LADY HARDINGE MEDICAL COLLEGE
& ASSOCIATED HOSPITALS
NEW DELHI

INFORMATION AND GUIDELINES FOR RESEARCH PROPOSALS

November 2018

Research & Project Committee
Lady Hardinge Medical College, New Delhi 110001

LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS

RESEARCH AND PROJECT COMMITTEE

INFORMATION AND GUIDELINES

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LHMC: RESEARCH AND PROJECT COMMITTEE
INFORMATION AND GUIDELINES

1. Background:

The Director, LHMC has constituted Research & Project Committee (LHMC-RPC) with the prime objective of facilitating and monitoring funded clinical, biomedical and epidemiological research being conducted by various departments of LHMC and Associated Hospitals.

2. Terms of Reference:

Following are the specific Terms of Reference of the Research & Project Committee:

- To critically assess funded research projects prepared by departments of LHMC and associated hospitals in various disciplines (bio-medical, clinical, epidemiological, behavioral and social)
- To forward and recommend funded research projects based on merit and strength of the protocol to the Institutional Ethics Committee ECHR for consideration from ethical point-of-view
- To build capacity of various departments by orientation of their faculty and resident doctors and other research staff on research design, methodology, data analysis and scientific documentation for publication in peer-reviewed journals
- To facilitate implementation of projects awarded to LHMC and associated hospitals and review their progress
- To build networks, alliances and partnerships with research organizations and academic institutions for multi-centric projects

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

3. Scope:

LHMC-RPC will review and recommend all 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-RPC 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.

As per new ECHR guidelines, dissertations submitted by Post-graduate Students or non-funded projects are to be sent to the Ethics subcommittee directly and not to be routed through RPC.

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 RPC.

5. Conduct of Meetings:

- RPC Meetings would be presided over by the Chairperson. The meeting would be chaired by Co-chairperson when Chairperson is not available on scheduled date of 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 members of the RPC and the PI/researchers
- All members of the RPC should maintain absolute confidentiality of all discussions during the meeting.
- It is essential for all members of RPC 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.
- The RPC would meet at least quarterly and more frequently if situation demands (depending on quantum of work).
- An effort shall be made to synchronize the RPC and ECHR meetings, so that the RPC meeting will be held at least 2 weeks before the ECHR meeting.

6. Guidelines for Research Proposals

Research Proposals will be submitted to the LHMC-RPC 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 for examination by the RPC as well as IEC.

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

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

The proposals should be submitted to the Chair-person of LHMC-RPC and not to the Director, LHMC. All the proposals sent to the RPC 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 RPC.

7. Review procedures:

- Vetting of Proposals would be done in RPC 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 RPC will be intimated to all members of the RPC and the PI/ Researcher.
- The meeting of the LHMC-RPC will be held on scheduled intervals as prescribed. Additional meetings may be held as and when the proposals are received for review.
- Researchers will be invited to make presentation on the proposal and/or for clarifications if need be.
- LHMC-RPC 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 RPC 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 RPC 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
- Budgetary provision- especially the institutional overheads and compensation costs
- Whether the investigator(s) are receiving any pecuniary benefits and they have sought administrative approval for the same.

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 RPC will be communicated by the Member Secretary in writing to the PI. Suggestions for modifications, if any, will be sent to the PI in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting. In case a proposal has been rejected, RPC will also inform the reasons for rejection to the researchers.

10.Expedited Review

In case the RPC returns the proposal for major revision, the revised protocol would also have to be submitted in 4 copies for re-examination by the RPC. 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 RPC.

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 RPC 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 RPC.

12. Record keeping and Archiving

The RPC 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** 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 seven (7) years from the closure of the project.

