modification or further information,
   - Disapproval, Termination / suspension of research proposal / study and reasons for the same.

e) Notification of Review Outcome: The outcome of committee's review will be recorded in writing and conveyed to the Principal Investigator within a week as per Annexure 3.

f) Procedure for Appeal: For Research proposals rejected by the committee, the applicant may appeal for repeat review in writing within the next 10 days with due justification relevant to issue / objections raised.

g) Review of the amendments to already approved research proposals: All amendments to approved research proposal shall be submitted immediately to the committee for its review. No change in the protocol be initiated without prior approval of the committee except when necessary to eliminate immediate hazards to the patients or when the changes involve only logistic or administrative aspect of the trial / study.

h) The committee will adopt a method of keeping all the members informed about the approvals under expedited review procedure. Only chairperson will make a decision to allow an expedited review

i) A research activity may be disapproved only after review in accordance with non- expedited review procedure.

j) Review of advertisements for patients' recruitments: All the advertisements shall be reviewed and approved by the committee prior to their implementation in the study.

k) Review of On-going studies: The committee will conduct continuing review of each on-going study by obtaining the status report from the sponsor at intervals appropriate to the degree of risk to the human subjects but at least once a year.

l) The investigator will promptly report to the IEC the following:
   - Any amendments made to the protocol, and will not enroll any patients till it is approved, except if the amendment is of concerns to the safety of the subjects.
   - All adverse events both serious and unexpected, within 7 days.
   - New information that may affect adversely the safety of the subjects or conduct of the study.

m) The IEC will promptly review any serious adverse events (SAE) that have been reported to it and decide if any urgent action is warranted to be taken e.g. amendment to the protocol, continuation of the study or its termination.

n) The investigator / research sponsor will have to submit following reports to the Committee – Annual report after one year after first approval of the project.

7.4.2 Expedited Review

The proposals involving no more than minimal risk to research participants may be subjected to expedited review. It may be carried out by chairperson or one or more experienced members designated by the chairperson.

An expedited review may be conducted, only if the protocols involve:

1. Revised proposal previously approved through full review by the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis or health record research
2. Anonymous surveys and retrospective chart reviews
3. Research activities that involve only procedures listed in one or more of the following categories:
   - Clinical studies of drugs and medical devices only when –
     i. Research is on already approved drugs except when,
        - Study of drug interaction
        - Conducting trial on vulnerable population

     OR

     ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes

4. Other documents which would be considered for expedited review are as follows but may not restrict to:

- Minor deviations from originally approved research during the period of approval (usually of one year duration)
- Change in the Dr Ram Manohar Lohia Institute of Medical Sciences , address of sponsor
- Change in contact details of PI and DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC
- Change in PI or hand over of trials or projects
- Inclusion or deletion of name/s of co-investigator/s
- Request for change in PI , Co-I, change in any member involved in the research
- Minor amendments in the protocol, CRF
- Minor corrections in budget
- Other administrative changes in the IB, ICF, etc.

7.4.3 Review process for vulnerable population

a. Vulnerability occurs when a person's ability to protect himself/herself is absent or diminished. Vulnerable populations are more susceptible to both intentional and inadvertent harm.
b. Vulnerable populations are those populations who are at a higher risk of being subjected to harm (pregnancy, elderly population), or are unable to provide informed consent due to legality (children) or medical factors (cognitively impaired persons), or are under obligations of the researcher/institute/hospital/office (students, residents, prisoners and employees).
c. The Dr Ram Manohar Lohia Institute of Medical Sciences-IEC will take a special consideration for review of studies involving vulnerable subjects, and shall protect the rights, safety and well-being of the vulnerable population.

7.5 Decision making

Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

Decision is arrived at by consensus, if consensus not possible voting would be carried out.

7.6 Serious adverse events (SAE)

7.6.1 Review of Serious adverse events (SAE)

The primary responsibility of the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC is to review and address SAE and unexpected events involving risks to research participants.

Dr Ram Manohar Lohia Institute of Medical Sciences -IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC secretariat is responsible for receiving the complete SAE / unexpected events reports and directing them to the sponsor and regulators (if applicable) for detailed review.

Notifying the SAE to Dr Ram Manohar Lohia Institute of Medical Sciences -IEC does not relieve the PI from his/her responsibility to notify the sponsor and regulatory authorities.

The Chairperson, Dr Ram Manohar Lohia Institute of Medical Sciences -IEC on basis of the information and comments received from the investigator, and applying his/ her judgment will direct the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC secretariat to any one or more actions listed below, but are not limited to:

- Suspending enrolment of new research participants till further review by the Dr Ram Manohar Lohia Institute of Medical Sciences-IEC.
- Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC

34

- Suspend some trial-related procedures (listed by the secretariat)
- Calling for an emergency review meeting by the Dr Ram Manohar Lohia Institute of Medical Sciences-IEC:
    - This review should be initiated within 48 working hours (2 working days) of receipt of information.
    - This review could be done through a meeting, teleconference, email or telephonic conversation.
    - The IRB Secretariat will take appropriate steps to ensure that Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members are informed about this meeting.
    - Depending upon the complexity of the issue(s) involved, the chairperson could direct the Member Secretary, DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC, to invite one or more experts whose opinion would be valuable.

- Soliciting opinion of one or more expert in writing. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality clause and abide by the rules and regulations of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.
- The expert would be requested to provide an opinion in writing within 2-14 working days, depending upon the gravity and seriousness of the matter.

7.6.2 Action on Serious adverse events (SAE)

If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC discussion. Some of which are listed below:

- Terminate the study;
- Suspend the study till review is completed;
- Suspend the study till additional information is obtained;
- Suspend the study for a fixed duration of time;
- Suspend the study till amendments requested for by the Dr Ram Manohar Lohia Institute of Medical Sciences - IEC are accepted;
- Suspend enrolment of new research participants;
- Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
- Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- Request additional details;
- Request further follow up information;
- Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.
- Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.

7.6.3 Follow up action on Serious adverse events (SAE)

- The IRB secretariat will send a formal letter to the investigator/s with instructions for specific actions as per the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC decision.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will instruct the PI to forward follow-up reports of the SAE to the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will instruct the PI regarding compliance to actions recommended by the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC within 14 days of receipt of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC letter.
- In case a PI fails to respond to the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC letter, the matter will be discussed at the next Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting and a decision will be taken for specific action by simple majority.

7.7 Premature termination / suspension / discontinuation of a research study

- It is the responsibility of the Chairperson, Dr Ram Manohar Lohia Institute of Medical Sciences -IEC to terminate any study that the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk.
- The Secretariat is responsible for management of the premature termination /suspension /discontinuation process.

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members /Chairperson can prematurely terminate the study if protocol non-compliance /violation are detected and Dr Ram Manohar Lohia Institute of Medical Sciences -IEC decision is to terminate the study.
- SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
- The Secretariat will make notification letter acknowledging the approval of termination or query letter to request information regarding the premature termination.
- The Secretariat will send the notification letter to the PI for their records within 14 days after the meeting.

7.8 Detection of Protocol deviation/ non-compliance/ violation/waiver

7.8.1 <u>Detection of Protocol deviation/ non-compliance/ violation/waiver</u>

- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance / violation, if the project is –
    - Not conducted as per protocol / national / international regulations
    - When scrutinizing annual / periodic reports / SAE reports
    - Any other communication received from the Investigator / trial site / sponsor /study monitor / CRO

- The Secretariat can detect protocol deviation / non-compliance / violation from failure to:
    - Comply with statutory requirements
    - Respond to requests from Dr Ram Manohar Lohia Institute of Medical Sciences -IEC within reasonable time limit
    - Respond to communication made by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC
- The PI himself / herself may forward protocol deviation / non- compliance /violation /waiver reports to inform the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC:
    - Protocol Waiver is analogous to a Protocol Deviation, except that prior IRB approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not
    - e.g. Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a subject who does not satisfy the approved inclusion /exclusion criteria for enrollment.
- Communication / complaint / information received from research participant who has been enrolled or any individual who has been approached for enrolment
- Any report / communication brought to the notice of member secretary / Chairperson of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC
- Communication received from regulators/ inspectors about an alleged protocol violation / non-compliance / protocol deviation

7.8.2 <u>Discussion on protocol deviation/ non-compliance/ violation/waiver</u>

If the protocol deviation / non-compliance / violation is detected by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member during monitoring visit he/she will present the protocol deviation / noncompliance / violation information.

If detected by Secretariat /forwarded by PI, the Secretary will present the protocol deviation / non-compliance / violation / waiver information.

The Chairperson / Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members will review the information available and take a decision depending on the seriousness of the violation.

The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.

The actions taken by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC could include one or more of the following:

- Inform the PI that Dr Ram Manohar Lohia Institute of Medical Sciences -IEC has noted the violation / noncompliance / deviation and inform the PI to ensure that deviations / noncompliance / violations do not occur in future and follow Dr Ram Manohar Lohia Institute of Medical Sciences -IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations /noncompliance / violations do not occur in future.
- Reprimand the PI

- Call for additional information
- Suspend the study till additional information is made available and is scrutinized
- Suspend the study till recommendations made by the Dr Ram Manohar Lohia Institute of Medical Sciences - IEC are implemented by the PI and found to be satisfactory by the Dr Ram Manohar Lohia Institute of Medical Sciences –IEC
- Suspend the study for a fixed duration of time
- Revoke approval of the current study
- Inform DCGI / other relevant regulatory authorities (if applicable)
- Keep other research proposals from the PI/ Co-PI under abeyance
- Review and / or inspect other studies undertaken by PI/Co-PI

7.8.3 Notification of protocol deviation/ non-compliance/ violation/waiver

- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC secretariat records the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC decision Drafts and types a notification letter.
- The Chairperson / Secretary signs and dates the letter.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Secretariat makes four copies of the notification letter.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Secretariat sends the original copy of the notification to the investigator.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Secretariat sends the second copy of the notification to the relevant national authorities (if applicable) and other trial sites, in case of multi-centric trial.
- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Secretariat sends the third copy to the sponsor or the CRO of the study.
- Keeps the last copy of the notification letter in the "non-compliance' file.

