Standard Operating Procedures 2018

Ethics Committee for Human Research

Lady Hardinge Medical College & Associated Hospitals, New Delhi

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Lady Hardinge Medical College & Associated Hospitals,
New Delhi-110001.

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES

सत्यमेव जयते

लेडी हार्डिंग मेडिकल कॉलेज एवं सह अस्पताल
नई दिल्ली-११०००१ (भारत)
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& ASSOCIATED HOSPITALS
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FOREWORD

Medical research is an essential component of medical education. Medical colleges have to contribute in research on national and locally relevant issues in order to make medical care suitable to the population it serves. At the same time, it is equally important to instill in its students the aptitude for research.

Lots of newer developments are taking place in medical science and also in the way medical research is conducted. It is the need of the hour that we at Lady Hardinge Medical College, New Delhi not only remain updated with these developments but also include them in our research projects. Recently, Indian Council of Medical Research have come out with new national ethical guidelines for biomedical research, 2017. Regulations governing research in India have also been updated with several amendments in Drugs and Cosmetics Act, 1940. We need to include these guidelines and provisions in the regulations in our processes of approval of research projects.

I am happy to learn that the Standard Operating Procedures of Ethical Committee for Human Research, Lady Hardinge Medical College have been revised to include all these developments. I am also happy to note that these SOPS are being distributed to all researchers and faculty of LHMC. This will certainly motivate the researchers to conduct ethical research and will also make the process of approval more transparent.

I look forward to see more and more research is done in Lady Hardinge Medial College and Associated Smt Sucehta Kripalni Hospital and Kalawati Saran Children's Hospital, New Delhi.

New Delhi

Dated: 9 March 2018

[Dr Rajiv Garg]

Director

PREFACE

The concepts of bioethics change with changes in the social, cultural, religious and legal scenario in community and country. In view of these changes we, the physicians also need to change the way we practice. As our practices have to be 'evidence based' we need to inculcate these changes in the research we conduct and thus in the 'evidence' generated.

It is important to promote research amongst students and faculty of a medical institute. Ethical Committee for Human Research of Lady Hardinge Medial College, New Delhi has a mandate not only to approve and review medical research but also to promote research. We also need to take care of rights and safety of research participants involved in clinical research. We also need to update the processes of approval and conduct of research in our institute. This has become more necessitated by the revision of National Ethical Guidelines for Biomedical Research by Indian Council of Medial Research in 2017 and the recent amendments in Drugs and Cosmetics Act. 1940 and Rules, 1945.

ECHR-LHMC has revised its Standard Operating Procedures (SOPs) for including the changes in national guidelines and the regulations. It has also made the process of submission of various types of research protocols clearer. It has decided to disseminate these SOPS widely to all researchers and faculty of LHMC to make it more transparent and also to have research proposals in line with these developments in ethics and regulatory affairs in our country.

We, at ECHR hope that the researchers in LHMC will be benefited by these SOPs and more and more research will be conducted and be published in national and international journals of repute.

Dated: 9 March 2018

Dr AK Dutta, Chairperson,
Dr Harish K Pemde, Member Secretary,
Ethics Committee for Human Research,
Lady Hardinge Medical College and
Associated Hospitals, New Delhi.

ACKNOWLEDGEMENT

We acknowledge with gratitude the inspiration and patronage of Dr Rajiv Garg, Director Lady Hardinge Medial College and Associated Hospitals, New Delhi for supporting the revision of these SOPs and also for making it possible to disseminate of it to the researchers and faculty of LHMC.

Inputs from the Chairman and members of Ethical Committee for Human Research of LHMC were important to streamline the SOPs to recent changes in ethical guidelines and regulations. The contribution of Mr. Ezekiel Isaac Malekar and Dr Manish Goel is duly acknowledged for reviewing the manuscript.

We thank and acknowledge the contribution of the previous ECHR of LHMC under the leadership of Dr Kalyan Ganguly (Chairman), Dr JK Sahni (Vice Chairman) and Dr Anunpam Prakash (Member Secretary) who developed the first version of SOPs.

We are thankful to Dr VK Sharma Additional Medical Superintendent, LHMC, New Delhi for his support in bringing out the SOPs in this shape of a booklet and also in enough numbers to reach every faculty of LHMC. We also thank Shri Avanish Singh, Store Officer and the support staff of Stores of LHMC for their logistic support.

