STANDARD OPERATIVE PROCEDURES OF INSTITUTIONAL RESEARCH CELL, LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS, NEW DELHI

March 2026

CONTENTS

This document is a living document. This framework will be expected to evolve and change in correlation with evolving technologies and further developments.

A. OBJECTIVES OF THE INSTITUTIONAL RESEARCH CELL (IRC)

1. **Promote Scientific and Academic Excellence:**
   To foster a culture of high-quality, ethical, methodologically sound research among faculty, residents, students, and research staff.
2. **Ensure Scientific Rigor:**
   To review the scientific merit, feasibility, rationale, methodology, and relevance of all research proposals before they are submitted to the Institutional Ethics Committee (IEC) or external sponsors.
3. **Administrative Facilitation for funded extramural and intramural proposals:**
   To act as the nodal body for scientific clearance and end to end facilitation of all funded research projects extramural and intramural, whenever the intramural funding facility is initiated.
4. **Strengthen Research Infrastructure:**
   To streamline pre-submission guidance, internal review mechanisms, and interdepartmental collaborations and facilitate post-approval execution of the project including staff recruitment, procurement of equipment etc.
5. **Monitor Scientific Progress:**
   To ensure scientific validity throughout the project cycle, including amendments, interim reports, and final outcomes.

B. SCOPE & MANDATE

1. **Applicability:**
   Institutional Research Cell shall function as the Institute's **single window academic body and** shall review *all* funded research proposals conducted at LHMC and its associated hospitals.
2. **Scientific Review Role:**
   Institutional Research Cell does **not** replace the IEC. Both function independently; IEC review begins only **after** IRC approval.
3. **Coverage: All National and International funded studies including:**
   - Clinical trials
   - Public health research
   - Diagnostics/biomarker studies
   - Observational studies
   - Laboratory-based research

- Epidemiological studies
- Registries
- Qualitative research
- Multi-centric studies
- Concept note- Initial Technical Feasibility review will be followed by complete review as per IRC protocols but the concept note has to be submitted at least 1 week prior to the last date of submission to the funding agency. The PI has to give an undertaking for the same.
- Collaborations & Agreements: Institutional Research Cell will review academic and research-related collaborations to ensure alignment with institutional interests by facilitating MoUs / Material Transfer Agreement (MTAs)/ Clinical Trial Agreement (CTA) / Confidentiality Disclosure Agreement (CDAs), data sharing (multi/cross site studies) with other institutes/organizations for the purpose of research.
- IRC will specifically look for the Institutional responsibility and interest in terms of Tripartite Agreement, terms and condition of the Research Grant.

4. Following type of projects will NOT come under the purview of IRC

- Non funded projects including STS projects of ICMR will be examined by 3 faculty members of the department (in case of smaller departments, members from related departments may be co-opted) and forwarded to IEC through the HOD*.
- Post Graduate Thesis will be reviewed by Post graduate cell after review in the department and sent to the IEC
- All external projects in which faculty of the institute are not involved will not be examined by the IRC
- Purely service delivery or implementation related activities with external funding from the Government/ private funding //non funded facility will not be in the purview of IRC. However, any research conducted by these services will follow the same rules for funded and non-funded projects as mentioned above.
- Once IRC starts functioning, the Institutional Scientific Committee will cease to exist

*HOD must forward the project to IEC with his/her comments conveying approval or otherwise within a period not exceeding 15 days from receipt of the project.

C. COMMITTEE COMPOSITION & MEETING SCHEDULE

1. Composition

- **Chairperson:** (Principal, LHMC)
- **Co- Chairperson**
- **Member Secretary**
- **Members:** Representatives from major clinical and nonclinical departments, one of them would be designated as **Link officer of member secretary**,
- **Ex-officio members** for HR and financial matters will be Deputy Director (Administration), Drawing and Disbursing officer (DDO), and store officer, LHMC. They will not be the full time members but will provide expertise regarding above stated matters

COMPOSITION OF INSTITUTIONAL RESEARCH CELL, LHMC, MARCH 2026			
1.	Principal	LHMC	Chairperson
2.	Dr. Anju Seth	Dir. Professor, Paediatrics	Member
3.	Dr. Jyoti Khandekar	Dir. Professor, Community Medicine	Co- Chairperson
4.	Dr Praveen Kumar	Dir. Professor, Paediatrics	Member
5.	Dr. Kiran Agarwal	Dir. Professor, Obstetrics and Gynaecology	Member
6.	Dr. Lalit Gupta	Dir. Professor, Pharmacology	Member
7.	Dr Pikee Saxena	Dir. Professor, Obstt. & Gynae.	Member Secretary
8.	Dr. Anupam Prakash	Dir. Professor, Medicine	Member
9.	Dr. Sangeeta Pahuja	Dir. Professor, Immunohematology and blood transfusion	Member
10.	Dr. Nitin Hayaran	Dir. Professor, Anaesthesia	Member
11.	Dr. Sudipta Saha	Dir. Professor, Surgery	Member
12.	Dr. Ramesh Agarwal	Professor, Medicine	Member
13.	Dr Parijat Gogoi	Professor, Biochemistry	Link Officer – Member Secretary
14.	Dr. Anu Maheshwari	Professor, Paediatrics	Member
15.	Dr. Sanjib Gogoi	Professor, Microbiology	Member
16.	Dr. Mamta	Professor, Community Medicine	Member
17.	Dr. Bhavuk Garg	Professor, Psychiatry	Member
18.		DD(A)	Ex officio member
19.		DDO	Ex officio member
20.		Store Officer	Ex officio member

21	Dr Prerna Kukreti	Member Secretary IEC	Ex officio member

Subject experts will be co-opted as and when required. They will be provided with the copy of the project well in advance on case-to-case basis and will be invited to attend the meeting of the IRC when it will be held.

