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LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS NEW DELHI

INFORMATION AND GUIDELINES FOR RESEARCH PROPOSALS

March 2021

Institutional Scientific Committee
Lady Hardinge Medical College, New Delhi 110001

INFORMATION AND GUIDELINES

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LHMC: RESEARCH AND PROJECT COMMITTEE
INFORMATION AND GUIDELINES

1. Background:

The Director, LHMC has reconstituted Institutional Scientific Committee (LHMC-ISC) by amalgamating the Research & Projects Committee (RPC) and the Institutional Ethics Sub-Committee (IESC) with the prime objective of facilitating and monitoring funded & non funded clinical, biomedical and epidemiological research being conducted by various departments of LHMC and Associated Hospitals. (Vide office order no. NNM/9120/ISC/2021/1618 dated 23rd Feb'2021)

2. Terms of Reference:

Following are the specific Terms of Reference of the Institutional Scientific Committee:

- To critically assess scientific content of
  a. funded and non-funded research projects prepared by departments of LHMC and associated hospitals in various disciplines (bio-medical, clinical, epidemiological, behavioral and social)
  b. ICMR approved students STS projects

- To review, comment and recommend funded and non-funded research projects based on merit and strength of the protocol to the Institutional Ethics Committee for Human Research (ECHR) for consideration from ethical point-of-view

- To facilitate implementation of projects awarded to LHMC and associated hospitals and review their progress

LHMC-ISC will meet at least once every two months or as and when required. The expenditure for the functioning of LHMC-ISC will be regulated at par and in accordance with the guidelines issued by ICMR for research related meetings.

3. Scope:

LHMC-ISC will review and recommend all funded and non-funded research proposals including those involving human participants for support and consideration by LHMC ECHR. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects. LHMC-ISC 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.

4. Quorum requirements:

A minimum of 5 members are required to compose a quorum ordinarily. All decisions should be taken in meetings and not by circulation of project proposals except in extraordinary circumstances where an expedited approval is indicated or the project has been earlier discussed in the ISC

5. Conduct of Meetings:

- ISC Meetings would be presided over by the Vice Principal who will be an ex officio Chairperson of the ISC.
- 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 members of the ISC and the PI/researchers
- All members of the ISC should maintain absolute confidentiality of all discussions during the meeting.
- It is essential for all members of ISC to declare in advance all forms of Conflicts of Interest (COI) in writing. COI include financial, relationship, patient care related, commercialization etc. All such COIs would be recorded and minuted.

6. Guidelines for Research Proposals

- All the research proposals will be submitted by the investigator directly to the Institutional Ethics Committee (IEC) which will forward a copy to Member Secretary, Institutional Scientific Committee (ISC)

- For all funded projects, a copy will be forwarded by the IEC to the
  i. Finance and Procurement Committee (FPC) – AMS (Store)
  ii. Director

- For all funded projects, all new recruitments will be made by PI with atleast one member of FPC in the selection committee. If only some honorarium is being paid to an existing clinical research scholar, it only needs to be intimated to FPC. The FPC has to be in loop for all major equipment purchases.

- **There will be a single platform presentation of all proposals which will be attended by all members of the following committees jointly**
  i. ECHR
  ii. Institutional Scientific Committee
  iii. Finance & Procurement Committee for all funded projects - atleast 2 members

- The doubts raised by any of the Committee members of any of these committees will be clarified by the investigator on a single platform there and then. Minutes of the meeting will be prepared separately by the ISC, which will forward it the ECHR, documenting their objections /suggested modifications /clarifications required /approval. The FPC will also give their approval /suggested amendments /clarifications /objections in writing to the IEC for all funded projects.

- The ECHR will issue a final letter of approval /objection/clarification required before approval /resubmission with suggested modifications to the investigator.

Research Proposals will be submitted giving details of the proposal generally under the following headings:

- Introduction,
- Review of literature,
- Rationale and Justification,
- Aim(s) & Objectives,
- Research Design, Methodology and Tools,
- Outcome measures,
- Statistical analysis
- Plans for publication of results

Information in model form (Form 1) should be provided by the Principal Investigator to IEC for further examination by the ISC as well as IEC.

For a thorough and complete review, all research proposals should be submitted to ECHR with the following documents/information:

Four (4) consolidated copies of the following documents should be submitted and a consolidated PDF should be mailed to lhmcisc@gmail.com

- Form 1 (HOD)
- Form 2 (Checklist and PI details)
- Protocol
- Budget details- This should be itemized, and details of any financial benefits to the PI should be mentioned.
- PIS in English and Hindi (in the required format)
- Consent form in English and Hindi
- Brief CV of the investigators
- Undertaking (Form 3)

All Research Projects should be routed to the IEC through the HODs. The HODs would give their comments and recommendation on a structured format (Form 1). HOD should comment on following issues:

- Whether routine patient care would be compromised as a result of this project?
- Whether functioning of the department would be affected?
- Would the project lead to improvement in the skills of manpower?