Dated: 9 March 2018

Dr AK Dutta, Chairperson,
Dr Harish K Pemde, Member Secretary,
Ethics Committee for Human Research,
Lady Hardinge Medical College and
Associated Hospitals, New Delhi.

Ethics Committee for Human Research

Lady Hardinge Medical College and Associated Hospitals, New Delhi

2017-2020

1.	Dr AK Dutta	Chairperson & Social Scientist, External Member
2.	Dr Harish K Pemde	Member Secretary & Clinician (Pediatrics)
3.	Mr Ezekiel Isaac Malekar	Legal Expert, External Member
4.	Ms Sonia Puri	Public Person, External Member
5.	Dr JS Arora	Hon Gen Secretary, NTWS, External Member
6.	Dr Anil Gurtoo	Clinician (Medicine), Internal Member
7.	Dr Aparna Agarwal	Clinician (Medicine), Internal Member
8.	Dr Sonal Saxena	Basic Scientist (Microbiology), Internal Member
9.	Dr Pikee Saxena	Clinician (Obs & Gynecology), Internal Member
10.	Dr Sangeeta Pahuja	Basic Scientist (Blood Bank), Internal Member
11.	Dr Ekta Malik	Basic Scientist (Biochemistry), Internal Member
12.	Dr Manish Goel	Public Health, Internal Member
13.	Dr Indranil Banerjee	Basic Scientist (Pharmacology), Internal Member

1. Objectives

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee for Human Research so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Research 2017 and National Ethical Guidelines for Biomedical Research Involving Children 2017 (henceforth jointly referred to as ICMR Ethical Guidelines, 2017), and Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 (including the amendments).

The Institutional Ethics Committee for Human Research, Lady Hardinge Medical College & Associated Hospitals, New Delhi-110001, is registered by the DCGI as Ethics Committee for Human Research, Lady Hardinge Medical College & Associated Hospitals, New Delhi, India and will be referred as ECHR in this document.

2. Roles and responsibilities of ECHR

ECHR will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. Human samples/material likely to affect human health will also come under the purview of the ECHR. Internal audit and prescription audit will however, require only an intimation to the ECHR. The goals of research, however important, should never be permitted to override the health and wellbeing of the research subjects.

The ECHR will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice 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.

The mandate of the ECHRs will be to review all research projects involving human

subjects to be conducted at the Institute, irrespective of the funding agency or when no external funding agency is supporting the research.

The ECHR members are responsible for

declaration of Conflict of Interest to the Chairperson / Member Secretary at each meeting and it will be ensured that the same is recorded in the minutes.

3. Composition of ECHR

The Director, LHMC shall constitute the ECHR, of which the Chairperson shall be from outside the institute. The ICMR Ethical Guidelines, 2017 and/or Schedule Y of CDSCO shall be followed while constituting the ECHR.

As the present ECHR has 13 members, a minimum of FIVE persons will be required to compose a quorum. The quorum should include both medical, non-medical members. Minimum one non-affiliated member should be part of quorum. Preferably lay person should be part of quorum. Preferably Chairperson and Member Secretary should be present in all meetings. The Member Secretary shall belong to the same Institution and should conduct the business of the Committee. The affiliations, qualifications, member specific roles and responsibilities of ECHR will be according to the ICMR Ethical Guidelines, 2017 and the same is given in Annexure-1.

If required, subject experts will be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. However, such member(s) will not take part in decision making on the project.

4. Authority under which ECHR is constituted

The Institutional Head (Director) shall constitute the ECHR.

5. Membership requirements

a. The duration of appointment initially shall be for a period of 3 years

b. At the end of 3 years, the committee should be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the ECHR shall be phased out and new members taken in against the vacant posts).

c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.

e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

f. Conflict of interest should be declared by members of the ECHR

if any is there at any time for any project or decision.

6. Quorum requirements

A minimum of 05 members are required to compose a quorum. All decisions will be taken in meetings and not by circulation of project proposals only.

7. Conduct of meeting

The Chairperson will conduct all meetings of the ECHR. If for reasons beyond control, the Chairperson is not available; the members present in the meeting will elect one of the members as Chairperson who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers. The records shall be archived for a period of 5 years from the end of the project. Possibility of e-archiving should be explored in view of the space and cost constraints. Where indicated, archiving may be done for a longer time.