Secretarial staff –

- Dedicated administrative officer,
- Data Entry Operator,
- MTS

Sub-committees within the IRC:

- **Human resource sub-committee**
- **Procurement sub-committee**
- **Monitoring sub-committees**

COMPOSITION OF IRC SUB-COMMITTEES

HUMAN RESOURCE SUB-COMMITTEE (for staff recruitment)		
1.	Principal/ Co-Chair IRC	Chairperson
2.	PI	Member
3.	Co-PI	Member
4.	HOD or nominated faculty	Member
5.	Member secretary IRC/ link officer	Member
6.	Administrative officer IRC	Member
7.	DDA	Ex officio member
PROCUREMENT SUB-COMMITTEE (for procuring equipment, kits, consumables etc)		
1.	Principal/ Co-Chair IRC	Chairperson
2.	PI	Member
3	Co-PI / Faculty from user department	Member
4.	Member secretary RC/ link officer	Member
5.	Store officer of SSKH or KSCH for procurement committee	Ex officio Member
6.	Administrative officer IRC	Member

2.

MONITORING SUB-COMMITTEE (for follow-up of projects underway)		
1.	Principal/ Co-Chair IRC	Chairperson
2.	Member secretary RC/ link officer	Member
3.	Member of IRC	Member
4.	Administrative officer IRC	Member

Meeting Frequency and reviews

- **Regular Meetings:**
  - Held during the **3rd or 4th week** of the month, **once in 1–2 months** depending on the proposals received.
- **Quorum:**
  - **50% of members**, including **Chair/Co-Chair IRC and Member Secretary (or designated link officer).**
- **Urgent/Circulation Review:**
  - Conducted only for **time-sensitive submissions** with justification.
  - Decisions will be **ratified in the next regular meeting**.
- **Regular Project Review:**
  - All funded projects to be reviewed by **at least three reviewers**:
    - **Two IRC members**
    - **One co-opted subject expert**
  - Reviewers will receive a **copy of the project in advance and will be invited to attend the scheduled meeting.**
  - **It will be mandatory to present the project protocol in IRC meeting.**
  - **Concept note-** Only preliminary technical approval may be given initially on the basis of presentation in IRC and a project originating from the concept has to follow the same protocol as per the policy of IRC (presentation in IRC followed by approval from IEC).

3. Communication Timeline

Each project will be assigned a unique IRC number for all correspondence.

An exclusive project file folder will be maintained in IRC to facilitate appointments, procurement, documentation and follow up.

After presentation in IRC, decisions will be conveyed to PI within 7 working days of the meeting. Possible outcomes:

1. Approved:
   - Project will be forwarded to Institutional Ethics Committee (IEC).
2. Modifications Suggested:
   - Project must be resubmitted to IRC after modifications.

- No Project will be forwarded to IEC without IRC approval.

3. Rejected:
    - Rejection reasons provided in writing.

D. SUBMISSION & REVIEW PROCESS

1. Submission Requirements to Institutional Research Cell

 Mode:

- Soft copy (PDF) via email + 2 hard copies to IRC, LHMC.

 Address:

- **IRC Office, R. No 719, New Academic Block, Email: irclhmc@gmail.com.**

 Deadline:

Projects must be submitted at least 2 weeks prior to the scheduled IRC meeting to be considered in a meeting

2. Documents Required (See Annexure 1 Checklist):

1. Cover letter via HOD*
2. IRC and IEC submission-forms 1, 2 and 3 in Annexure 6 duly Forwarded by HOD, proforma and undertaking by PI
3. Full protocol (version/date)
4. Data collection tools/CRFs
5. Budget & justification with overhead charges
6. Draft MoUs / Material Transfer Agreement (MTAs)/ Clinical Trial Agreement (CTA) / Confidentiality Disclosure Agreement (CDAs) (if applicable)
7. CVs of PI/Co-PIs
8. In addition to all of the above, Multi centric projects initiated by other site/ institute where LHMC must submit the following documents

    - Lead site details
    - IEC approval from the lead Institute
    - Draft MoU
    - Publication right
    - IP/Background IP
    - Data ownership
    - Benefit to Institution

*HOD must forward the project to IRC with his/her comments conveying approval or otherwise within a period not exceeding 15 days from receipt of the project. A project not forwarded within the stipulated time, may be reviewed by the IRC, Chairperson directly.

3. Conflict of Interest

Any IRC member involved in the project (as PI/Co-I/consultant) must excuse themselves during discussions.

4. Sequence of Approvals

- IRC approval → Project forwarded to **IEC** with assigned project number.
- After IRC & IEC approval → PI applies to **funding agency**.
- PI informs IRC about **funding approval**.
- PI seeks **administrative approval** from IRC.
- **Project initiation** allowed only after administrative approval:
    - Project account opened
    - Funds transferred from **Director LHMC account**
- For **intra-mural grants**, IRC reviews applications. The process for application for the same will be decided as and when the facility becomes available.