HOD would give his/her recommendation after looking into above mentioned aspects. In cases a proposal is not recommended by HOD, justification for the same would have to be mentioned specifically.

All the proposals sent to the ISC within 2 weeks of a scheduled meeting will be reviewed. All incomplete proposals and those submitted in an inappropriate form will not be considered by the ISC.

7. Review procedures:

- Vetting of Proposals would be done in ISC meetings only, and NOT by circulation.
- Proposals would be circulated to members beforehand for its expeditious processing during the meeting.
- The date of meeting of ISC will be intimated to all members of the ISC and the PI/ Researcher.
- The meeting of the LHMC-ISC will be held on scheduled intervals as prescribed. Additional meetings may be held as and when the proposals are received for review.
- LHMC-ISC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. They are required to give their specialized views and will generally not take part in the decision making process. However, the chairperson may invite subject-experts to take part in the meeting of the ISC in specific circumstances

- Decisions will be taken by consensus after discussions
- The decisions shall be minuted and circulated to all members, after obtaining Chairman's approval.
- Decision regarding a proposal would ordinarily be communicated to PI within 7 days of finalization of the minutes of the ISC meeting.

8. Elements of Review

The proposals will be objectively examined in depth in a transparent and unbiased manner and assessed on the following parameters:

- Strength of Scientific design of the study.
- Relevance and potential benefits of the study
- Competence of investigators, research and supporting staff
- Facilities and infrastructure of study sites
- Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria
- Examination of predictable risks/harms and management of research related injuries, adverse events and compensation provisions.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and confidentiality.
- Plans for data analysis and reporting

9. Decision-making

- Members will discuss the various issues before arriving at a consensus decision.
- A member should 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.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.

The decision of the ISC will be communicated by the Member Secretary in writing. In case a proposal has been rejected, ISC will also inform the reasons for rejection to the ECHR.

10. Expedited Review

In case the ISC returns the proposal for major revision, the revised protocol would also have to be submitted for re-examination by the ISC. However, for minor revisions, after checking that the appropriate corrections have been made, the member secretary may issue the approval.
Expedited review may be taken up in cases of nationally relevant proposals requiring urgent review. Such reviews will be carried out by identified members convened by the Chairman to expedite decision making. The nature of the applications, amendments, and other considerations that will be eligible for expedited review will be specified and approved by ISC.

11. Follow up procedures

- Progress reports on approved projects should be submitted annually for review.
- Any changes in protocol, adverse events, premature closure, staff joining or leaving should also be intimated to the ISC on an as and when basis.
- Final report should be submitted at the end of the study.
- Protocol deviation, if any, should be informed with adequate justifications. Any amendment to the protocol should be resubmitted for renewed approval
- Any new information related to the study should be communicated.
- Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites should be informed to the ISC.
-

12. Record keeping and Archiving

The ISC will compile following information and documents

- Copy of all study protocols with enclosed documents, progress reports and final reports
- Minutes of all meetings duly signed by the Chairperson.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Final report of the approved projects.
- Scientific Publications of all departments of LHMC & Associated Hospitals
- Annual Report on **Funded and non-funded** Research Work carried out at LHMC and Associated Hospitals and material for inclusion in Annual Report of LHMC and Annual Report of the Ministry of Health & FW
- All documents should be archived for Three (3) years from the closure of the project.

ANNEXURE 1

LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS COMPOSITION OF INSTITUTIONAL SCIENTIFIC COMMITTEE

1.	Dr. Aparna Agrawal	Vice-Principal	Chairperson
2.	Dr. Anil Gurtoo	Director Professor of Medicine	Advisor
3.	Dr. Sunita Sharma	Dir. Prof & Head of Pathology	Member
4.	Dr. Manju Puri	Dir. Prof & Head of Obstt. & Gynae	Member
5.	Dr. Vibhu Mendiratta	Dir. Prof & Head of Dermatology	Member
6.	Dr. Anju Seth	Director Professor of Pediatrics	Member
7.	Dr. J G Prasunna	Director Professor of Community Medicine	Member
8.	Dr. Varinder Singh	Director professor of Pediatrics	Member
9.	Dr. Ranju Singh	Dir. Prof of Aneasthesia	Member
10.	Dr. Archana Puri	Prof of Pediatric Surgery	Member
11.	Dr. Gyan Saurabh	Professor of Surgery	Member Secretary
12.	Ex- Director (In service at LHMC)		Advisor

Annexure 2: PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Hindi, in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website, which can be understood by them:

i) Title of the Study/Project
ii) Aims and methods of the research.
iii) Expected duration of the subject participation.
iv) The benefits to be expected from the research to the subject or to others.
v) Any risk to the subject associated with the study.
vi) Provision of free treatment for research related injury.
vii) Compensation of subjects for disability or death resulting from such injury.
viii) Maintenance of confidentiality of records.
ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
x) Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned.
xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.
xii) Telephone number/contact number of Principal Investigator and Co investigator at the top of each page.
xiii) In case of drug trials: a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned b) Initial Bio equivalent study of the drug / references should be provided.
xiv) Statement that there is a possibility of failure of Investigational Product (IP) to provide intended therapeutic effect
xv) Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect
xvi) Plans for publication including photographs