8. Independent consultants

ECHR may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients,

HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the ECHR. Member Secretary can take comments of experts (prior to the meeting) if it is likely to assist the ECHR in the review of the project.

9. Application procedures

a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation; along with a pdf copy by e-mail to the Member-Secretary, ECHR. (Email-lhmcethicom@gmail.com).

b. All relevant documents should be enclosed with application form (Annexure-2).

c. Three copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ECHR. A soft copy should also be submitted in pen drive / CD/DVD or by email to echrlhmc@gmail.com.

d. The funded projects should first be reviewed by Research and Projects Committee (RPC) and non-funded projects by the Institutional Ethics

Sub-Committee (IESC). The protocols for MD/MS/DM/MCh thesis/ dissertations should be submitted to Registrar Office. Non-funded projects include all MD/MS, DM/MCh thesis protocols, student projects (including ICMR-STS projects), thesis projects of other institutions where LHMC faculty is co-supervisor or co-investigator (e.g. MPhil, PhD etc), and investigator initiated projects (other than thesis research projects by PGs/SRs/Faculty). The projects approved by the RPC and IESC would be sent for consideration of ECHR. Thus NO protocol would come to ECHR directly. The research protocols for MD/MS/DM/MCh should reach the ECHR (after review by protocol committee of LHMC) at least 4 weeks before the last date of submission of projects to the university. All research projects (except those of MD/MS/DM/MCh thesis and ICMR STS) should be submitted at one place for onward review by RPC/IESC and then by ECHR.

e. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications. A powerpoint presentation should be kept handy.

f. Presently, the Research and Projects Committee, which has been constituted to review all funded research proposals, shall be submitting the approved proposals to the Member-Secretary, ECHR; so that the same can be considered by the ECHR. Non-funded proposals will be received from the Institutional Ethics Sub-Committee which will be constituted with Vice Principal as Chairperson and the Member-Secretary shall be the same as the Member-Secretary of ECHR/ ECHR. The RPC and the IESC will be constituted by the Institutional Head.

g. The decision will be communicated in writing. In case of Research Proposal where the Principal Investigator (PI) happens to be the Member-Secretary of ECHR, the approval letters and routine correspondence shall be signed/countersigned by the Chairperson of ECHR.

h. If revision is to be made, the revised document (3 printed copies) and also the soft copy (pdf copy) should be submitted within a stipulated period of time as specified in the communication or 2 weeks before the next meeting.

i. Funded projects will be levied a charge of 10% of the total budget of the research projects/clinical trial (5% of the total budget will go to the ECHR/ECHR).

10. Documentation

For a thorough and complete review, all research proposals should be submitted

with the following documents:

1. Cover letter / Submission Performa to the Member Secretary;
2. Type of review requested [Exempt from review/ Expedited review /Full committee review];
3. RPC/IESC/ECHR Application Form for initial review;
4. Protocol*;
5. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable);
6. Case record form/questionnaire;
7. Recruitment procedures: advertisement, notices (if applicable);
8. Patient instruction card, diary, etc. (if applicable);
9. Investigator's brochure (as applicable for drug/biologicals/device trials);
10. Details of funding agency/sponsor (including potential funding agencies) and fund allocation (if applicable) including those related to insurance;
11. Brief curriculum vitae of all the study researchers;
12. A statement on Conflict of Interest, if any;
13. Good Clinical Practices training certificate (preferably within 5 years) of investigators (clinical trials);
14. Any other research ethics/other training evidence;
15. List of ongoing research studies undertaken by the principal investigator (include all studies including PG Thesis, investigator initiated studies, regulatory studies, etc.);
16. Undertaking (Annexure-3) with signatures of investigators [including undertaking to report any serious adverse events (SAE) to ECHR within 24 hours]; undertaking to comply with the relevant national and applicable international guidelines;
17. Regulatory permissions (as applicable);
18. Approval by RPC or Ethics Sub-committee and other relevant administrative approvals (such as HMSC approval for International trials);
19. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable);
20. MoU in case of studies involving collaboration with other institutions/ agencies/ organizations/ companies etc (if applicable);
21. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable);

22. Documentation of clinical trial registration (preferable);

23. Site specific Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable) as per Amended Schedule Y of Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules and Regulations 1945;