File Movement Flow:

PI → HOD→ IRC→IEC→ PI ⟶ Funding agency → PI →IRC →Director →Principal →DDA →DDO → Account opening of the project → Institutional Research Cell Overhead Account (Will also receive IEC fee as applicable)

5. Overheads (OH)

- PI should ensure overhead charges are **clearly indicated** in PI's budget.
- **Rates:**
    - Private/Industry/NGO: 10% of sanctioned budget (unless funder specifies higher)
    - Government agencies: As per agency norms
- Overheads and IEC fees credited to **IRC Overhead Account**. (**Institutional Research Cell account number 5942011573** in **Central Bank of India, LHMC Branch)**

6. Grants Receipt & project accounts

- **Grant Receipt:** All funds initially received in **Director's Account**

- **Dedicated Project Account:** Opened for each project; **signatories**: Chair IRC, PI, Co-PI, DDO
    - Any 3 of 4 signatures required; PI & either Chair/DDO **mandatory**
- **Bank Procedures:** PI submits **letter via Chair IRC**; IRC office forwards to bank
- **Fund Transfer:** Via IRC on PI request
- **File Movement**

PI → Institutional Research cell → DDO→ DDA → Chair, IRC → Director

E. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR (PI)

1. Ensure compliance with funding agency regulations and LHMC SOPs.
2. Obtain IEC approval after IRC clearance.
3. Follow all Codal formalities for procurement, staff recruitment, and utilisation of funds
4. Submit annual scientific progress reports to IRC.
5. Maintain study documents, raw data, records, and regulatory files as per Indian Council of Medical Research, 2017 and its updates and donor agency (if any). These will be preserved for 3 years in case of biomedical and health research and 5 years for clinical trials.
6. Ensure no conflict of interest or personal financial gain from research funds.
7. Report protocol deviations, amendments, and serious adverse events (if applicable).
8. PI is responsible to maintain all records of the research projects as per the Guidelines of Indian Council of Medical Research, 2017 and its updates and donor agency (if any).

F. PROCUREMENT OF EQUIPMENT /KITS/ OTHERS

1. General Guidelines & Coordination

All project-related procurements—including medical kits, laboratory consumables, and equipment—must be executed in strict compliance with the General Financial Rules (GFR) 2017 (incorporating the latest amendments as per OM No. F.1/3/2024-PPD dated 10.07.2024) and existing LHMC institutional procurement protocols.

- Oversight: Procurement activities will be coordinated by the IRC Procurement Sub-Committee in close consultation with the Store Officer and the Drawing and Disbursing Officer (DDO).
- GeM Mandate: Procurements must be prioritized through the Government e-Marketplace (GeM) portal. Only when items or kits are unavailable on GeM should alternative GFR-compliant methods be explored, accompanied by the requisite GeM non-availability report (GeMARPTS).

2. Procurement Thresholds and Procedures

The financial thresholds for procuring kits, consumables, and equipment are categorized as follows:

Value of Goods (₹)	Applicable GFR Rule	Standard Operating Procedure
Up to Rs. 50,000	Rule 149 (GeM) / Rule 154	The Principal Investigator (PI) may procure items directly through GeM

		or via direct purchase (single quotation) if unavailable on GeM. Bills must be submitted with the standard GFR Rule 154 certificate.
Rs. 50,001 to 10,00,000	Rule 149 (GeM) / Rule 155	Purchases must be made directly from GeM (L1 / bidding). For non-GeM procurements, the PI must propose a Local Purchase Committee (LPC) comprising at least 3 members. The LPC must be approved by the Director via the IRC Procurement Sub-Committee. The LPC will conduct a market survey, evaluate quotations, and submit proper documentation.
Above Rs. 10,00,000	Rule 155 & 158	Procurements must be routed through competitive bidding on GeM or via the Central Hospital Procurement Section following standard open tender rules.

3. Specific Protocols for Kits and Consumables

- Uniformity in Rules: The procurement of research kits, reagents, and clinical consumables is subject to the exact same financial thresholds and GFR compliance protocols as standard capital equipment.
- LPC Requirement: For any kit or consumable purchase falling between ₹50,001 and ₹10,00,000, the constitution of a 3-member Local Purchase Committee by the PI is mandatory, subject to final approval by the Director.

4. Proprietary Article Certificate (PAC) Procurements (GFR Rule 166)

- For specialized research kits or reagents available from only a single original equipment manufacturer (OEM) or authorized distributor, procurement must be supported by a formally justified Proprietary Article Certificate (PAC).
- PAC procurements require prior administrative approval from the Director, routed through the Institutional Research Cell.

 References:

- **GFR Rule 149,154, 155** and **158** (amended 10/07/2024, OM No. F.1/3/2024-PPD) and subsequent amendments.
- Institutional procurement guidelines (LHMC/Hospital SOPs).

G. RECRUITMENT OF RESEARCH STAFF AND ANNUAL CONTRACT RENEWAL

- Recruitment subcommittee of the IRC will coordinate all project related procurements.
- PI drafts **TORs, eligibility, remuneration and submits to IRC**
- Administrative Research Cell officer will make available standard advertisement and contract form

- Vacancies must be advertised/circulated at least **2 weeks** before interviews on the Institute website.
- Selected candidates' details must be sent to DDA after IRC approval.
- Approval of IRC will be required for annual contract renewal of the candidate through the DDA
- LHMC bears **no liability to staff** once the contract is competed or project is completed or terminated. Template in Annexure is attached.
- Attendance of the recruited staff to be maintained by PI.
- All project staff should have an ID to be issued by DDA after approval through the IRC
- All salary cheques to be signed by account holders as specified above.

H. PROJECT FOLLOW-UP & CLOSURE

- Will be done by the project monitoring sub-committee
- Annual or periodic (depending on duration of the project) scientific progress report to be submitted to the IRC as well as IEC as per the requirement of the funding agency by the PI
- Annual/periodic statement of expenditure and UC of funds as per the requirement of the funding agency
- Details of any publication or scientific presentations related to the proposal should also be submitted to the IRC
- Upon project completion the PI needs to submit the final report of the project as being submitted to funding agency to IRC and IEC
- A copy of the final Audited account statement after refund of unutilized funds to the funding agency & Closure of project account.
- IRC maintains a project-wise monitoring file (Annexure 3 & 4).