7.9 Administrative Procedures:

- The office of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC would be at the address below:

  Research Cell Office
  Room No.35, 2nd floor Administrative Block
  RMLIMS
  Contact No. 0522-4918504
  Extension No. 2016
  E mail: researchcellrmlims@gmail.com

- The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC review meetings may be conducted at the office or any other location as per the need of space and quorum expected for the meeting.
- Periodic training of members. The chairperson, in consultation with the members shall consider arranging training of the members of the IEC at convenient timing and location as per deliberations, felt need and consensus decision.
- The member secretary shall be responsible for the day to day functioning of the IEC. He shall maintain all the records to validate the functioning of the IEC during an audit or an inspection, such as current list of members and their CVs, current version of SOP, reference documents used by the IEC for its functioning e.g. ICH- GCP guidelines, CDSCO guidelines, ICMR ethical guidelines, Declaration of Helsinki, Drugs and Cosmetics Act and Rules, Schedule Y, Rule 122 E. Copies of these have been and shall continue to be made available to all the members by email or in other suitable media and shall have to be updated.
- Member secretary shall maintain a file for each proposal received, reviewed, followed, concluded, with chronological documentation. He should maintain records of all the meetings, comprising the notice, attendance log and minutes.
- Fourty percent **(40%)** of the total processing fees collected would be allocated for the maintenance & utilization of office space, storage space and administrative charges for functioning of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.
- Invited members / experts would be paid honorarium as per decision in meeting. The balance amount will be paid to the members participating in the meeting as compensation in lieu of their conveyance charges and loss of work hours spent for the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC activities.
- A separate bank account of the Dr Ram Manohar Lohia Institute of Medical Sciences-IEC is maintained to record its receivables and expenditure. The audit of accounts would be done if required.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

8. Conflicts of interest

In conducting human subject research, a conflict of interest is defined as a situation in which an individual (or someone in his/her immediate family) has a significant financial, professional or personal, interest in the approval or outcome of a study and the interest could affect decisions related to either the design, conduct or reporting of the research or adversely affect the rights and welfare of research subjects. Such conflicts must be identified and managed appropriately.

Immediate family means spouse, children, and any other person living in the same household. Interest related to the research means an interest in the sponsor of the research or a product or service being tested. For example, if an investigator conducts a non- sponsored study on drug X and the investigator owns stock in the manufacturer of drug X, that interest is considered an interest related to the research.

8.1 Identify and declaring conflicts of interest:

It is recognized that the potential for conflict of interest will always exist but has faith in the EC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. It is the policy of the EC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the EC.

The member shall immediately disclose to the Chairperson of the EC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or voting in respect of such proposals.

If an applicant submitting a protocol believes that an EC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

The EC Committee must ensure that a Conflict of Interest, whether potential, actual or perceived, in no way influences:

- The rigour of the processes used to review and approve proposed research projects
- The selection of participants in a research project
- The protection of the privacy & rights of research participants
- The interpretation & use of the data, outcomes & results of a research project

8.2 Conflict of Interest involving Researcher's

- All aspects of the funding and other support of the project that would be pertinent to the Committee's deliberations regarding the project.
- Provision of details about former or recent relationships with research sponsors.
- Any financial or other interest in any entity contributing to the funding or other support to the project
- Any significant change in either the funding or other support of the research project or in the nature or extent of the interests of the researcher during the course of the project. The requirement applies to any stage of the project up to and including the last publication of the data, outcomes or result derived from the project.

8.3 Conflict of Interest involving Committee members

Any actual, potential or perceived conflict of interest in any research project that is submitted for consideration by the committee, these interest may include any personal involvement or participation in the research, any financial interest in the outcome of the research or any involvement in competing research.
Each member is required to fill and sign the conflict of interest agreement form as per the annexure 20.

9. Site inspection by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members

It is the responsibility of the Dr Ram Manohar Lohia Institute of Medical Sciences-IEC members to perform or designate some qualified agents to perform on its behalf on-site inspection of selected study sites of relevant projects it has received for review or approved by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

The site visit report would be submitted and subsequently reviewed by the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC during the meeting for eligibility of the investigator and the site, adherence to necessary guidelines.

Reviewing the report, Dr Ram Manohar Lohia Institute of Medical Sciences -IEC may recommend changes and actions to be taken by the site to comply with regulatory and ethical guidelines.

10. Compensation in case of trial related injury

Research related injury is an injury that occurs to the subject as a result of research participation. Injuries may range from relatively minor harms (such as bruises or infected wounds) to major injuries (such as organ damage or temporary disability) to catastrophic injuries (such as permanent disability or death).

An injury may require only acute or emergency care, or it may require continuing care. Injuries can be physical or psychological/emotional.

In case of trial related injury, the trial subject shall be entitled for financial compensation as per the recommendation of the Ethics Committee. In case of death of the subject, his /her nominees are entitled for financial compensation as per the recommendation of the Ethics Committee. The financial compensation shall be over and above any expense incurred on the treatment of the subject.

The decision for compensation shall be taken during the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting and adequately decided as per the provisions of rule 122DAB of The Drugs and Cosmetics Rules, 1945, and other guidelines provided by CDSCO.

11. Patient's/ subjects requests and complaints

It is the responsibility of the Dr Ram Manohar Lohia Institute of Medical Sciences-IEC secretariat (chairperson and member secretary) for providing required information to the research participants in case of queries received from research participants.

It is the responsibility of the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred, if complaints are received from research participants.

In case of complaint received from a research participant, the Chairperson initiates a process to identify and address any injustice that may have occurred.

The Chairperson will direct the Member Secretary to consider the matter for discussion at a Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting or to call an emergency meeting of 2 or more Dr Ram Manohar Lohia Institute of Medical Sciences-IEC members for discussion or to appoint a subcommittee of 2 or more Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members for enquiry in order to resolve the matter.

The Chairperson / Member Secretary / designated Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC will insist on factual details to determine reality between truth and individual perception.

The final decision will be informed to the research participant by the Secretariat.

12 Review of Study Completion Report

It is the responsibility of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members to review the study completion report and notify it or request for further information, if necessary.

The IRB Secretariat should keep the study completion reports (received in duplicate from the principal investigator) on the agenda for Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting.

The members will discuss the report in the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting.

If appropriate to the discussions, the Chairperson may call for consensus to accept it or request further information or take any other action as suggested by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC decision is communicated to the investigator. In case

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

further information/action is requested, the same should be followed by the PI and communicated to the Dr Ram Manohar Lohia Institute of Medical Sciences - IEC office within 30 days. This update will be discussed in the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting.

13 Document archival

It is the responsibility of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC secretariat to ensure that all study files are prepared, maintained, and kept securely for a period of three years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time).

13.1 Document maintenance:

Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Trial master files should be established at the beginning of the trial, in the secretariat.

The approved study files are assigned unique identifiers (serial project no.).

Gather, classify and combine all related documents together of the approved study files appropriately.
Keep all active files in a secured file cabinet with controlled access.

Maintain the study files in an easily accessible and secure place for at least 5 years after the study closure.

All closed study files will be separately archived.

Final disposal of study/master files on completion of archival period.

13.2 Accessibility / Retrieval:

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.

13.3 Disposal of closed files:

The trial master file will be maintained in the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC office or a document archival center (outsourced by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC) for a period of three years following closure of the study.

After completion of archival period the closed files will be shredded and disposed of. However, all the copies of research projects and documents submitted for Dr Ram Manohar Lohia Institute of Medical Sciences-IEC review will be shredded off by the authorized Dr Ram Manohar Lohia Institute of Medical Sciences -IEC personnel after the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC meeting without any notification to PI. A log book of disposed documents will be maintained.

14 Review fees of Dr Ram Manohar Lohia Institute of Medical Sciences –IEC for sponsored clinical trial

The scheduled fees for initial review process are as below (in INR)

Studies involving new drug/device (As per Schedule-Y)	50000.00
Expedited approval (As per Schedule-Y)	10000.00
Expedited Approval New (multinational studies)	15000.00
IEC SOP Form	500.00
Resubmissions/Amendments	10000.00

14.2 Project completion

- It is the responsibility of the PI to submit the final report within 6 months of completion of the project along with a copy of abstract/publication.
- The Bioethics cell will receive 6 copies of Study Completion Report in the prescribed format (as per SGSOP 11/V3).
- The Bioethics cell will send reminders for completion report to PI, 15 days prior to the date of completion.
- The Bioethics cell will verify the completeness of the Study Completion Report Form (SGSOP 11/V3) filled by the PI and the study completion report will be tabled in the next full board meeting of IEC.

40

14.3 Clinical Trial Agreement (CTA) or Other Agreement for Sponsored Drug/ Device/ Collaborative Trials/ Study

After the approval from IEC, the sponsor/ principal investigator (PI) will submit the duly signed copies by the sponsor/ CRO of CTA/ other agreement on Rs. 100 quasi-judicial stamp papers (three copies) to the institute with counter signature by PI, for signature of the Director, RMLIMS. CTA/ other agreement and indemnity will safeguard the interest and right of the research participant, investigator and institute. It should contain the main constituents of the CTA draft as Schedule ad links As per existing policy of the institute, there would be 25% overhead charges in the financial part to the total cost of the total grant.

The drug trial shall be started by the PI after the agreement is signed by both the parties. Also, DCGI and other required regulatory approvals should be obtained for the concerned trial, and copy of the same should be submitted before starting the trial.

After approval of the CTA by the CTA screening committee (appointed by the Institute), a copy of the approved and duly signed CTA should be submitted to the Bioethics Cell before starting the trial.

