CHANAKYA UNIVERSITY

CHANAKYA UNIVERSITY

Standard Operating Procedures

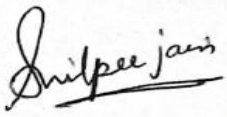
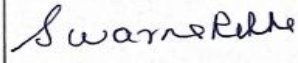
for

Institutional Human Ethics Committee - Chanakya University

(IHEC-CU)

Chanakya University Global Camous

Bengaluru

	Name	Designation	Signature	Date
Prepared by	Dr. Sumi. S	Member Secretary, IHEC-CU		12 June 2026
Reviewed by	Dr. Shilpee Jain	Alternate Member Secretary		15 June 2026
Approved by	Dr. Swarnarekha Bhat	Chairperson IHEC-CU		17 June 2026

DATE OF IMPLEMENTATION: 01-05-2026

VERSION NUMBER: 1

VALID TILL: 30-04-2028

CHANAKYA UNIVERSITY

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FORMS

1. Introduction

In a world grappling with complex challenges that often clash with dharma and nature, Chanakya University emerges as India's premier institution dedicated to nurturing transformative leaders and pioneering new paradigms. Established in 2022 through a State Legislature Act, Chanakya University is a beacon of excellence, committed to addressing developmental challenges with innovative solutions. Our mission is to expand knowledge through world-class scholarship and impactful research, preparing students with abundant wisdom (*jñāna*), indomitable will (*ichhā*), and meaningful action (*kriyā*) that honour both Indian traditions and universal values.

Institute Human Ethics Committee, Chanakya University, Bengaluru (IHEC-CU) has been constituted by Vice Chancellor, Chanakya University to facilitate research involving human subjects following the ICMR Ethical guidelines. This standard operating procedure (SOP) will define the role, operation and management of the committee.

2. Objectives

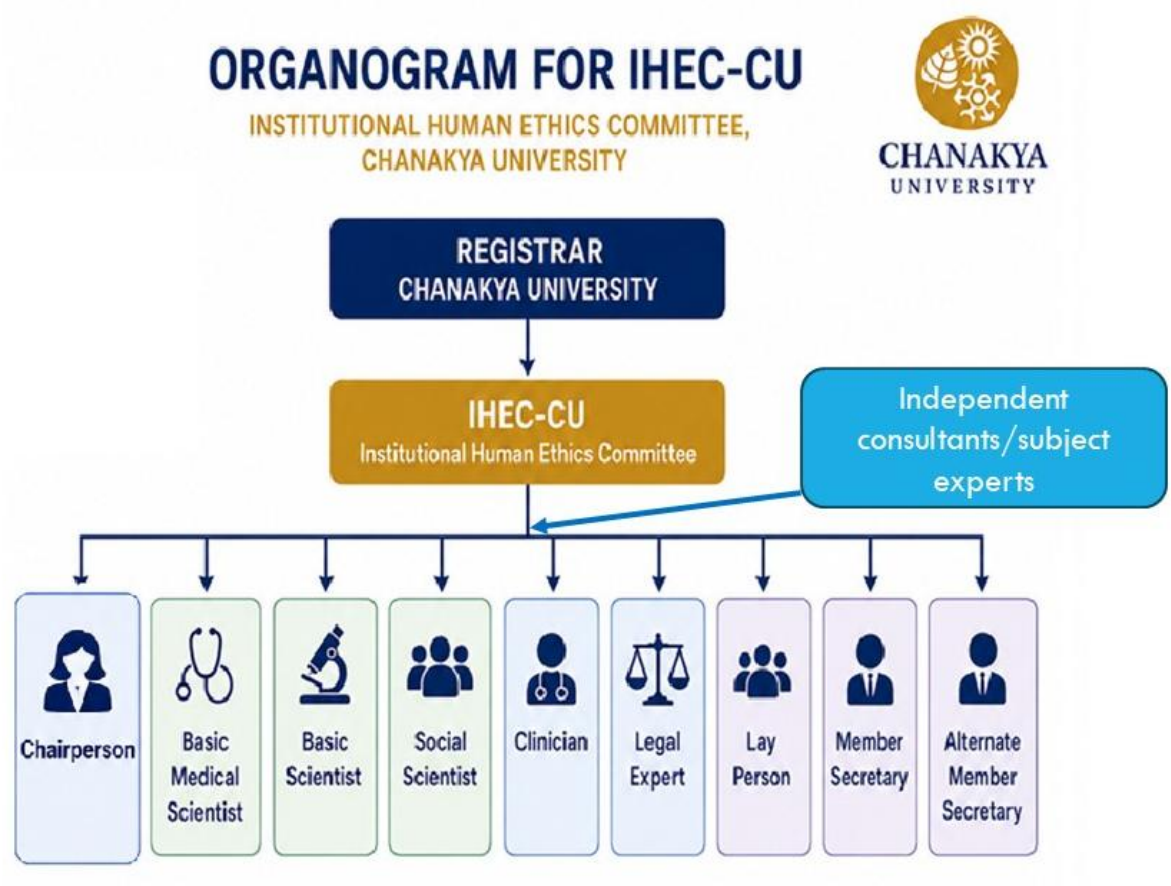
The objective of this SOP is to maintain effective functioning of the IHEC-CU, and to ensure technical excellence and consistent ethical review of all the submitted health and biomedical research proposals involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects published in 2017.