I. RESEARCH CELL REQUIREMENTS:

1) Designated office space
2) Dedicated Administrative Officer for IRC
3) Data Entry Operator
4) MTS

J. INSTITUTIONAL RESEARCH CELL OVERHEAD ACCOUNT

Institutional Research cell, Overhead Account: Institutional Research Cell account number 5942011573 in **Central Bank of India, LHMC Branch** will receive Institutional overhead funds and IEC fee from the projects. These funds will be utilized for capacity building of Institute's faculty and students in research, day to day working of IRC, organization of Annual Institutional Research Day

(tentatively on Foundation Day of the Institute, 17Th March every year), instituting awards for felicitating exemplary researchers among the Institute's faculty/Residents, or any other research related activities as decided by the IRC after approval from the Director. Intramural funding for insurance or other research related purposes may also be considered as decided by the Research cell if adequate funds are available.

The signatories for IRC Overhead Account will be-

Director, Principal, DDO, and member secretary IRC. Any 3 of the above 4 signatories can sign. Signatures of the Director/ Principal and DDO are essential.

The Institutional overhead funds will be transferred by the PI from the respective project accounts one time or proportionately with instalments, as per the funds received from the funding agency.

ANNEXURES

- **Annexure 1:** IRC Submission Checklist
- **Annexure 2:** LHMC Workflow for Research Approvals
- **Annexure 3:** Institutional Research Cell Monitoring Checklist (Annual)
- **Annexure 4:** Offer letter with terms of recruitment of Staff
- **Annexure 5:** PIS and ICF template,
- **Annexure 6: IEC** Form 1, 2 and 3

ANNEXURE-1

LHMC – IRC Submission Checklist

The following documents must be included in the submission packet:

IRC and IEC forms as in Annexure 6 (form 1, 2 and 3) forwarded by HOD

1. **Complete Research Protocol** (version/date):
    - Background & rationale
    - Aims and Objectives
    - Methodology
    - Sample size/statistics
    - Inclusion/exclusion criteria
    - Outcomes
    - Timeline (Gantt chart)
    - Patient Information Sheet (PIS) and Informed Consent Form (IFF)
2. **Case record forms (CRFs)/Questionnaires/Study Tools**
3. **Budget with justification**
4. **Overheads clearly indicated**
5. **Roles & responsibilities of investigators/sponsors**
6. **Draft Agreements (if applicable):**
    - MoU/CTA/CDA/MTA
    - DCGI Approval
7. **Compensation & insurance plan** (interventional/risk studies)
8. **Plan for statutory approvals:**
    - IEC
    - CTRI (if interventional clinical trial)
9. **Data management & security plan**
10. **Data sharing/transfer agreements** (if multicentric or external collaboration)
11. **DSMB/DSMP plan** (if high-risk study)
12. **CVs of PI and Co-PIs**
13. **Timeline-bound submission proof (if EOI or concept note)**
14. **For multicentric proposals:**
    - Lead site details
    - Responsibilities
    - Draft agreements
    - Publication rights
    - IP/background IP
    - Data ownership
15. **Proprietary items justification** (equipment/consumables)

ANNEXURE-2

LHMC Workflow for Review & Approval of Funded Research Projects

Stepwise Flow

1. PI prepares proposal
2. HOD forwards proposal to IRC
3. PI presents the project to the IRC. Presentation will be mandatory for approval
4. IRC reviews scientific merit & feasibility.
5. Approval/queries communicated to PI
6. Once IRC approval is obtained → IRC forwards the protocol with assigned unique number to IEC
7. IEC approval granted
8. PI submits to the funding agency
    - On funding approval → PI notifies IRC
9. IRC processes request for **Administrative Approval from Principal and Director**
10. Administrative approval issued by Principal, LHMC- New file created
11. PI opens project account
12. Project is initiated- Recruitment and procurement
13. Project monitored periodically by monitoring subcommittee
14. Annual scientific progress reports submitted to IRC
15. Renewal of contract for project staff annually
16. On completion:

- Final report submitted
- Financial closure
- Account closure after audit
- **Final report** and **audited SOE + UC submission** to IRC
- Any publication or presentation to be submitted to IRC.

Flow of file: PI → HOD→ IRC→IEC→PI→ Funding agency → PI →IRC →Director →Principal →DDA →DDO → Account opening of the project → Institutional Research Cell Overhead Account (Will also receive IEC fee as applicable)

ANNEXURE-3

Institutional Research Cell Project Monitoring Checklist (To be maintained by IRC Office)

Project Details

- Project Title: _____
- PI Name & Department: _____
- IRC Approval No.: _____
- IEC Approval No. (attach copy)
- Funding Agency (if applicable): _____
- Start Date: _____
- Expected Duration: _____

Budget & Overheads

- Total Budget Approved: _____
- Total Overheads: _____
- Budget Breakup Provided: Yes / No

Fund Flow

Instalment	Amount Received	Date Received	Amount Utilized	Balance
1				
2				
3				
4				

Scientific progress

- **Staff recruitment**
- **Procurement**

ANNEXURE-4

FORMAT OF OFFER LETTER TO BE ISSUED TO SUCCESSFUL CANDIDATES TO BE ENGAGED ON PRPOJECT

LHMC letter head

File no _____ Date:

To,

<Name of the successful candidate>
<Address>

Subject: Offer for engagement on project position of _____, **purely on time bound contractual basis.**

Dear Candidate,

Consequent upon your selection to the aforesaid project position, purely on time bound basis in the project titled, "_____", under guidance of _____, I am directed to convey the approval of the Competent Authority to engage you on the said Project Human Resource Position, against lump sum amount of Rs. ____/-(Rupees _____ _____Only) per month.