Material transfer agreement (MTA):

For any study, where there is exchange of biological samples, by import or export from abroad, there has to be an MTA as per ICMR format; and it should be submitted along with the study protocol to the IEC. After the approval from IEC, PI has to obtain endorsement from HSMC, ICMR before starting the study.

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

41

Annexures

Annexure 1: Format for submission of Research Proposal fro IEC

<On Investigator's Letter Head>

(Date) To,
The Chairperson/Member Secretary,
Dr Ram Manohar Lohia Institute of Medical Sciences - Institutional Ethics Committee
Cell:
Tel.:
E-mail:

Subject: Research proposal titled *<Title of the research protocol with version number & date>* for review & approval.

Dear Sir,

I am enclosing the subject research proposal for your review. If you need any clarifications on the same, I or my representative shall be available at the meeting convened by your Committee to discuss the same. The proposal submitted herewith comprises of the following:

S.No	*Document*	*No. of copies*
1.	A covering letter addressed to the Chairperson and/or Member Secretary (Annexure 1)	2
2.	Current CV of the Principal Investigator (signed and dated)	03
3.	Undertaking by the Principal Investigator in Schedule-Y format (Annexure 5)	
4.	Study-protocol synopsis	03
5.	Full Version of the Study Protocol and latest amendments, if any, to it	03
6.	Case Report Form (CRF)	03
7.	Patient Information Sheet / Document (PIS/PID) in English and other languages (.....) languages.	03
8.	Informed consent form (ICF) in English and other languages (..... .....) as with back translations if appropriate.	03
9.	Investigator's Brochure (IB) for new products / Official prescribing information for products which are marketed in India/other countries / Scientific literature of the drug substance or product supporting the use of the drug in the said indication.	03
10.	Regulatory status of the new drug in India and developed countries.	03
11.	Permission from appropriate applicable regulatory authorities for study or study related activities.	03
12.	If it is a new drug, approval of DCGI (Drug Controller General of India) Permitting the trial.	03
13.	Subject Recruitment Procedure, whenever applicable.	03
14.	Available safety information and procedure for reporting any adverse reactions.	03
15.	Details of research grant (if any).	03

16.	Information about payment and compensation/ insurance/ indemnity to subjects/ investigator team for participation including healthy volunteers.	03
17.	Any other document	03

Also find herewith a Online/ D.D. should in the name of "M/S Research Cell RMLIMS Lucknow" payable at Lucknow

I request you to review the proposal at your next meeting and convey your decision to me. Yours truly,

[Signature]

Name: Principal Investigator.

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 1.1 Format for Research Proposal

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)

_____

	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 and keep this with you as a record . The investigators should sign their CV.			
Sponsor Information :			

44

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							

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

iv. Is it an Investigational New Drug? **If yes,**	Yes ☐	No ☐
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

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 (Tick the appropriate boxes) Yes ☐ No ☐

Pregnant women ☐	Children ☐	Elderly ☐
Fetus ☐	Illiterate ☐	Handicapped ☐
Terminally ill ☐	Seriously ill ☐	Mentally Challenged ☐
Economically & socially backward ☐	any other ☐	

vii. Special group subjects (Tick the appropriate boxes) Yes ☐ No ☐

Captives ☐	Institutionalized ☐	Employees ☐
Students ☐	Nurses/Dependent ☐	Armed ☐
Any Other ☐	Staff ☐	Forces ☐

46

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 **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes ☐ Yes ☐	No ☐ 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 **If yes,** has Bhabha Atomic Research Centre (BARC) Approval for Radioactive Isotopes been obtained?	Yes ☐ ☐ Yes	No ☐ ☐ 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 ☐

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

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	☐
Compensation for study related injury	☐	e.g. genetic basis for drug development	☐
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: Applicable/Not applicable 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 ☐ by any other company ☐	Yes ☐	No ☐

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

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

Date:

Se

Annexure 1.2

Consent of Head of the PI's Department

Date: .....

I have reviewed the project "....." submitted by ..... Principal Investigator from my department. I endorse the project and have 'no objection' for submission for consideration by Ethics committee.

I concur with the participants / investigators included in the study.

.....	.....	.....
Signature & date	**Name**	**Department**

Note: To avoid conflict of interest, if the Head of the Department is himself/herself the PI, this form is not to be submitted.

Annexure 1.3 Research Committee/Department Research committee /Doctoral Committee/Scientific Committee/MD Protocol Committee Approval

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

51

The project titled "....." with all the accompanying documents listed above was reviewed by the Research committee/Department Research Committee /Doctoral committee/M. D Protocol Committee present on at SGPGI. The committee has granted approval on

the scientific content of the project.

The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Signature of *HOD or Chairperson**Doctoral/Scientific Committee

Name: .....

Date: .....

***In case of student (MD/DM/MCh) or independent project/extramural/intramural**

****In case of PhD or any other project**

Not applicable to sponsor/CRO initiated drug/device trials

Kindly attach a copy of minutes of 'Research committee/Department Research Committee /Doctoral committee/scientific committee/ MD Protocol Committee'.

52

Annexure 1.4-Undertaking by the Principal Investigator

1. **Name of the project:**
2. **Name, designation and department of the principal investigator:**
3. **Other members of the research team:**
4. **Name and address of any other medical college, hospital or institution where parts of the study will be done:**
5. **Number of ongoing projects/clinical trials in which you are PI:**

a. **Number of sponsored clinical trials with active enrolments: _____**

b. **Number of sponsored clinical trials with follow up only: _____**

c. **Total number of ongoing projects (any) (Projects+a+b): _____**

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
3. I confirm that the Co-PI and other members of the study team have been informed about their obligations and are qualified to meet them.
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under national regulatory and ICMR guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, regulatory authorities, sponsors or their authorized representatives.
6. I will inform the IEC and the sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.

8.I will inform IEC if there is change in funding agency/status.

9.I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

_____

Signature of PI

Name_____ **Date**_____

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 1.5**Conflict of Interest Declaration by PI**

To,

The Member Secretary

Institutional Ethics Committee

SGPGI, Lucknow.

Project entitled: .....

Name of PI:

Conflict of Interest

[ ] I hereby declare that I have no conflict of interest in my project.

[ ] I have following conflict of interest:

_____

Signature of PI

Name_____ **Date**_____

54

Annexure 1.6

Format for Executive summary of Research proposal (not more than 3-4 pages)

1. Title of the project

2. Collaborators

3. Potential funding agency

4. Background of the work

5. Brief review

6. Objective

7. Methodology (will include study type, study setting, study duration, sample size and assessment, A flowchart must also be included to explain the methodology clearly)

8. Data analysis

9. Intervention

10. Inclusion exclusion criteria

11. Ethical issues in the study and plans to address these issues

12. Time line

13. Budget

14. References

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure1.7

डा0 राम मनोहर लोहिया आयुर्विज्ञान संस्थान, लखनऊ

सूचित सहमति पत्र

अध्ययन विशयण्ण
अध्ययन नम्बरण्ण..
सहभागी का पूरा नामण्ण..
जन्मतिथि/उम्रण्ण..
पताण्ण...

अध्ययन अन्वेशक का नामः मोबाइल नम्बरः

1. मेरी पुश्टि है कि मैने उपरोक्त परीक्षण हेतु जानकारी पत्र दिनांकण्ण...............को पढ़ व समझ लिया है, तथा मुझे प्र न पूछने के अवसर प्रदान किये गये।

अथवा

मुझे अध्ययन अन्वेशक ने विस्तार से सब तथ्यो को समझा दिया है तथा मुझे प्र न पूछने का अवसर प्रदान किया।

2. मैने समझ लिया है कि इस अध्ययन मे मेरी प्रतिभागिता स्वैच्छिक है, तथा यह कि मै बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारो पर प्रभाव पड़े बिना हट जाने के लिए स्वतंत्र हूँ।

3. मैने समझ लिया है कि इस चिकित्सीय संयोजक की ओर से काम करने वाले अन्य, नैतिकता समिति तथा विनियामक अधिकारियों का चालू अध्ययन तथा इससे सम्बन्धित तथा हो सकने वाले किसी अनुसंधान से सम्बन्धित मेरे स्वास्थ्य अभिलेखों को देखने के लिए मेरी अनुमति की आव यकता नही होगी, भले ही मै इस परीक्षण से हट ही क्यो न जाऊ। तथापि मैने समझ लिया है कि तृतीय पक्ष को दी गई या प्रका ित की गई किसी जानकारी मे मेरी पहचान को उजागर नही किया जाएगा तथा मुझे किसी प्रकार की क्षतिपूर्ति देय नही होगी।

4. इस अध्ययन मे प्राप्त किन्ही आकडो या परीक्षणो के प्रयोग पर पाबंदी न लगाने के लिये मै सहमत हूँ ब र्ते कि ऐसे प्रयोग मात्र वैज्ञानिक प्रयोजन/नों के लिये ही हो।

5. अध्ययन की सम्पूर्ण प्रकियां /तरीका मैंने भली भाति पढ़ लिया है /पूर्ण रूप से समझा दिया गया है। मैंने उसे पूर्ण रूप से सम्भावित खतरों सहित समझ लिया है एवं अपनी स्वेच्छा से अपनी सहमति दे रहा हूँ

सहभागी के हस्ताक्षर या अगूठें का नि ान/ कानूनी रूप से स्वीकार्य प्रतिनिधि

हस्ताक्षर करने वाले का नाम ....दिनांक.............................
अध्ययन अन्वेशक के हस्ताक्षर............................ दिनांक............................
अध्ययन अन्वेशक के नाम................................. दिनांक............................
गवाह के हस्ताक्षर.. दिनांक............................
गवाह का नाम ....