13. Capacity Building for Research

- The RPC will proactively develop capacity for Research by Faculty, Residents and Staff of LHMC and Associated Hospitals.
- RPC will circulate all relevant new guidelines to the members of RPC and Heads of the Departments.
- Members of RPC, Faculty and Researchers of LHMC would be encouraged to publish scientific papers in peer reviewed national and international journals and presentations in national and international conferences
- Capacity building through training relating to clinical, biomedical, epidemiological research will be facilitated for maintaining high quality of research by the institution.

14. Appointment of Research Staff

- Recruitment of Research Staff will be made through HR sub-committee only.
- The PI will coordinate with the Member Secretary for following the procedure for advertisement and screening of candidates.
- Applications for Research Staff will be invited by putting up notification through LHMC website and circulars posted in various Departments. The notification will clearly indicate requisite qualifications, experience, job responsibilities, duration of appointment and remuneration.
- HR sub-committee will scrutinize applications for eligibility. In case of large number of eligible applicants, the sub-committee may short-list eligible applicants based on pre-defined criteria and/or written/ skills test.
- Short-listed eligible applicants shall appear for an interview before the Interview Committee which would have at least 3 members from RPC HR subcomittee, the PI of the project, and one co-opted member (subject expert).
- Selected candidates will be recommended for appointment to Director, LHMC for approval.
- Letters of appointment will be issued by the Chairperson/Member Secretary RPC LHMC within 7 days of approval. The appointments will be strictly “on contract” and an undertaking in the prescribed format will be signed by the selected candidates in this regard.
- Remuneration to staff would be as per norms of Funding Agency; where these are not specified ICMR norms may be applied.
- HR sub-committee would prepare a panel of candidates with selected candidates and a waiting list for a particular position. Candidates would be called up for joining from this panel. If a candidate resigns the post, the next candidate on the panel waiting list may be called for joining if this resignation occurs within 12 months of the interview. If more than 12 months have passed since the interview, fresh interviews should be conducted.

15. Procurement of Goods

- The procurement subcommittee will decide on the procurement of goods (value Rs 25,000 to Rs 2, 50,000) as per GFR guidelines issued by the Government.
- For purchase of goods up to the value of Rs 25,000: These goods may be purchased without quotation. Purchase of goods up to the value of Rs 25,000 only on each occasion may be made without inviting quotations or bids on the basis of a certificate to be recorded by the PI in the following format:
  "I, am personally satisfied that these goods purchased are of the requisite quality and specification and have been purchased from a reliable supplier at a reasonable price."
- Purchase of goods costing above Rs 25,000 and upto Rs 2, 50,000 on each occasion (Limited quotation) may be made on the recommendations of the procurement subcommittee of the RPC. The committee will survey the market to ascertain the reasonableness of rate, quality and specifications and identify the appropriate supplier. Before recommending the placement of the purchase order, the members of the committee will jointly record a certificate as under:
  "Certified that we, members of the purchase committee are jointly and individually satisfied that the goods recommended for purchase are of the requisite specification and quality, priced at the prevailing market rate and the supplier recommended is reliable and competent to supply the goods in question, and is not debarred by Department of Commerce/Ministry of Health and family welfare.
- For purchase of goods costing between Rs 2.5 Lakhs to Rs 25 Lakhs, the procedure will be by Limited Tender Enquiry as per GFR Rule162 with the approval of the Director LHMC.
- Minutes of the meeting of the Procurement sub-committee will be submitted to the Director LHMC through Chairperson of the RPC committee for approval.
- Orders for procurement may be issued by the PI of the project within 7 days of approval by RPC.
- Repeat orders should also follow the same procedure and the PI shall provide an account of the consumption of goods and utilization report with the demand.
- Any materials/goods which are procured under the project could be retained by to the department for appropriate utilization and maintenance after the project is over. The custodian of such material can be decided by the concerned PI in consultation with the funding agency.