The engagement to the project position will be subject to the following terms and conditions:

1. You are requested to furnish an undertaking to the effect that you shall not be entitled to claim for continuation of your fixed term engagement and/or for any other right, which has not been expressly conferred upon you, in the terms of engagement, from LHMC (Annexure- C).

2. The engagement to the project position is purely on time bound contract basis and the Competent Authority reserves the right to dispense with the engagement, at any time without assigning any reasons.

3. The present assignment is for one year up to _____

4. The engagement to the project position will automatically cease on the end date of engagement. The incumbent shall have no right to claim for further engagement. In any case, whatsoever, any request/representation in this regard will not be entertained.

5. The engagement can be terminated during the tenure at any time by giving one- month notice on either side. Your engagement can be terminated forthwith or before expiry of the notice period, by making payment of a sum equivalent to one-month project position remuneration. However, you will not be permitted to surrender one- month remuneration, in lieu of the period of notice of unexpired portion thereofand you will be required to serve the full period of notice. (Note- The mandate of one- month notice from either side, as stated herein, will not be applicable in case the project is decided to be closed by the competent authority witihin a period of less than 30 days/one month).

Contd…P/2

6. You will not be treated as an employee of LHMC. You will not have any claim on any regular post in LHMC. You shall give an undertaking to this effect before joining the project position.

7. You will be under the administrative control of the host Institute and will be subject to all the rules and regulations of the host Institute as applicable to fixed term project positions/persons during the tenure/period of engagement.

8. You will be posted for work as per project requirement including, office/field/site work/travel etc. at the study site; however, you may be temporarily posted to other study sites in the interest of project work.

9. You will not be entitled to any other allowances such as Dearness Allowance, Transport Allowance, LTC, Bonus, etc. You will also not be provided any medical facility under CGHS / CS (MA) Rules as admissible to regular employees.

10. No travelling and/or daily allowance will be admissible either for joining the assignment or on expiry of the contract. However, while travelling in connection with the assigned work during the period of engagement, you will be entitled to draw TA/DA in accordance with your Stipend / Emoluments, but it will not be at par with the regular / permanent employees of LHMC.

11. Leave Provisions:

    (a) CCS (Leave) Rules shall not be applicable to project positions.

    (b) Paid Leave of absence may be allowed at the rate of 1.5 days for each completed month of engagement, or as prescribed by the Competent Authority from time to time. No other kind of leave shall be admissible.

    (c) Leave shall not be carried forward beyond one-year contract. Accumulation of leave beyond a calendar year shall not be allowed.

    (d) On termination of the engagement, you shall not be entitled to the benefit of encashment of un-availed portion of leave.

    (e) Maternity Leave of 180 days, for female Project staff, in terms of ICMR OM No.16/50/2015-Admn.II dated 11/02/2016.

    (f) In the event of leave without prior permission of PI / Guide / Head of Institute and / or any willful unauthorized absence, the engagement shall be ceased automatically and the concerned person holding project position will not be permitted to resume duty, without prior permission of Head of the host Institute.

Contd…P/3

12. You will not be entitled for any terminal benefits after completion of project period or otherwise.

13. You should submit a medical certificate in the enclosed prescribed format. If you fail to submit this certificate or found unfit in the medical examination, this offer to engage you on the aforesaid position shall stands cancelled automatically.

14. You will not divulge any information gathered or outcome of research work during the period of your assignment to anyone who is not authorized to have the same.

15. Payment of stipend or emoluments to the project position will be subject to availability of funds from the funding agency of the project.

16. The project service will not confer any right for further assignment.

17. Other general responsibilities / obligations of Project Positions are enclosed at Annexure — D, which shall strictly be followed.

In case you are willing to accept the above-mentioned conditions, please report to your Project Investigator immediately and complete the pre-engagement formalities, such as Medical Examination, Character Certificate, etc., **within fifteen days,** failing which the offer shall stand cancelled automatically. Formats of pre-engagement formalities are enclosed at Annexure — E (i to vi). A copy of this letter duly signed by you in token of acceptance of aforesaid terms and conditions should also be furnished to this office along with joining report.

Yours faithfully,

Administrative Officer

Enc1: Annexure — C, D and E.

Copy to:

1. PS to Director
2. IRC
3. Project Investigator
4. DDO

Annexure-5 (a)

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 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

Annexure-5 (b)

INFORMED CONSENT FORM (ICF)

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 Name

Signature

Annexure-6

Form 1

LADY HARDINGE MEDICAL COLLEGE & ASSOCIATED HOSPITALS
INSTITUTIONAL RESEARCH COMMITTEE (IRC)
Form for Comments of Head of Department

To

The Chairperson

Institutional Research 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 IRC 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 IRC

(b) Recommended subject to above comments

(c) Not-recommended due to following reasons

Date ***Signature (Name & Designation with seal)***

Annexure-6

Form 2

Form to be filled by the Principal Investigator (PI) for submission to Institutional Research Committee (IRC) and Institute's Ethics Committee (IEC)

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 Centre ☐ Multicentric ☐ Behavioral ☐

2. Status of Review: New ☐ Revised ☐

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

Does the study involve use of : Drug ☐ Devices ☐ Vaccines ☐

Any other ☐ NA ☐

Indian Systems of Medicine/

Alternate System of Medicine

i. Is it apprpoved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involve a achange in use, dosage, route of administration? **If yes**, whethe DCGI's/ Any other Regulatory authority's Permission is obtained? **If yes**, Date of permission:	Yes Yes	No No
iv. Is it an Investigational New Drug? **If yes**, IND No:	Yes	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 dione elsewhere? **If Yes,** attach details	Yes	No