Annexure1.8

रोगी सूचना प्रपत्र

महत्वपूर्णः कृपया प्रत्येक बिन्दु का संक्षिप्त विवरण दें।

प्रत्येक बिन्दु की स्पश्ट रूप से व्याख्या की जानी चाहिए।

हर जगह <u>लागू नहीं</u> नहीं लिख सकता हूँ

अध्ययन विशय;

1. इस अध्ययन को भाोध की तरह व्यक्त करने का स्वाभाव एवं उद्दे य

2. इस अध्ययन में भाग लेने वालों की संख्या एवं अवधि

3. आप इस अध्ययन में आमंत्रित है क्योंकि आप इस रोग से पीड़ित है।(सरल भाशा मैं रोग का संक्षिप्त विवरण) इस अध्ययन में आपकी भागीदारी स्वैछिक है बिना कोई कारण बताए आप किसी भी समय चिकित्सीय देखभाल पर प्रभाव पड़े बिना इस अध्ययन से हट जाने के लिए स्वतंत्र है। अगर आप सहमत है तो इस कार्य प्रणाली का अनुकरण किया जाएगा।

4. कार्यप्रणाली विवरण

5. जाँच यदि कोई भी हो का किया जाना (सहभागी पर कोई वित्तीय भार नहीं पड़ेगा)

6. पूर्वाभासी खतरा या असुविधा का पूर्ण विवरण एवं की क्या योजना में न्यूनतम से ज्यादा खतरा है

7. सहभागी समुदाय या चिकित्सीय पे ोवर को लाभ जैसा की लागू हो

8. क्षतिपूर्ति की नीतिः यदि भाोध अध्ययन के परिणाम स्वरूप भाोध में भाग लेने वाले व्यक्ति में कोई प्रतिकूल प्रभाव पड़ता है, तो संस्थान द्वारा अपनी लागत पर इलाज किया जाएगा। वित्तीय मुआवजे के लिए कोई भी दावा संस्थान के विरूद्ध मान्य नहीं होगा

9. क्षतियॉ जोखिम प्रबंधन की चिकित्सीय उपलब्धता

10. वैकल्पिक चिकित्सा यदि उपलब्ध है

11. गोपनीयता सुनि चित करने के लिए उठाये जाने वाले कदम

12. अध्ययन से वापसी पर लाभ का खत्म होना

13. व्यवसायी करण की द ा में होने वाले लाभ को साझा करना

14. भाोध या क्षति की द ा में अधिक जानकारी के लिए मुख्य अन्वेशक या स्थानीय अन्वेशक का संपर्क विवरण

15. अधिकारों के उलंघन की द ा में संस्थान के आचार समिति के सदस्य सचिव का संपर्क विवरण

16. यदि एच0आई0वी0 या अनुवां िक जाँच होनी है तो ऐसी द ा में सहमति के लिए पराम ि को राश्ट्रीय दि ा निर्दे ा के अनुसार नि चत रूप से दिया जाना

17. जैविक नमूने की संग्रह अवधि एवं सम्बंधित आकड़ों का भविश्य में उपयोग के लिए विकल्प का सहभागी को प्रस्ताव देना संग्रह की अस्वीकृति और परिणामों की रसीद देने के सम्बन्ध में

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure1.9

Patient Information Sheet

Informed Consent of Participants: For all biomedical research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the **Informed Consent Form with Participant/Patient Information Sheet**. The latter should have following components as may be applicable:

IMPORTANT: Each point should be explained clearly. Please do not remove the text written under points 1-17. Clear distinction should be made between 'Heading' and 'Description'.

Don't write "not applicable" everywhere

Title of the study

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. You are being invited to take part in the study as you have ....this disease (brief description of disease) your participation in the study is voluntary, If you disagree to participate your medical health care will not be affected.
If you agree the following procedure will be followed.....
4. Procedure of study
5. Investigations, if any, to be performed: Please mention clearly that no financial burden (other than routine investigation) to be borne by the patient
6. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
7. Benefits to participant, community or medical profession as may be applicable
8. Policy on compensation: If any adverse effect takes place in the subject as a result of research study will be treated by the institute at its own cost. No claim for award of financial compensation will be maintainable against the institute for the same
9. Availability of medical treatment for such injuries or risk management
10. Alternative treatments if available
11. Steps taken for ensuring confidentiality
12. No loss of benefits on withdrawal
13. Benefit sharing in the event of commercialization
14. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury
15. Contact details of Member Secretary of the IEC for appeal against violation of rights
16. If test for genetics and HIV is to be done, counselling for consent for testing must be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

58

A copy of the participant/patient information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits.

Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained. When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of EC is required for such procedures. For drug trials, if the volunteer can give only thumb impression then another thumb impression by the relative or legal custodian cannot be accepted and an unrelated witness to the project should then sign.

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES, LUCKNOW
INFORMED CONSENT FORM

1. Study Title- _____
Study Number_____
Subject's Full Name__ _____
Date of Birth/Age_____
Address_____

Name Department of Principal Investigator Contact No.

1. I confirm that I have read and understood the information sheets dated_____ for the above study and have the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medicine care or legal rights being affected.
3. I understand that the sponsor of the clinical trial/ project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and my further research that may be conduct in relation to it, ever if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published. I will not be entitled for any compensation.
4. I agree not to restrict the use of any data or result that arises from this study [provided such a use is only for scientific purpose(s)
5. The entire methodology/process of the study has been completely read over and/or clearly explained to me including the risks involved if any. I have completely understood the same and hereby giving my consent with free will Signature (or Thumb impression) of the Subject/Legally Acceptable

Representative :_____
Signatory's Name_____ Date_____
Signature of the Investigator_____ Date_____
Study Investigator's Name_____
Signature of Witness_____ Date_____
Name of Witness_____

60

Annexure1.11

Request For Waiver Of Consent For Retrospective study / Retrospective Part Of The Study

Name of the study-

Applicant Name-

IEC Number –

Guide/ PI Name –

Address –

Phone No. –

Email Id –

The project includes the retrospective study hence waiver for the study /that part of study is requested to the members of ethical committee.

The following instruction will be followed –

1). All efforts have been made to contact the patient and seek his consent.

2). The identity and information regarding patients has been kept confidential.

3). All efforts have been taken to protect the privacy/ secrecy of information regarding patient as per required guidelines.

4). If the patient is not found alive Legal Acceptance Representative (LAR) will be taken.

(Signature of Principal Investigator))

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure1.12

पूर्वव्यापी अध्ययन / अध्ययन के पूर्वव्यापी भाग के लिए सहमति की छूट (वेवर आफ कंसेंट) के लिए अनुरोध

विषय –

अध्ययन अन्वेषक का नाम –

कांटेक्ट नंबर –

आई ई सी नंबर

गाइड का नाम

पता

फोन नंबर

ईमेल आईडी

ये पूर्वव्यापी अध्ययन है / इस परियोजना में पूर्वव्यापी अध्ययन भी शामिल है, इसलिए इस अध्ययन / उस भाग के लिए छूट (**वेवर आफ कंसेंट**) को नैतिक समिति के सदस्यों द्वारा अनुमोदित करने का अनुरोध किया जायेगा।

निम्नलिखित निर्देश का पालन किया जाएगा-

1. रोगी से संपर्क करने और उसकी सहमति लेने के लिए सभी प्रयास किए गये।
2. मरीजों के संबंध में पहचान और जानकारी को गोपनीय रखा गया।
3. आवश्यक दिशानिर्देशों के अनुसार रोगी के बारे में जानकारी की गोपनीयता की रक्षा के लिए सभी प्रयास किए गये।
4. यदि रोगी जीवित नहीं पाया जाता है तो कानूनी स्वीकृति प्रतिनिधि (एलएआर) लिया जाएगा।

अध्ययन अन्वेशक के हस्ताक्षर.....

62

Annexure1.13

Child Assent Form

Study Title_____
Study Number_____
Subject's Full Name (with father's name) _____
Date of Birth/Age_____
Address of subject
_____
_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled: "
"

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any study/trial related injury, which has causal relationship with the said study/trial drug. I am also aware of right to opt out of the study/trial, at any time during the course of the study/trial, without having to give reasons for doing so.

_____ Date: _____
Signature of the study participant

Name of the study participant: _____

_____ Date_____
Signature of the Witness
Name of the Witness: _____

_____ Date: _____
Signature of the attending Physician
Name of the attending Physician: _____

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure1.14

[illegible]

[illegible] ____________________

[illegible] ____________________

[illegible] ([illegible]) ____________________

[illegible]

[illegible] ____________________

[illegible] ____________________

[illegible] ____________________ [illegible]

[illegible] ____________________ [illegible] ________

[illegible] ____________________ [illegible] ________

[illegible] ____________________

[illegible] ____________________ [illegible] ________

[illegible] ___

64

Annexure 1.15 :
Guidelines for Devising a Participant / Legally Acceptable Guardian Information Document (PID) in English

Kindly refer to Table 3.2 for the essential elements of an informed consent document. For example, of PID in non-interventional studies, see appendix (AP7/V3). For 'Recommended Terms for use in Informed Consent Document', see appendix (AP12/V3)

1. **Study Title**

Is the title self-explanatory to a lay person? If not, an additional simplified title may also be included.

2. **Invitation Paragraph**

You should explain that the patient is being asked to take part in a research/trial study. "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."

3. **What is the purpose of the study?**

The background and aim of the study should be given here.

4. **Why have I been chosen?**

You should explain how and why the patient/volunteer was chosen and how many other patients will be studied.

5. **Do I have to take part?**

You should explain that taking part in the research/trial is entirely voluntary. States:
"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. **What will happen to me if I take part?**

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use States:

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual –
i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double-blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

7. **What do I have to do?**

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the

patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if necessary) that the patient should take the medication regularly and dangers of non-compliance.

8. **What is the drug or procedure that is being tested?**

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. **What are the alternatives for diagnosis or treatment?**

For therapeutic research/trial the patient should be told what other treatment options are available.

10. **What are the side effects of taking part?**

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side effects.