24. Site specific Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable);

25. Any additional document(s), as required by EC (such as other EC clearances for multi-centric studies);

26. Ethical issues in the study and plans to address these issues;

27. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available;

30. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants and

31. Any other information relevant to the study.

*The protocol should include the followings-

1. the face page carrying the title of the proposal with signatures of the investigators;

2. brief summary/ lay summary;

3. background with rationale of why a human study is needed to answer the research question;

4. justification of inclusion/exclusion of vulnerable populations;

5. clear research objectives and end points (if applicable);

6. eligibility criteria and participant recruitment procedures;

7. detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;

8. duration of the study;

9. justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;

10. procedure for seeking and obtaining informed consent with a sample of

the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;

11. plan for statistical analysis of the study;
12. plan to maintain the privacy and confidentiality of the study participants;
13. for research involving more than minimal risk, an account of management of risk or injury;
14. proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
15. provision of ancillary care for unrelated illness during the duration of research;
16. an account of storage and maintenance of all data collected during the trial; and
17. plans for publication of results –positive or negative – while maintaining confidentiality of personal information/ identity.
18. ethical considerations and safeguards for protection of participants.

11. Review procedures

a. The meeting of the ECHR will be held almost every month and at least 9-10 meetings will be held annually. Additional meetings may be called upon by the Member-Secretary after approval of the Chairperson.

b. The proposals (as soft copy) will be sent to members at least 10 days in advance by e-mail. For every proposal, one primary and one secondary reviewers will be identified from amongst the ECHR members. These reviewers will first study the submitted documents and enclosures as defined above in 10 and will lead the discussion during ECHR meeting.

c. Decisions will be taken by consensus after discussions in the meeting, and whenever needed voting will be done.

d. Researchers will be invited to offer clarifications, if need be.

e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed. Opinion of independent expert may be taken by mail/email, if needed.

f. ECHR will carry out various types of reviews including (1) Exemption from review, (2) Expedited review, and (3) Full committee review.

g. The decisions will be minuted and Chairperson's approval taken in writing/by email/mail.

12. Elements of review

ECHR will consider the following ethical issues related to reviewing a protocol-

a. Social values;

b. Scientific design and conduct of the study;

c. Benefit-risk assessment;

d. Selection of study population and recruitment of research participants

e. Payment for participation;

f. Protection of research participants' privacy and confidentiality;

g. Community considerations;

h. Qualification of researchers and adequacy assessment of study sites;

i. Disclosure or declaration of potential conflict-of-interest(s);

j. Plan for medical management and compensation for study related injury;

k. Review of the informed consent process;

l. Justification for placebo in control arm, if any;

m. Availability of products after the study, if applicable;

n. Adherence to all regulatory requirements and applicable guidelines;

o. Competence of investigators, research and supporting staff;

p. Facilities and infrastructure of study sites; and

q. Criteria for withdrawal of patients, suspending or terminating the study.

13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review will be specified at the time of the consideration of the original proposal. An expedited review, when designated for a particular proposal during its original discussion, will require the Chairperson, Member-Secretary, one Internal member and one External member. Approvals granted through expedited review must be ratified in next full review committee meeting. Verification of furnished documents and regulatory clearances can be done at the level of the Member-Secretary.

14. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.

b. A member will be required to withdraw from the meeting during

the decision procedure

concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d. Only members can make the decision. The expert consultants will only offer their opinions.

e. Decisions by ECHR may be (1) approved – with or without suggestions or comments, (2) revision with minor modification / amendments, (3) revision- with major modifications for re-submission or (4) not approved.

f. Specific suggestions for modifications and reasons for 'non approval' should be given. No conditional approval would be granted.

g. Modified proposals may be reviewed by an expedited review through identified members.

h. Procedures for appeal by the researchers include representation within four weeks of the decision communicated to the researcher. The appeal should be directed to the Member-Secretary and will need to be taken up in the next ECHR meeting.

15. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing. In case of Research where the Principal Investigator (PI) happens to be the Member-Secretary of ECHR, the decisions of ECHR and other routine correspondence shall be signed/ countersigned by the Chairperson ECHR.

b. Suggestions for modifications, if any, will also be communicated by Member Secretary.

c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by the ECHR should be communicated to the PI.