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 rational (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/ exclusiuon criteria given	Yes	No
v. Type of subjects Volunteers ☐ Patients ☐		
vi. Vulnerable subjects (Tick) Pregnant Women ☐ Children ☐ Fetus ☐ Handicapped ☐ Elderly ☐ Terrminally ill ☐ Seriously ill ☐ Mentally Challanged ☐ Econonmically & Socially Backward ☐ any other (specify) ☐		
6. Privacy and confidentaially i. Study Involves - Direct Identifiers ☐ Indirect Identifiers ☐ Completely anonymised/ delinked ☐		
ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous material i. Use of Fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained ?	Yes Yes	No No
iv. Use of pre-existing/ stored/leftoverr samples	Yes	No
v. Collection for banking/ futurer research	Yes	No

	vi. Use of ionising radiation/radioisotopes **If yes**, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
vii.	Use of Infectious/biohazardous specimens	Yes	No
viii.	Proper disposal of material	Yes	No
ix.	Will any sample collected from the patients be sent abroad? **If yes**, justify with details 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 reason….

Facility not ababilanle 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 infromation	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for paricipation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐		

*If written consent is not otained, give reasons:

ii. Who will obtain coonsent? PI/Co-PI ☐ Nurse /Counsellor ☐

Research Staff ☐ Any Other ☐

9. Will any advertising be done for recruitment of Subjects? (posters, f lyers, 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?	Yes	No

If Yes, less than Minimal risk Minimal Risk Minor increase over minimal risk or Low risk More than minor increase or High risk		
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 / Voard (DSMB)	Yes	No

. 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 plans for interim analysis of data?	Yes	No
i. Are there plans for storage and maintenance of all trials 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: Signature & Designation of PI/Co-PI/Collaborator

Date:

Annexure-6

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 Institutional Research Committee, Institutional 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 IRC and IEC 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 guidelines are met.

E. I agree to report to the IRC and IEC 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 to make those records available for adult / inspection by the Sponsor, IRC, IEC, 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 IRC and IEC within 24 hours of their occurrence.

J. I agree to promptly report the IRC and IEC all changes in the clinical trial activities 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.

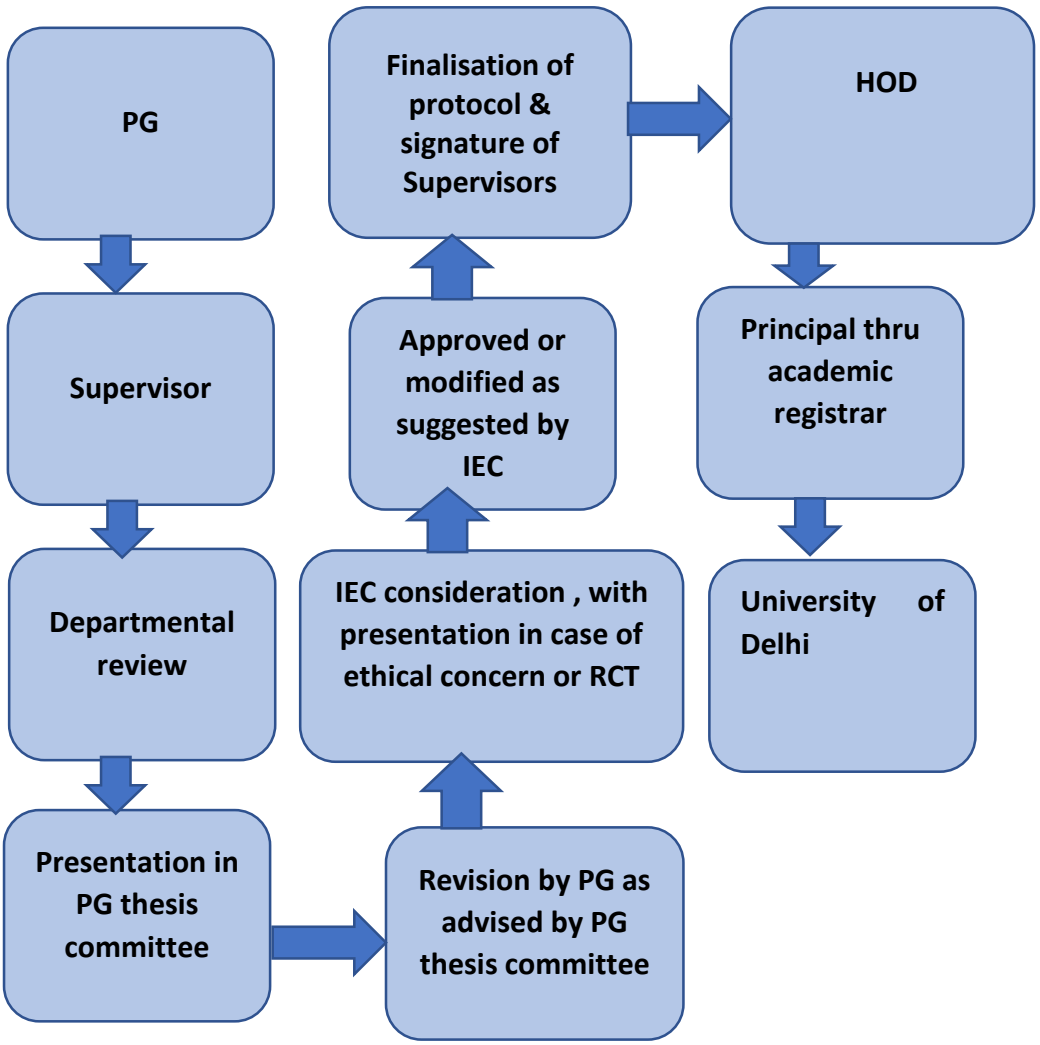
L. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trials.