11. **What are the possible disadvantages and risks of taking part?**

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study. States:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. **What are the possible benefits of taking part?**

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. States:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. **What if new information becomes available?**

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. States:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be

asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You would also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event. You should incorporate following line in PID "In case of study related injury or death, (name of CRO/ company), will provide the complete medical care as well as compensation for the injuries or deaths".

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. "If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The information should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether he has to pay for drugs/tests, the doctor conducting the research/trial is being paid for including and looking after the patient in the study. The information regarding payment and compensation should be included in PID.

19. Will the drug be made available after trial is over? (new drug requires continued use, till it is marketed in India)

Please explain to participant regarding the query of availability of study drug.

20. Who has reviewed the study?

You may should mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

21. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers.**

Remember to thank your patient for taking part in the study!

The PID should be dated and given a version number. It should state that the participant will be given a copy of the information sheet and the signed consent form.

Signature of PI

_____

Name_____

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 2: Check-list for documents submitted (acknowledgement)

S.No	*Document*	*Please tick*	*No. of Copies*
1.	A covering letter addressed to the Chairperson and/or Member Secretary		
2.	Current CV of the Principal Investigator (signed and dated)		
3.	Undertaking by the Principal Investigator in Schedule-Y format		
4.	Study-protocol synopsis		
5.	Full Version of the Study Protocol and latest amendments, if any, to it		
6.	Case Report Form (CRF)		
7.	Patient Information Sheet / Document (PIS/PID) in English and other languages (.....) languages.		
8.	Informed consent form (ICF) in English and other languages (.....) as with back translations if appropriate.		
9.	Investigator's Brochure (IB) for new products / Official prescribing information for products which are marketed in India/other countries /Scientific literature of the drug substance or product supporting the use of the drug in the said indication		
10.	Regulatory status of the new drug in India and developed countries.		
11.	Permission from appropriate applicable regulatory authorities for study or study related activities.		
12.	If it is a new drug, approval of DCGI (Drug Controller General of India) permitting the trial.		
13.	Subject Recruitment Procedure, whenever applicable.		
14.	Available safety information and procedure for reporting any adverse reactions.		
15.	Details of research grant (if any).		
16.	Information about payment and compensation/ insurance/ indemnity to subjects / investigator team for participation including healthy volunteers.		
17.	Any other document.....		

The above documents are received by the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES - IEC, Thane for review process.

Sign. & seal
(Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member/secretary/chairman)

68

Annexure 3: Format for Communication of decision of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC to the Investigator

<Date>

To,
<Investigator Name>
<Designation, Address>
<Contact Details>

Reference: *<Protocol title with version & date>* Dear

Dr._____

The DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES - Institutional Ethics Committee reviewed and discussed your application to conduct the clinical study entitled *< Protocol title with version & date>* on *<date>*.

The following documents were reviewed:

a) Study-protocol synopsis
b) Study Protocol (including protocol amendments), dated_____Version No(s)_____
c) Patient Information Sheet and Informed Consent Form (including updates if any) in any) in English and/ or vernacular language.
d) Investigator's Brochure, dated _____Version No. _____
e) Official prescribing information for products which are marketed in India/other countries / scientific literature of the drug substance or product supporting the use of the drug in the said indication.
f) Regulatory status of the new drug in India and developed countries.
g) Approval of the DCGI no. _____dt. _____.
h) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
i) Principal Investigator's current CV.
j) Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
k) Investigator's Agreement with the Sponsor/CRO.
l) Details of research grant
m) Investigator's Undertaking (Annexure 5).

The following members of the ethics committee were present at the meeting held on (date, time, and place) and voted:

1. _____Chairman of the Ethics Committee
2. _____Member secretary of the Ethics Committee
3. _____Name of each member with designation

None of the study team members including principal investigator were a part of the voting procedure.

DECISION

- We approve the study to be conducted in its presented form.
- The validity of this approval is for one year from date of approval.
- Applicable mandatory regulatory and other permissions to be obtained prior to commencement of the study.
- The investigator team members should be trained on the protocol & protocol related procedures and the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
- The study to be registered at the "Clinical Trials Registry – India (CTRI)" at

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

"http://ctri.in" before commencement of study subjects (first patient in (FPI)).

- Participating subjects should not be put to additional financial burden due to participation in the study.
- The Institutional Ethics Committee / Independent Ethics Committee expects to be informed about the following:

1. Periodic safety update reports (PSUR).
2. Any other safety related information received by the PI from sponsor/CRO/any other source to be communicated to the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC immediately.
3. Any SAE occurring in the course of the study to be communicated within 24 hours of information to the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC and the sponsor/CRO.
4. Progress of the study to be reported annually to the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC.
5. Any amendments/changes in the protocol and/or patient information /informed consent document.
6. To provide an abridged copy of the final report after completion of the study. Yours sincerely,

Chairperson / Member Secretary

Ethics Committee.

<*Seal of* Dr Ram Manohar Lohia Institute of Medical Sciences -*IEC*>

70

Annexure 4: Checklist for contents of the informed consent documents

A. ***Essential Elements:***

1. Statement that the study involves research and explanation of the purpose of the research.
2. Expected duration of the Subject's participation.
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Statement describing the financial compensation and medical management as under :
    - In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management s long as required.
    - In the event of a trial related injury or death, the Sponsor or his representative whosoever has obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation for the injury or death.
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
11. The anticipated prorated payment, if any, to the Subject for participating in the trial
12. Subject's responsibilities on participation in the trial
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Any other pertinent information

B. Additional elements, which may be required

1. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
2. Additional costs to the Subject that may result from participation in the study.
3. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
4. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
5. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.
6. Approximate number of Subjects enrolled in the study

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 5: Format for Informed Consent Form (ICF)

Study Title: Study

Number:

Subject's Initials: _____Subject's Name:_____

Date of Birth / Age: _____

Address of the Subject : _____ Qualification : _____

Occupation : Student / Self-Employed / Service / Housewife / Others (Please tick as appropriate)

Annual Income of the subject

Name and address of the nominee(s) and his relation to the subject……..(for the purpose of compensation in case of trial related death).

		Please initial box (Subject)
(i)	I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.	[ ]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]
(v)	I agree to take part in the above study.	[ ]

Representative:_____

Date: _____/____/_____

Signatory's Name: _____

Annexure 6: Letter of the IEC to members for the meeting

[Date]
To,
<Name of member>
<Designation in IEC>
<Address of IEC>
<Contact Details>

Subject: Institutional Ethics Committee meeting scheduled for <date & day>

Dear *<Name of IEC member>*

The next meeting of the NAME Independent Ethics Committee, Thane is scheduled for [day], [date], from [time] to [time], at [place].
The agenda / list of protocols to be discussed are listed below:

1. Protocol Title "Title of protocol with version & date"
2. Protocol Title "Title of protocol with version & date"
3. *<Any other issues to be discussed>*

Also find herewith the minutes of the last meeting, for your review, suggestions and approval. The minutes would be finalized during the meeting as above.
Copies of the documents related to the proposals are enclosed herewith for your review so that you can come prepared with your queries, comments, or suggestions:
Request you to kindly treat all these documents as confidential and bring them with you for the meeting.

Yours sincerely,

Member Secretary / Chairperson
NAME-IEC, Thane.

Enclosures:

1) Study Protocol and Synopsis
2) CRF
3) ICF- Marathi, Hindi, English
4) ICF Back translations
5) Patient information Sheet (PIS)
6) Investigators brochure
7) DCGI letter
8) Statement regarding status of study drug apropos section 122E of the Drugs and Cosmetics Act.
9) Details of payments to subjects
10) CV of Principle investigator and co-investigator
11) Details of Research Grant
12) Other document (if any)

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 7: Undertaking by the Investigator (Schedule-Y)

(For Clinical Trial)

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator).
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s))
   Medical Council Registration Number: .....
   CV Attached: .....

3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. NAME – Institutional Ethics Committee

C/O

Cell:

Tel.:

E-mail:

6. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
7. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
   "..... ...."

8. Commitments:
   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
   iii. I agree to personally conduct or supervise the clinical trial at my site.
   iv. I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
   v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s)in accordance with the regulatory requirements and Good Clinical Practices guidelines.
   vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
   vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
   viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and allunanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as theethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish thereason for the delay to the satisfaction of the Central Licencing Authority along with the report of the seriousadverse event.

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with Date

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 8: Template for CV of the Investigator

Complete Name	
Gender	
Date of birth (dd/mm/yyyy)	
Qualification (all academic qualifications)	
Specialization/subject	
Contact details (phone/fax/cell)	
E-mail address	
Address (Clinic/Hospital/Site)	
Address (Residence)	
Medical Council registration no. (State)	
Additional Medical Council registration no.	
Professional experience	
□ Academic / Teaching	
□ Hospital /Consulting	
Clinical trial experience	
Research publications	

76

Annexure 9: Review fees of Dr Ram Manohar Lohia Institute of Medical Sciences –IEC for sponsored clinical trial

The scheduled fees for initial review process are as below (in INR)

Studies involving new drug/device (As per Schedule-Y)	50000.00+GST
Expedited approval (As per Schedule-Y)	10000.00+GST
Expedited Approval New (multinational studies)	15000.00+GST
IEC SOP Form	500.00+GST
Resubmissions/Amendments/ extension	10000.00+GST

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 10: List of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members (as approved by Governing Body meeting, Dr RMLIMS, 28.11.19)