PARTICIPANT INFORMED CONSENT FORM (PICF)

Protocol / Study number: _____
Participant identification number for this trial: _____
Title of project: _____

_____

_
Name of Principal Investigator:_____Tel. No(s)._____
The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from LHMC. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter / Spouse of: _____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Name and Signatures of the Principal Investigator/Research staff taking consent
Date:
Place:

In case of illiterate participant giving thumb impression, the consent should be taken in the presence of impartial witness
Witness

Signature

Form 1

LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS
INSTITUTIONAL ETHICS COMMITTEE

Form for Comments of Head of Department

To,

Chairperson
Institutional Ethics Committee
LHMC & Associated Hospitals
New Delhi

Title of the Project:_____

Principal Investigator:_____

Date of submission by PI to HOD: _____

I have gone through the Protocol along with Annexures submitted by PI for consideration of IEC and have following comments to offer:

1	Whether routine patient care would be compromised as a result of this project?	Yes/ No /NA
2	Whether functioning of the department would be adversely affected?	Yes/ No /NA
3	Would the project lead to improvement in the skills of faculty/staff of the Department	Yes/ No /NA
4	Whether PI/Co-PI has adequate capacity to undertake the Project?	Yes/ No /NA
5	Whether facilities and/or equipment available in the Department would be made available to PI and his team?	Yes/ No /NA
6	Any other comment on the Project	

The Proposal is forwarded and

(a) Recommended for approval by ISC/IEC
(b) Recommended subject to above comments
(c) Not-recommended due to following reasons:

Date

Name and Signature with seal

Form 2

Form to be filled by the Principal Investigator (PI) for submission to Institute's Ethics Committee for Human Research (ECHR)

Please fill the form completely. Incomplete forms are liable to rejection.

Reference No.	*To be entered by IEC)*

Proposal Title:

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

Tick appropriately

Sponsor Information:

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

2. International Government ☐ Private ☐ UN agencies ☐

3. Industry National ☐ Multinational ☐

Name and Contact Address of Sponsor:

Total Budget:

A. Does the budget reflect a) Institutional overheads Y/N Please give details? _____
B. Any payments / benefits to the investigators Y/N If Yes, Please give details_____

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

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

2. Status of Review: New ☐ Revised ☐

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

Does the study involve use of:

Drug ☐ Devices ☐ Vaccines ☐

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

i. 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 :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
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?	Yes	No
If Yes, attach details		

i. **Brief description of the proposal** – 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 rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i.	Number of Subjects :		
ii.	Duration of study :		
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)

Pregnant women ☐ Children ☐ Fetus ☐ Handicapped ☐

Elderly ☐ Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐

Economically & Socially Backward ☐ any other (specify) ☐

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	Yes	No
iii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	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 of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

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

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

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

Consent form: (tick the included elements)

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			

*If written consent 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 so kindly 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? **If Yes,** Less than Minimal Risk ☐ Minimal Risk ☐ Minor increase over minimal risk or Low risk ☐ More than minor increase or High risk ☐	Yes	No
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? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial databases? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify:** **In case the investigator(s) are receiving any payment or direct benefit due to the project, it may be considered a conflict of interest and should be detailed here. NOTE: It shall be the responsibility of the investigator(s) to take Appropriate administrative permissions for the pecuniary benefits *a priori.***	Yes Noted	No

Checklist for attached documents: 4 consolidated copies of the following

Form 1, Form 2, Form 3	☐
Project proposal	☐
Patient information sheet in English and Hindi	☐
Informed Consent form in English and Hindi	☐
Investigator's brochure for recruiting subjects	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Copy of clinical trial protocol and/or questionnaire	☐

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Form-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:

A. 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

B. 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 Funding agency/Sponsor and prior review and documented approval) and favorable opinion from the ISC and Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when changers involved are any logistical or administrative in nature.

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

D. 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.

E. I agree to report to the ECHR all adverse experiences that occur in the course of the investigation(s) in accordance with regulatory and GCP guidelines.

F. I have read and understood the information in the investigator's brochure, including the potential risks and side effects of the intervention.

G. I agree to maintain adequate and accurate records and t make those records available for adult / inspection by the Sponsor, Ethics Committee, Licensing Authority or Their authorized representatives, in accordance with regulatory and GCP provisions, I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

H. I 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 trials

I. I agree to inform all unexpected serious adverse events to the Funding agency/Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

J. I agree to promptly report the ethics Committee all changes in the clinical trial activates and all unanticipated problems involving risks to human Subjects or others

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

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

Signature of PI with date