16. Follow up procedures

The following should be adhered to by PI-

a. Reports of the on-going projects/ studies should be submitted at yearly intervals for review. Status report of the on-going projects [non-thesis projects] should be submitted twice a year by 31 July and 31 January each year.

b. Final report should be submitted at the end of study.

c. All SAEs and the interventions undertaken should be intimated. Causality assessment of all SAEs should also be submitted as early

as possible and within 24 hours of occurrence by PI to ECHR, Head of the Institute, and Sponsor. In next 14 days the sponsor has to submit an analytic report of causality assessment to the ECHR, DCGI and Head of Institution. ECHR has to review it over next 30 days and decide on causality of injury, quantum of injury and compensation to research subject.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted for renewed approval.

f. Any new information related to the study should be communicated.

g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

h. Change of investigators / sites should be informed.

17. Record keeping and archiving

The following documents should be stored.

a. Curriculum Vitae (CV) of all members of ECHR.

b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.

c. Minutes of all meetings duly signed by the Chairperson/Member Secretary.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

e. Copy of all correspondence with members, researchers and other regulatory bodies. Email prints to be archived (certified by the Member-Secretary).

f. Final report of the approved projects.

g. All documents should be archived for five-year period, unless there is a specific requirement for a longer time.

18. Updating ECHR members

a. All relevant new guidelines should be brought to the attention of the members.

b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

19. Validity of the ECHR SOPs

The SOPs enlisted above shall remain in force for a period of three years. However, these may be amended/updated from time to time by the ECHR and same shall be archived appropriately.

Annexure-1

Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S.No.	Members of EC	Definition/Description
1	Chairperson/ Vice Chairperson (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2.	• Member Secretary/ Alternate Member Secretary (optional) Affiliated Qualifications - • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
3.	Basic Medical Scientist(s) Affiliated! non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report

	• In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• For clinical trials, pharmacologist to review the drug safety and pharmacodynacnics.
4.	Clinician(s) Affiliated! non-affiliated Qualifications • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	Legal expertis Affiliated / non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Ctrnirat Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any

6.	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications - • Should be an individual with social/ behavioural science/ philosophy/ religious qoalification and training and/ or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any • Serve as a patient/participant! societal / community representative and bring in ethical and societal concerns.
7.	Lay person Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science' health-related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns_ • Assess on societal aspects if any.

Annexure-2

ETHICS COMMITTEE FOR HUMAN RESEARCH
LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS,
SHAHID BHAGAT SINGH MARG, NEW DELHI-110001, INDIA.

Protocol/Project Submission Form

Model form to be filled by the Principal Investigator (PI) for submission to E.C.H.R..

Proposal Title:

	Name, Designation & Qualification	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI / Collaborators			
1.			
2.			
3.			
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Is the research proposal funded/planned for funding? Yes ☐ NO ☐ *If no skip the next box.*

Sponsor Information:

1. Indian a) Government Central ☐ State ☐ Institutional ☐

b) Private ☐

2. International Government ☐ Private ☐ UN agencies ☐

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget :

1. Type of study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐

Clinical: Single center ☐ Multi-centric ☐ Behavioral ☐
Observational Analytic ☐ Trial ☐

Please describe study type _____

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials: Drug /Vaccines/Device/Herbal Remedies / Others.

I. Does the study involve use of :

Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ ☐ Any other ☐ NA ☐
Alternate System of Medicine

ii. Is it approved and marketed In India☐ UK & Europe☐ USA☐ Other countrys, 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? If yes provide copy.		Yes	No
Date of permission :			
iv. Is it an Investigational New Drug/new equipment/ new procedure.		Yes	No
If yes			
a) Investigator's Brochure submitted		Yes	No
b) In vitro studies data		Yes	No
c) Preclinical Studies done		Yes	No
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV☐			
e). Are you aware if this study /similar study is being done elsewhere ? **If Yes,** attach details		Yes	No
4. Attach copy of the protocol – Introduction, 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 rational sample size with justification.			
5. Subject selection: I. Number of Subject : ii. Duration of study : iii. Will subjects from both sexs be recruited iv. Inclusion / exclusion criteria given		Yes Yes	No No

v. Type of subjects Volunteers☐ Patients ☐

vi. Vulnerable subjects (Tick)