	Name	Designation	Qualification	Current organization	Telephone, fax no., email ID. and mailing address	Designation/Role of member	Affiliation to Dr. RMLIMS
1	Prof. M.K. Mitra	Chairman IEC	MD Medicine	Former Professor & Head, Department of Medicine, KGMC, Lucknow	mksmitra@gmail.com 9415020124	432/11, T.G. New Civil Lines, Kala kankar Yojna, Old Hyderabad, Lucknow-226007	Not affiliated
2	Prof. Nuzhat Husain	Member Secretary	MD Pathology	Dean, Faculty In Charge, Research Cell and Head, Department of Pathology RMLIMS Lucknow	drnuzhathusain @hotmail.com 9415333729	2/182,Vishwas Khand Gomtinagar, Lucknow 226010	Affiliated
3.	Dr Ritu Karoli	Co-Member Secretary	MD Medicine	Associate Professor of Medicine RMLIMS, Lucknow	ritu.karoli@rediffmail.com 9415547894	255/100, Kundari Rakabganj, Lucknow	Affiliated
4	Dr. Pradeep Kumar Maurya	Clinician/ Member	MD,DM Neurology	Professor (Jr.) Dept of Neurology, RMLIMS, Lucknow	pkm730@gmail.com 7275068938	303, Faculty Apartment, RMLIMS, Lucknow.	Affiliated
4	Prof. Arun Chaturvedi	Clinician/ Member	MBBS,MS,MAMS (Surg Onc)	Professor & Head, Department of Surgical Oncology, KGMU, Lucknow	drchatur@gmail.com 9415405087	Head, Dept. of Surgical Oncology, Shatabdi Phase II, 3rd Floor, K.G.'s Medical University, Lucknow	Not Affiliated
5	Dr.Manodeep Sen	Basic Medical Scientist/ Member	MD Micro	Professor, Department of Microbiology, RMLIMS, Lucknow	sen_manodeep6@yahoo.com 9839446858	6,BN Verma building Kamla Nehru,Chowk, Lucknow.	Affiliated
6	Dr. Anil Balapure	Basic Medical Scientist/ Member	M.Sc., PhD	Ex-Chief Scientist &Head, Biochemistry Division at CSIR-CDRI, LKO	anilbalapure58@gmail.com 9415063603	E5/1, Paper Mill Colony, Nishatganj, lucknow-226006	Not Affiliated
7	Sri D.P. Singh	Lay person/ Member	M.A. Pol. Sc. LLB	Retired Govt. Officer	dpsinghjs1956@gmail.com 8756811282	C-122, Shivani Vihar (Near Ramleela Park), Kalyanpur, Lucknow.	Not Affiliated
8	Mr. Rajesh Kapoor	Lay person/ Member	B.Com	Collectrate Treasury, Kaiser bagh, Lucknow	rajesh111kapoor@gmail.com 9415424498	C-5/11, Balda Colony, New Hyderabad, Lucknow.	Not Affiliated
9	Mr. Amitabh Mishra	Social Worker/ Member	M.A.	Programme Director in Grameen Development Services (GDS), Aliganj, Lucknow	9415110758 amitabh1960@gmail.com	B1/42, Sector – A, Aliganj Lucknow 226024	Not Affiliated

78

10	Dr. Saurabh Paliwal	Social Worker/ Member	M.S.W., Ph.D.Social Work	Lecturer at Vidyant College, Lucknow	9235796596 drsaurabhpaliwal@gmail.com	SS26, Motijheel Colony, Aishbagh, Lucknow	Not Affiliated
11	Adv Anupras Singh	Legal Advisor/ Member	B.E , LLB	Legal Advisor, Lawyer	9936560909, anuprassingh@gmail.com	A-1, Sapru Marg Lucknow	Affiliated
12	Hon'ble Justice S.S. Upadhyay	Legal Advisor/ Member	B.A., LLB,	Retired Judge, Ex. Legal advisor, Hon'ble Governor, U.P.	9453048988 ssupadhyay28@gmail.com	Residence: 28, Raj Bhawan Colony, Lucknow. Postal Address: Flat No. 301, Block-A, Kaveri Apartments, Gomti Nagar Extension, Lucknow	Not Affiliated

IEC Sub-Committee

(A)Expedite Review Committee			
S.No.	**Member**	**Name**	**Affiliation**
1	Member Secretary	Prof. Nuzhat Husain	Dean, Faculty In Charge, Research Cell and Head, Department of Pathology RMLIMS
2	Member (outside the inst.)	Prof. Arun Chaturvedi	Professor & Head, Dept of Surgical Oncol, K.G.M.U
3.	Member (inside the inst.)	Dr. Manodeep Sen	Professor Department of Microbiology, RMLIMS
4.	Member (inside the inst.)	Dr. Ritu Karoli	Associate Professor Department of General Medicine RMLIMS

(B). Three- member Sub-Committee			
S.No.	**Member**	**Name**	**Affiliation**
1	Member Secretary	Prof. Nuzhat Husain	Dean, Faculty In Charge, Research Cell and Head, Department of Pathology RMLIMS
2	Member (outside the IEC member)	Prof. Arun Chaturvedi	Professor & Head, Dept of Surgical Oncol, K.G.M.U
3.	Member ((outside the IEC member)	Dr. Saurabh Paliwal	Lecturer at Vidyant College, Lucknow

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

(C). SAE Sub-Committee			
S.No.	**Member**	**Name**	**Affiliation**
1	Member Secretary	Prof. Nuzhat Husain	Dean, Faculty In Charge, Research Cell and Head, Department of Pathology RMLIMS
2	Chairman(senior faculty member of the institute)	Dr. Atul Jain	Prof. & Head Department of Pharmacology RMLIMS
3.	Member (inside the institute)	Dr Anil Balapure	Ex-Chief Scientist & Head, Biochemistry Division at CSIR-CDRI, Lucknow
4.	Member (inside the institute)	Pradeep .Maurya	Professor$_{(Jr.)}$ Dept of Neurology, RMLIMS
5.	Member (inside the institute)	Dr Sanjay Bhat	Associate Professor Department of General Surgery, RMLIMS
6.	Member (inside the institute)	Dr. Ritu Karoli	Associate Professor Department of General Medicine RMLIMS

Annexure 11: Definitions of terms used

Adverse Drug Reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Amendment

A written description of a change(s) to or formal clarification of documents.

Applicable Regulatory Requirement(s)

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

Approval (in relation to Institutional Review Boards)

The affirmative decision of the IEC/IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IEC/IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

Audit

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Blinding/Masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

Clinical Trial/Study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial/Study Report

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Comparator (Product)
An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

Compliance (in relation to trials)
Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

Confidentiality
Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Coordinating Investigator
An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

Contract Research Organization (CRO)
A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Documentation
All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Impartial Witness
A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject is legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Audio- Video Consent
A person who is independent of the trial, who attends the informed consent process and as per required protocol.

Independent Ethics Committee (IEC)
An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

89

Informed Consent
A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Institution (medical)
Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

Institutional Review Board (IRB)
An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Interim Clinical Trial/Study Report
A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

Investigational Product
A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator
A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Sub-investigator.

Investigator / Institution
An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements".

Investigator's Brochure
A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

Legally Acceptable Representative
An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

Minimal risk:
Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life (ICMR 2019).

Monitoring
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Multicentre Trial

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Nonclinical Study
Biomedical studies not performed on human subjects.

Opinion (in relation to Independent Ethics Committee)
The judgment and/or the advice provided by an Independent Ethics Committee (IEC).

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

Randomization
The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Regulatory Authorities
Bodies having the power to regulate.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)
Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect

Sponsor
An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Sponsor-Investigator
An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard Operating Procedures (SOPs)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Sub-investigator
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

Subject/Trial Subject
An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Trial Site
The location(s) where trial-related activities are actually conducted.

84

Unexpected Adverse Drug Reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information.

Vulnerable Subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Well-being (of the trial subjects)

The physical and mental integrity of the subjects participating in a clinical trial.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

SPECIFIC RECRUITMENT GUIDELINES

1. In addition to its review for scientific merit and protection of subjects from unnecessary research risks, the HEC will evaluate all protocols for subject recruitment especially with respect to women with childbearing potential, minority groups and children. Exclusion of minorities, women or children will be recommended or approved when inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

2. Patients may be identified as potential research subjects through direct contact of the PI with his or her patients, collaboration with physicians of other medical specialties, contact with individual attending physicians, posted written notices, radio announcements, or other approved methods.
   a. Inpatients:
      i. May be recruited by the investigator or other member of the research team only after consultation with the patient's attending physician

   b. Outpatients:
      i. For minimal risk research which does not bear directly upon a specific continuing therapeutic relationship between the individual and the participating physician, outpatients may be recruited* without prior notification of their personal physicians. However, when possible, each subject's personal physician should be notified of the study and informed that the patient has been entered into a minimal risk study.
      ii. For more than minimal risk research or any research bearing directly upon a specific diagnosis or treatment, the subject's personal physician should be notified before enrolling* the subject.

* If the potential research subject is a minor, then contact must be via a parent or legal guardian

Annexure 13: Policy on Research Costs to Subjects

If a research participant may have to bear any costs, which would be unnecessary if the subject had declined to participate in the research, all potential subjects must be fully informed of the nature and estimated extent of these costs when obtaining consent.

Examples of additional research costs include:

1. Prolongation of treatment or hospitalization.
2. Extra diagnostic tests necessary for the research.
3. Extra clinical or laboratory assessments to evaluate research treatment outcome.
4. A research treatment (whether randomly assigned or not) which may be more costly than a standard treatment.
5. Other substantial costs associated with extra visits to the study site.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 14: Guidelines on Compensation for Research Subjects

COMPENSATION FOR PARTICIPATION (Rule 122-DAB of the Drugs & Cosmetics Rules 1945)

Subjects may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. However, payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgment (inducement).

The decision for compensation shall be taken during the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC meeting and adequately decided as per the provisions of rule 122DAB of The Drugs and Cosmetics Rules, 1945, and other guidelines provided by CDSCO.

All payments, reimbursement and medical services to be provided to research subjects should be approved by the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC.

Care should be taken:

1) when a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
2) when a subject is withdrawn from research for medical reasons related to the study the subject should get the benefit for full participation;
3) when a subject withdraws for any other reasons he/she should be compensated in proportion to the amount of participation.

Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research.

During the initial review of a research protocol, the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC can review both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence.

The following are some additional guidelines:

1) Any compensation should not be contingent upon the subject completing the study, but should accrue as the study progresses.
2) Unless it creates undue inconvenience or a coercive practice, compensation to subjects who withdraw from the study should be made at the time they would have completed the study, had they not withdrawn.
3) Compensation given as a "bonus" or incentive for completing the study is acceptable, providing that the amount is not coercive. The DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC is responsible for determining if the incentive amount is not so large as to be coercive or represent undue influence.
4) The amount of compensation should be clearly set forth in the informed consent document.

Annexure 15: Guidelines and Policy on Informed Consent

A. GENERAL REQUIREMENTS

Except as described below, investigators may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative, prior to enrollment of the subject in the research.

Investigators are responsible for ensuring that subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence.

Information given to potential subjects or their representatives must be in language that is understandable to the subject or representative. No process of obtaining consent may include language through which the subject waives any of their legal rights or releases or appears to release the investigator, sponsor, or institution or its agents from liability for negligence.

Any changes in the regulations and laws to be implemented in execution of the informed consent activity.

B. ELEMENTS OF INFORMED CONSENT

A current sample informed consent document with required phraseology may be found in Annexure-3. The sample consent form contains all the required elements of consent. The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC requires that all consent forms be written in the first person, e.g., "I understand that…".

The following are the basic required elements:

1. A statement that the study involves research, an explanation of the purpose of the proposed research, the duration of the subject's participation, a description of the procedures, and which procedures are experimental;
2. The number of subjects that will be involved with the study;
3. A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;
4. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;
5. A discussion of possible alternative procedures or treatments, if any, which are available to the subject. One alternative might be to choose not to participate in the research and this will not affect the usual standard of care;
6. A discussion of how confidentiality of records associated with the subject will be maintained;
7. A description of any compensation or reimbursement for time, inconvenience, travel, parking, and other similar costs to the subject;
8. A description of any provisions for treatment of or compensation for research related injury;
9. A statement of whom to contact for answers about the research and in the event there is a research related injury. (This is generally the PI or another staff member closely associated with the study.) A separate contact must be named for questions concerning the subject's rights;
10. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits;
11. If appropriate, any circumstances under which the subjects participation may be terminated, with or without the subjects consent; and
12. A description of additional costs for which the subject will be responsible, that are likely to result from participation in the research study.

C. WAIVER OF INFORMED CONSENT

The DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that:

1. The research could not practicably be carried out without the waiver or alteration; and
2. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by the use of a written consent form reviewed and approved by the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC and signed by the subject or subject's legally authorized representative.

A copy must be given to the subject or person signing the form. A copy of the signed consent form should also be placed in the subject's medical record or in the site file. It is assumed that the consent form is only part of the total consent process in which the investigator, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject's questions.

The investigator is responsible for ensuring that research subjects understand the research procedures and risks.

Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.

Any changes in the regulations and laws to be implemented in execution of the informed consent activity.

OBLIGATIONS OF INVESTIGATORS REGARDING INFORMED CONSENT

The investigator has the duty to:

1. Communicate to prospective subjects all the information necessary for informed consent.
2. There should not be any restriction on subject's right to ask any questions related to the study as any restriction on this undermines the validity of informed consent.
3. Exclude the possibility of unjustified deception, undue influence and intimidation. Deception of the subject is not permissible. However, sometimes information can be withheld till the completion of study, if such information would jeopardize the validity of research.
4. Seek consent only after the prospective subject is adequately informed. Investigator should not give any unjustifiable assurances to prospective subject, which may influence the subject's decision to participate in the study.
5. As a general rule obtain from each prospective subject a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case of incompetence to do so, a legal guardian or other duly authorised representative.
6. Renew the informed consent of each subject, if there are material changes in the conditions or procedures of the research or new information becomes available during the ongoing trial.
7. Not use intimidation in any form which invalidates informed consent. The investigator must assure prospective subjects that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

ESSENTIAL INFORMATION FOR PROSPECTIVE RESEARCH SUBJECTS

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language he or she is able to understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context:

1. The aims and methods of the research;
2. The expected duration of the subject participation;
3. The benefits that might reasonably be expected as an outcome of research to the subject or to others;

4. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which she / he is being subjected;
5. Any foreseeable risk or discomfort to the subject resulting from participation in the study;
6. Right to prevent use of his / her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research;
7. The extent to which confidentiality of records could be maintained i.e., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;
8. Responsibility of investigators;
9. Free treatment for research related injury by the investigator / institution;
10. Compensation of subjects for disability or death resulting from such injury;
11. Freedom of individual / family to participate and to withdraw from research anytime without penalty or loss of benefits which the subject would otherwise be entitled to;
12. The identity of the research teams and contact persons with address and phone numbers;
13. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;
14. Risk of discovery of biologically sensitive information;
15. Publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

MAMBER SECRETARY
IEC
DR. RMLIMS 73
LUCKNOW

ARCHIVAL OF STUDY DOCUMENTS

The principal investigator (PI) or project director shall maintain, in a designated location, all executed subject consents. These consent forms are to be available for inspection by authorized officials of the DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES -IEC, regulatory agencies and sponsors.

For DCGI/RA regulated test article studies, all signed subject consent forms shall be retained by the principal investigator for the appropriate period(s) as per the prevailing regulations and laws in India.

92

RESEARCH INVOLVING HEALTH RECORDS ONLY

Research projects may involve the study of Patient case files with the stipulations described below. Such studies raise issues of confidentiality that must be carefully addressed by the investigator and the official custodian of the records. If it is anticipated that an individual's records or specimens will likely be used for research purposes, the potential subject should be informed of the potential use of such materials upon entry into the institution or program in which the materials will be developed or collected and be given an opportunity to either provide or refuse consent to such research. Patient case files may always be used or disclosed for research purposes if it has been de-identified and linkage back to a specific patient would not be possible.

To use or disclose identifiable Patient case files without authorization of the research participant, the investigator must accomplish one of the following:

1. Complete and submit an Dr Ram Manohar Lohia Institute of Medical Sciences -IEC Form to request waiver of the requirements for obtaining informed consent;
2. Provide written documentation that the use of disclosure of patient case files is solely used to design a research protocol or to assess feasibility of conducting a study, or;
3. Document that the use or disclosure is solely for research on the patient case files of decedents. Investigators must maintain in their files a letter from the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC identifying the date on which the waiver or alteration of the requirements to obtain informed consent was approved by the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC, and a statement that the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC has determined that the waiver or alteration satisfies the following criteria:
4. The use or disclosure of patient case files involves no more than minimal risk to the research participants;
5. The alteration or waiver will not adversely affect the privacy rights and welfare of the subjects;
6. The research cannot practicably be conducted without the alteration or waiver;
7. The research could not practicably be conducted without access to or the use of the patient case files;
8. The privacy risks to individuals whose Patient case files is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonable be expected to result from the research;
9. There is an adequate plan to protect the identifiers from improper use and disclosure;
10. There is an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, and;
11. There are adequate written assurances that the Patient case files will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or
disclosure of Patient case files would be permitted by this policy.

MAMBER SECRETARY
IEC
DR. RMLIMS 75
LUCKNOW

SITE INSPECTION

It is the responsibility of the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members to perform or designate some qualified agents to perform on its behalf on-site inspection of selected study sites of relevant projects it has approved.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC members or Secretariat in consultation with the Chairperson may initiate an on- site evaluation of a study site for cause or for a routine audit.

Sites will be identified for routine monitoring at the time of approval of the project by the full committee which will be recorded in the minutes.

"For cause" monitoring will be performed at sites for reasons identified by any member of Dr Ram Manohar Lohia Institute of Medical Sciences -IEC, approved by Chairperson. For cause monitoring could be initiated, in any of the following conditions:

1. for high number of protocol violations,
2. large number of studies carried out at the study sites,
3. remarkable SAE reports,
4. high recruitment rate,
5. non-compliance or suspicious conduct, and
6. any other cause as decided by Dr Ram Manohar Lohia Institute of Medical Sciences -IEC.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member / independent monitor will also contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.

The Secretariat will make the appropriate travel arrangements for the Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member / Independent monitor.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member / Independent monitor will review the project files for the study and site profile and make appropriate notes.

The Dr Ram Manohar Lohia Institute of Medical Sciences -IEC member / Independent monitor will check the site for infrastructure and feasibility to conduct the study.

Annexure 20: Conflict of Interest Agreement Form for IEC Members

AGREEMENT ON CONFLICT OF INTEREST

[NOTE-Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records]

I agree to take reasonable measures to protect the Information Act. Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, _____ have read and accept the aforementioned terms and conditions as explained in this Agreement.

I acknowledge that I have received a copy of this Agreement signed by the Ethics Committee Chairperson and me.

_____

Date & Undersigned Signature

_____

Date & Chairman's Signature (Ethics Committee)

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

77

Annexure 21: Invitation to Attend a Meeting as Independent Consultant

To,

_____

_____

_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has nominated you as an independent consultant/observer to evaluate a research protocol submitted to the Institutional Ethics Committee for approval.

You are requested to attend the meeting of IEC on .....at.....and to provide written opinion regarding the assigned research proposal (IEC code no ..... and title of project.....). You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the Bio-Ethics Cell, RMLIMS after the meeting.

Yours faithfully,

Signature of the Member Secretary_____**Date** _____

Name of the Member Secretary _____

Enclosures:

1. Research protocol
2. Confidentiality document

Annexure 22: Invitation to Attend a Meeting as Observer

To,

_____

_____

_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has invited you as an independent observer to see functioning of the Institutional Ethics Committee meeting.