16. Financial Management

- The Finance sub-committee shall be constituted by Director, LHMC and will look into the financial issues of research and non-research projects.
- A copy of the sanctioned budget letter must be provided by the PI to the RPC upon approval of the project by the funding agency.
- The institutional overhead charges (3-5% in case of govt. agency funded projects and 10% in case of pharma company funded projects) must be submitted to the RPC in the form of cheque made to "Director LHMC". These would be submitted to the DDO to be deposited in the Director LHMC Central Back account by the RPC through proper channel.
- This overhead expenses from various projects is expected to create a corpus which can be used for capacity building of various departments by orientation of their faculty and resident doctors and other research staff on research design, methodology, data analysis and scientific documentation for publication in peer-reviewed journals

ANNEXURE 1

LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS
COMPOSITION OF RESEARCH & PROJECTS COMMITTEE

1.	Dr. Varinder Singh	Director professor of Pediatrics	Chairperson
2.	Dr. Anju Jain	Dir. Prof & Head of Biochemistry	Member
3.	Dr. Sunita Sharma	Dir. Prof & Head of Pathology	Member
4.	Dr. Ravinder Kaur	Dir. Prof & Head of Microbiology	Member
5.	Dr .H.S. Rehan	Dir. Prof & Head of Pharmacology	Member
6.	Dr. Manju Puri	Dir. Prof of Obstt. & Gynae	Member
7.	Dr. Reena Yadav	Dir. Prof of Obstt. & Gynae	Member
8.	Dr. Vibhu Mendiratta	Dir. Prof of Dermatology	Member
9.	Dr. Ranju Singh	Dir. Prof of Aneasthesia	Member
10.	Dr. Manoj Andley	Dir. Prof of Surgery	Member
11.	Dr. Gyan Saurabh	Professor of Surgery	Member
12.	Dr. Ghan Shyam Pangtey	Professor of Medicine	Member
13.	Dr. Ritika Sood	Assoc Prof of Medicine	Member
14.	Dr. Suvasini Sharma	Assoc. Prof. of Pediatrics	Member Secretary
15.	Mr. Neeraj Sachdeva	Deputy Director (Administration)	Member
16.	Mr. Mukesh Kumar	Senior Account Officer, LHMC	Member

RPC HR SUB-COMMITTEE

A.	Dr. Varinder Singh	Director Professor of Pediatrics	Chairperson
B.	Dr. Anju Jain	Director Professor & HOD Biochemistry	Member
C.	Dr. H.S.Rehan	Director Professor & HOD Pharmacology	Member
D.	Dr. Ravinder Kaur	Director Professor & HOD Microbiology	Member
E.	Dr. Sunita Sharma	Director Professor & HOD Pathology	Member
F.	Dr. Suvasini Sharma	Assoc Professor of Pediatrics	Member Secretary
G.		PI of Project	Member
H.		External Subject Expert	Member
I.		Deputy Director (Administration) (Ex-Officio)	Member

FINANCIAL SUB-COMMITTEE

i.	Dr. Varinder Singh	Director Professor of Pediatrics	Chairperson
ii.	Dr. Anju Jain	Director Professor & HOD Biochemistry	Member
iii.	Dr. Sunita Sharma	Director Professor & HOD Pathology	Member
iv.	Dr. Manju Puri	Director Professor of Obstt. & Gynae	Member
v.	Dr. Ranju Singh	Director Professor of Aneasthesia	Member
vi.	Dr. Suvasini Sharma	Assoc. Professor of Pediatrics	Member Secretary
vii.		Accounts Officer(Ex-Officio)	Member

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
RESEARCH AND PROJECT COMMITTEE

Form for Comments of Head of Department

To
Chairperson
Research & Projects 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 RPC 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 RPC/IEC
(b) Recommended subject to above comments
(c) Not-recommended due to following reasons:

Signature

(Name & Designation with seal)

Date

Form 2

Form to be filled by the Principal Investigator (PI) for submission to Research & Project Committee (RPC) and 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 RPC)*

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 elswhere ?	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	Yes	No
i. Use of fetal tissue or abortus		
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? I**f 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 RPC 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