Signature of PI with date

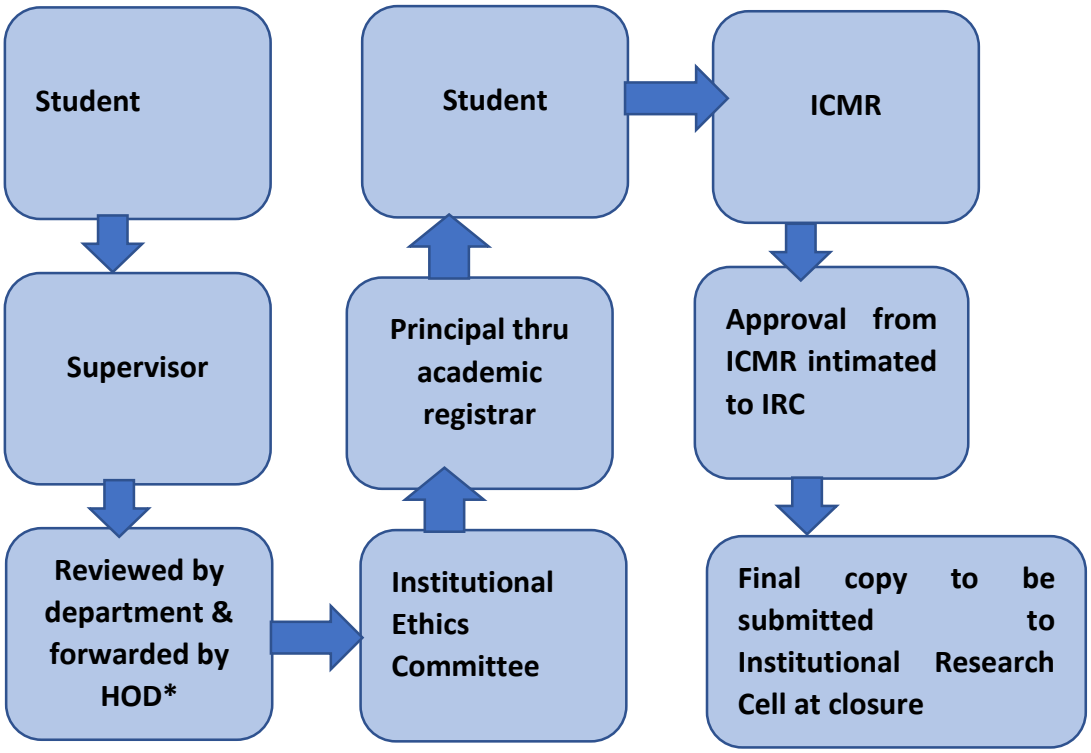
Annexure 7

Pathways for processing research protocols in LHMC

Pathway for PG thesis protocol

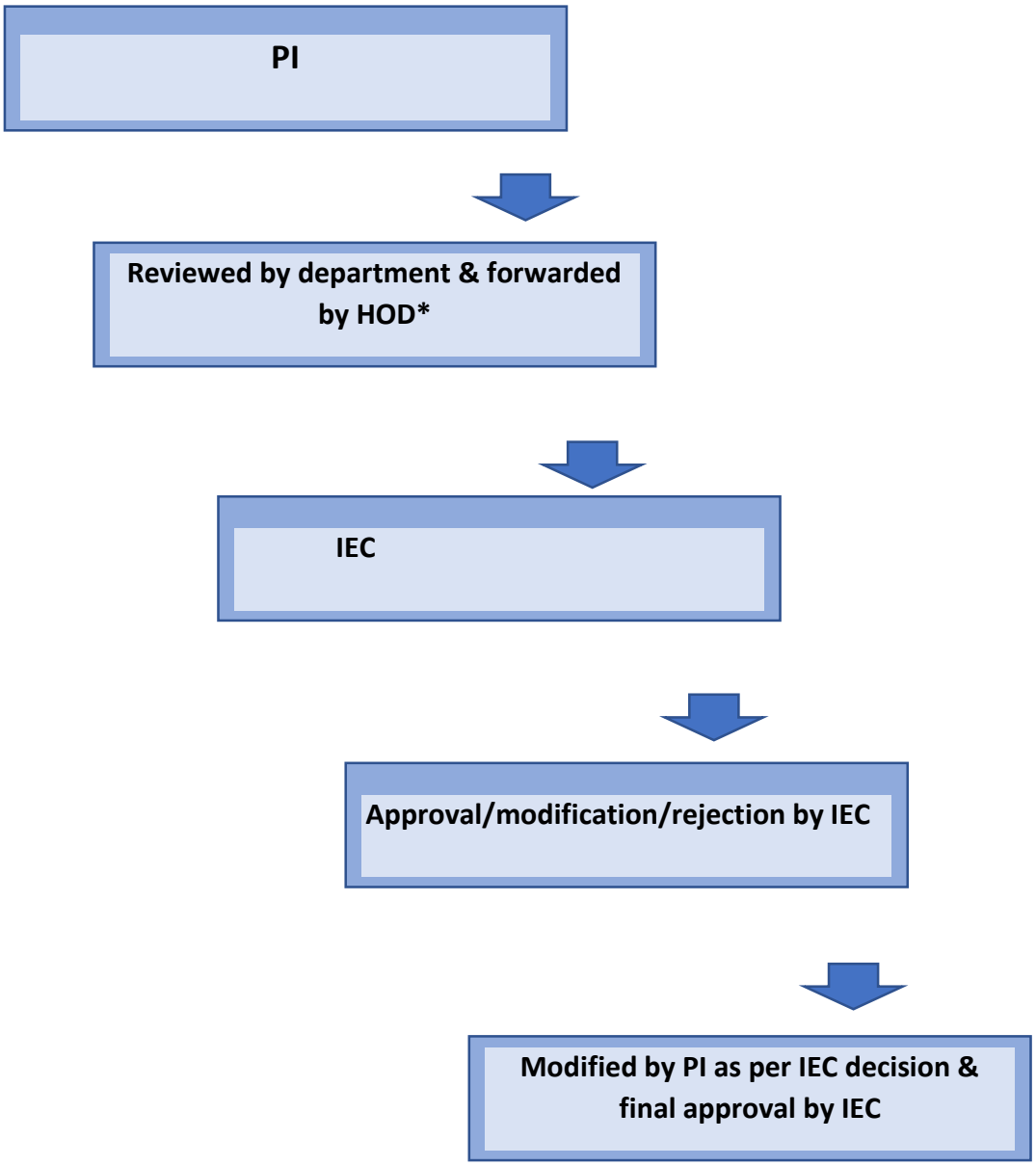


Pathway for UG STS protocols



*** Non funded projects including STS projects of ICMR will be examined by 3 faculty members of the department (in case of smaller departments, members from related departments may be co-opted) and forwarded to IEC through the HOD within 15 days of receipt in HOD office with his/her comments.**

Pathway for non-funded proposals by Faculty/Residents