You are requested to attend the meeting of IEC on ……..at..... You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Yours faithfully,

Signature of the Member Secretary_____**Date** _____

Name of the Member Secretary _____

Enclosures:

1. Confidentiality document

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 23:

Confidentiality Document Form for Observer Attendees to IEC, RMLIMS Meetings

I,..... ..... (name and designation) understand that I am invited to attend the IEC meeting scheduled on.....at.....am/pm as an Observer. In the course of the meeting of the IEC some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

.....

Signature

Name: .....

Date.....

98

Annexure 24:
Onsite Adverse Drug Event Reporting Form

1. IEC code no.:

2. Study/Protocol No. (For drug/device trials/any other):

3. Title of project:

4. Principal Investigator:

5. Suspected Adverse Reaction (diagnosis):

6. Report date:

7. Date of onset of SAE:

8. Report type:

a. Initial:

b. Follow up---------- If Follow-up report, state date of Initial report----------

c. Final:

9. Patient information:

a. Patient Initial and Case No./Subject ID.

b. Age: c. Gender:

d. Height: e. Weight:

10. Information related to no. of recruitment/prior SAE and death

	Total number of recruitment at	Total number of SAE (prior) occurred at	Number of similar SAEs (prior) occurred for same study at	Total number of death at
This site				
Other site (s)				

11. Tick which eve is applicable for serious adverse event

A] Expected event [ ] Unexpected event [ ]

B] Hospitalization [ ] Increased hospital stay [ ] Death [ ] Others [ ]

In case of Death, state probable cause of death.....

(If other, please specify: .....

C] No permanent significant functional/cosmetic impairment [ ] Permanent significant functional/cosmetic impairment [ ]

Not applicable [ ]

12. If there was a research related injury/hospitalization, the cost of treatment/

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

hospitalization was borne by: Patient [ ] Institute [ ] Sponsor/CRO [ ]
13. Suspect drug information a. Suspect drug (include generic name) device/intervention: b. Indication(s) for which suspect drug was prescribed or tested: c. Daily dose and regimen : d. Route(s) of administration: e. Dosage Form and Strength: f. Therapy dates (start and stopped date):
14. Did the reaction decline after stopping the drug/procedure (Dechallenge & Rechallenge information): YES [ ] NO [ ] NA [ ]
Concomitant drugs history and lab investigations
15. Concomitant drug (s) and date of administration:
16. Relevant test/laboratory data with dates:
17. Patient relevant history (e.g. diagnosis, allergies):
Reaction information
18. Description of adverse event a. Start date (and time) of onset of reaction: b. Stop date (and time) or duration of reaction: c. Setting (e.g. hospital, out-patient clinic, home, nursing home): d. [Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction, indicate if this is follow-up report and if so, include follow-up information only]:
19. Describe the medical treatment provided for adverse reaction (if any) to the research subject. This is an update on treatment given during hospitalization:
20. Outcome: Resolved [ ] Ongoing [ ] Death [ ]

21. Was the research subject continued on the research protocol?

Yes [ ] No [ ] NA (Mark 'NA' in case of death) [ ]

22. Has this information been communicated to sponsor/CRO/regulatory agencies?

Yes [ ] No [ ]

Provide details if communicated (including date):

23. In your opinion, does this reaction require any alteration in trial protocol?

Yes [ ] No [ ]

If yes then please specify:

24. Causality Assessment:

25. Details about the Investigator

Name:

Address:

Telephone number/email:

Profession (specialty):

_____

Signature of PI

Date _____

Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 25:
Form to Record Recommendations by IEC

• Noted and follow up report requested (if applicable) No [ ] Yes [ ]

• Changes to the protocol recommended? No [ ] Yes [ ]

If yes then recommendations:

_____

_____

• Changes to the informed consent form recommended? No [ ] Yes [ ]

If yes then recommendations:

_____

_____

• Request for additional information [ ]

Additional Information needed:

_____

_____

(Till additional information is received, new recruitment should be withheld)

• Terminate the project [ ]

Reasons for termination:

_____

_____

_____

• Any other including communicated of information to sponsor/CRO/regulatory agencies

_____

_____

Signature of the Member Secretary_____Date_____

Name of the Member Secretary _____

102

Annexure 26:Off-site Safety Reports Classification Form

Note to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Offsite Safety Reports.

IEC Code No.:
Project No.
Project Title:
Subject ID.:
Type of SAE (initial/follow up/any other):

Sr. No.	Questions	
1.	**Is adverse event serious? Yes/No**	
2.	**Is adverse event related to the trial medication/procedure? Yes/No**	
3.	**Is adverse event unexpected? Yes/No**	
4.	**Does warrant any change in protocol, PID? Yes/No**	**If yes, please provide details**

Date of reporting:

_____
Signature of PI

Name_____ **Date**_____

MEMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 27:
Off Site Safety Reports Log

Note to PI:

1. Please log in details of Off Site Safety Report.
2. The following log has to be maintained continuously until the end of the study.
3. This log should be submitted to the Bioethics cell every 3 months and/or along with Continuing Review report.
4. The log must be submitted to the Bioethics cell immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete sets of Offsite Safety Reports need to be sent to Bioethics cell as and when received.

IEC Code No.:
Study/Protocol No. (For drug/device trials/any other):

Project Title:

PI:

No. of Participants enrolled in SGPGI:_____No. of Participants enrolled globally:

_____

No. of subjects on trials at Dr RMLIMS __ No. of death at

No. of subjects on trials at Dr RMLIMS _____ No. of SAE at: _____
No. of death globally:

_____

S. No.	Subject ID/SAE No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Is any change in protocol, PID required on the basis these and of previously reported SAE? Yes/No, if yes, please provide details.

_____
Signature of PI

Name_____ **Date**_____

104

Annexure 28:
Form to Record SAE assessment by SAE monitoring subcommittee

1. Details of the communication between you & Investigator along with other details etc. with regard to the event.
2. Details of examination of event by the SAE monitoring subcommittee, minutes of meeting including cause of death & recommendation on compensation, if any.
3. Details of the documents considered during the assessment of the SAE.
4. Indicate with justification and documentary evidence to as whether the SAE (death) is related/no related to each of the following criteria mentioned under GSR 53 (E) dated 30.01.2013 and rule 122 DAB of the Drugs and Cosmetics Rules.
   (a) Adverse effects of investigational product(S);
   (b) Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
   (c) Failure of investigational product to provide intended therapeutic effect;
   (d) Use of placebo in a placebo-controlled trial;
   (e) Adverse effect due to concomitant medication excluding standard care necessitated as part of approved protocol;
   (f) For injury to a child in-utero because of the participation of parent in clinical trial;
   (g) Any clinical trial procedures involved in the study.
5. Inform the risk Factor depending on the Seriousness and severity of disease, presence of co-morbidity and duration of disease the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as per the compensation formula decided by IEC (available on website: cdsco.nic.in).
   (a) 0.50 terminally ill patients (expected survival not more than (NMT) 6 month).
   (b) 1.0 Patient with high (expected survival between 6 to 27 months)
   (c) 2.0 Patient with moderate risk.
   (d) 3.0 Patient with mild risk.
   (e) 4.0 Healthy Volunteers or subject of no

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 29:
Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):

- Yes_____No_____
- Remarks: _____

2. The consent is taken in language the participant/LAR understands best and is literate in.

- Yes_____No_____
- Remarks: _____

3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording

- Yes_____No_____
- Remarks: _____

4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.

- Yes_____No_____
- Remarks: _____

5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.

- Yes_____No_____
- Remarks: _____

6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.

- Yes_____No_____
- Remarks: _____

7. Explanation or narration by the person conducting the informed consent discussion.

- Yes_____No_____
- Remarks: _____

8. Questions asked by the potential participant/LAR are answered satisfactorily.

- Yes_____No_____
- Remarks: _____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

- Yes_____No_____
- Remarks: _____

10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.

- Yes_____No_____
- Remarks: _____

11. Documentation of signatures of all those involved in the Informed Consent Process.

- Yes_____No_____
- Remarks: _____

12. Clarity and completeness of AV recording

- Yes_____No_____
- Remarks: _____

13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.

- Yes_____No_____

Remarks: _____

MAMBER SECRETARY
IEC
DR. RMLIMS
LUCKNOW

Annexure 30:
Study Completion Report form
(For Non-Interventional Study, 3 copies required)

IEC code no.

Title of the project:

Principal Investigator (Name & Department):

Sponsor:

Date of sanction by IEC:_____Date of start: _____ Date of termination: _____
Duration of project:

Objectives of the study:

Total number of patients to be recruited for the study: _____
Number actually recruited: _____
Protocol deviation/violation (number): _____

Result:_____

_____

Conclusion:

Storage of document for more than 5 years, Yes [ ] No [ ] If yes, for how many years? _____

_____
Signature of PI

Name_____Date_____

References

- Indian Council of Medical Research. *National ethical guidelines for biomedical and health research involving human participants*. New Delhi: Indian Council of Medical Research; 2017. Available from: *https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf*
- ICMR-WHO Country Office India Report of Regional and National Consultation on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants; 2016.
- Ministry of Health and Family Welfare, Government of India. *The Drugs and Cosmetics Act, 1940, and drugs and cosmetics rules, 1945*. New Delhi: Ministry of Health and Family Welfare; 1945. Available from: *http://www.cdsco.nic.in/writereaddata/drugs&cosmeticact.pdf*, accessed on January 16, 2018.
- National Institute of Medical Statistics, ICMR. *Clinical trial registry of India 2007*. National Institute of Medical Statistics, ICMR. Available from: *http://www.ctri.nic.in*, accessed on June 2, 2018.
- Ministry of Health and Family Welfare, Government of India. *The Drugs and Cosmetics Act, 1940, and drugs and cosmetics rules, 1945*. New Delhi: Ministry of Health and Family Welfare; 1945. G.S.R.227(E) 19 March 2019.Available from https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/ last accessed on 15 th December 2019

108