Pregnant women☐ Children☐ Fetus☐ Handicapped☐

Elderly☐ Terminally ill☐ Seriously ill☐ Mentally Challenged☐

Economically & Socially Backward☐ any other (specify)☐

6. Privacy and confidentially

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 Yes No

ii. Use of organs or body fluids Yes No

iii. Use of recombinant/ gene therapy Yes No
If yes, has Department of Biotechnology (DBT) approval Yes No
for rDNA products been obtained? If yes provide copy.

iv. Use of pre-existing/stored/left over samples Yes No

v. Collection for banking/future research Yes No

vi. Use of ionising radiation/radiosotopes
If yes, has Bhaba Atomic Research Center (BARC) approval
for Radioactive Isotopes been obtained? If yes provide copy. Yes No

vii. Use of Infectius/biohazardous specimens Yes No

viii. Proper disposal of material Yes No

ix. Will any sample collected from the patients be sent abroad? Yes No
If Yes, justify with details of collaborators

a). Is the proposal being submitted for clearence from Health Ministry's Screening Committee (HMSC) for International Collaboration? Yes No

b). Sample will be sent abroad because (Tick appropriate box): If so, reason...

Facility not available in India ☐
Facility in India inaccessibl ☐
Facility available but not being accessed. ☐

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

Consent from : (tick the incuded elements)

Understandable language☐
Statement that study involves research☐
Sponsor of study☐
purpose and procedures☐
Risks & Discomforts☐
Benefits☐
Compensation for participation☐
Compensation for study related injury☐
Alternatives to participation☐
Confidentiality of records☐
Contact information☐
Statement that consent is voluntary☐
Rights to withdraw☐
Consent for futer use of biological material☐
Benefits if any on future commercialization☐

*If written concent is not obtained, give reasons:

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

9. Will any advertising be done for recruitment of Subjects?
(posters, flyers, brochure, websites – if sokindly attach a copy) Yes No

10. Risks & Benefits:

i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? Yes No

ii. Is there physical / social / psychological risk / discomfort? Yes No

If Yes, Less than minimal risk ☐
Minimal risk ☐
Minor increase over minimal risk or low risk ☐
More than minimal risk or high risk ☐

iii. Is there a benefit a) to the subject ? Direct☐ Indirect☐

b) benefit to society☐

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? Yes No
If Yes, reporting is done to :

Sponsors☐ Ethics Committee ☐ DSMB☐ Director☐

iii. Is there a plan for interim analysis of data? Yes No

iv. Are there plans for storage and maintenance of all trial database? Yes No

If Yes, for how long ?

12. Is there compensation for participation? Yes No

If Yes, Monetary☐ In kind☐
Specify amount and type:

13. Is there compensation for injury? Yes No

If Yes, by Sponsor ☐ by Investigator ☐

by insurance company ☐ by any other ☐

14. If needed, how compensation will be paid?

By sponsor ☐ By arrangement with insurance ☐

Any other please specify ☐

_____

Attach a copy (Insurance Policy Certificate).

15. Do you have conflict of interest? (financial/nonfinancial) Yes No

If Yes, specify :

Checklist for attached documents: Yes No

Not Applicable

1.	Project proposal – Research protocol	☐	☐
	3 Copies and pdf soft copy	☐	☐
2.	Curriculum Vitae of Investigators	☐	☐
3.	Patient information sheet	☐	☐
4.	Informed Consent form	☐	☐
5.	Investigator's brochure	☐	☐
6.	Copy of advertisements/Information brochures	☐	☐
7.	Copy of case record form and/or questionnaire	☐	☐
8.	GCP Training Certificate	☐	☐
9.	Any other research ethics / other training evidence	☐	☐
10.	List of ongoing research studies undertaken by PI.	☐	☐
11.	Undertaking with signature	☐	☐
12.	Regulatory permission	☐	☐
13.	MOU in case of studies involving collaboration with other institutions.	☐	☐
14.	Clinical trial agreement between sponsor, investigator and head of Institution.	☐	☐

15. Documentation of clinical trial registration.	☐	☐
16. Insurance Policy & Indemnity Policy.	☐	☐
17. Any other document, please spcify_____		

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Annexure-3

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
3. 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 I favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the changers) involved are only logistical or administrative in nature.

(iii) I agree to personally conduct and/or supervise the clinical trial at my site.

(iv) I agree to inform all Subjects; 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 OCP 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 regulatory and GCP 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 / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and OCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

(xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

(xii) 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