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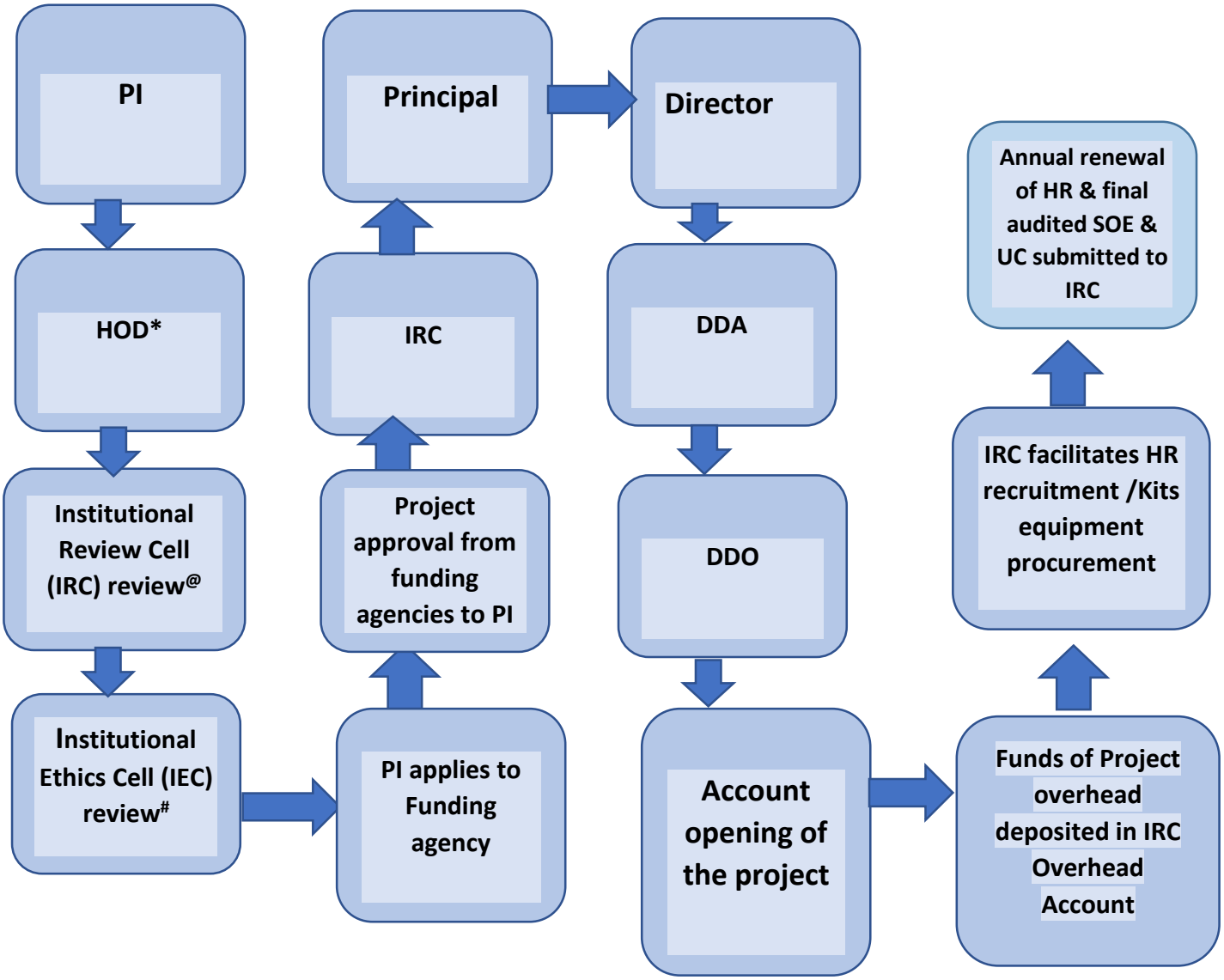
Pathway for funded research projects



**HOD must forward the project to IRC with his/her comments conveying approval or otherwise within a period not exceeding 15 days from receipt of the project.

@ Guidelines/SOP for IRC submission & review will be shared separately

After depositing IEC fee in IRC Overhead Account for Drug trials/Fees to be paid after approval in govt. funded trials