3. The complete list of IHEC-CU members are given below:

Sl No	Name	Affiliation	Designation
1	**Dr Swarnarekha Bhat**	Chairperson, Clinical Audit Committee, Jayadev Memorial Rashtrotthana Hospital and Research Centre, (Former Professor HOD Paediatrics & Neonatology. St John's Medical College). Bengaluru	Chairperson
2	**Dr. T.N. Sathyaprabha**	Associate Dean - Basic Sciences, Professor of Neurophysiology NIMHANS, Bengaluru	Member- Basic Medical Scientist (Vice chairperson) (dual role)

3	**Dr. Ketan Vilas Thorat**	Fellow E/ Scientist D Regulatory Compliance Officer, BRIC-Institute for Stem Cell Science and Regenerative Medicine, Bengaluru	Member- Basic Scientist
4	**Dr. Bhagya Venkanna Rao**	Associate Professor, KLE College of Pharmacy, KLE University, Bengaluru	Member-Basic Scientist (Pharmacologist)
5	**Dr. Sandeep Sreerama Reddy**	Assistant Professor, Dept of General Medicine, M.S. Ramaiah Medical College, Bengaluru	Member- Clinician
6	**Dr. Rajashree K**	Associate Professor, School of Law, Governance and Public Policy, Chanakya University, Bengaluru	Member- Legal expert
7	**Dr. Priyanka Dwivedi**	Associate Professor, School of Arts, Humanities and Social Sciences, Chanakya University, Bengaluru	Member- Social scientist
8	**Mr. Manu Narayan**	Senior Manager, Mavneir Systems Pvt. Ltd, Bengaluru	Member- Lay person
9	**Dr. Shilpee Jain**	Assistant Professor, School of Biosciences Chanakya University, Bengaluru	Member- Alternate Member Secretary (dual role)
10	**Dr. Sumi S**	Associate Professor, School of Biosciences Chanakya University, Bengaluru	Member Secretary

4. Organogram



5. List of Abbreviations

IHEC-CU	Institutional Human Ethics Committee – Chanakya University
ICMR	Indian Council of Medical Research
SOP	Standard Operating Procedure
GCP	Good Clinical Practice
TAC	Technical Advisory Committee
PI	Principal Investigator
IEC	Institutional Ethics Committee
DHR	Department of Health Research
EC	Ethics Committee
CU	Chanakya University
SAE	Serious Adverse Event
CV	Curriculum Vitae
PIS	Participant Information Sheet
ICF	Informed Consent Form
HEC	Human Ethics Committee
BRIC	Biotechnology Research and Innovation Council
GCP	Good Clinical Practice
IEC Secretariat	Institutional Ethics Committee Secretariat

IHEC-CU

SOP Code: SOP 01/V1

Title: Development, Review, Revision and Management of Standard Operating Procedures (SOPs)

Date: May 01, 2026

1.1. PURPOSE

The purpose of this SOP is to provide IHEC-CU with a systematic method for the preparation, review, approval, revision, implementation, and distribution of SOPs. These SOPs are designed to guarantee consistency, transparency, accountability, and compliance in all activities of the ethics committee in accordance with applicable national regulations and ethical guidelines governing biomedical and health research involving human subjects.

1.2. SCOPE

This applies to all SOP-related activities undertaken by IHEC-CU, including:

- Drafting of new SOPs
- Revision of existing SOPs
- Periodic review and updating of SOP documents
- Distribution and implementation

1.3. RESPONSIBILITY OF IHEC MEMBERS IN SOP PREPARATION

1.3.1. Chairperson, IHEC-CU

The Chairperson shall:

- Authorize IHEC member secretary to prepare SOP
- Review and approve finalized SOPs
- Ensure SOPs are periodically updated
- Ensure implementation of revised SOPs

1.3.2. Member Secretary

The Member Secretary shall:

- Prepare SOP
- Maintain master copies and SOP records
- Facilitate review by committee members
- Ensure controlled distribution of SOPs

1.3.3. Alternate Member Secretary

The alternate member secretary shall:

- Review SOPs
- Submit finalized drafts for approval in the absence of member secretary

1.3.4. IHEC-CU Members

IHEC-CU members shall:

- Review SOP drafts
- Provide recommendations and comments
- Adhere to currently approved SOPs

4. DETAILED INSTRUCTIONS

4.1 Identification of need for SOP revision

A requirement for a new SOP or revision of an existing SOP may arise due to:

- Changes in regulatory guidelines
- University policy changes
- Identification of procedural gaps
- Audit or inspection findings
- Recommendations from IHEC-CU members

Requests for modification may be submitted by any IHEC-CU to the Chairperson or Member Secretary.

4.2. SOP Structure and Formatting

Each SOP shall include:

- SOP number, Version number, Effective date, Title of SOP

Each SOP shall contain the following sections:

1. Purpose
2. Scope
3. Responsibility
4. Detailed Instructions
5. Flow Chart
6. Annexures/Forms
7. References

4.3. SOP Coding System

Each SOP shall be assigned a unique identification code using the following format:

SOP XX/VY

Where: XX = SOP serial number, V = Version, Y = Version number

4.4. Distribute and file SOPs

- SOPs are made available on the website of Chanakya University.

4.5. Periodic Review

- All SOPs shall undergo periodic review at least once in every three years, or earlier if required due to regulatory or procedural changes.

4.6. Revision of SOP

- Member Secretary/alternate member secretary will make necessary modifications which will be reviewed by Chairperson.
- Member secretary will submit the reviewed SOP to the IHEC-CU Members who will review it and confirm it.

- If a SOP supersedes a previous version, the latter will be indicated in the document.
- The final version will be presented to the Chairperson for review and approval. The authors, reviewers and the Chairperson will sign and date the SOP on the first page.
- All previous versions shall be withdrawn upon release of revised versions.

5. FLOW CHART

Activity	Responsibility
Identify need for new/revised SOP	IHEC Members
Draft SOP	Member Secretary
Review SOP draft	Alternate Member secretary
Final approval	Chairperson
Distribution and implementation	Member Secretary
Archival of superseded SOPs	Member Secretary
Periodic review	IHEC-CU

6. FORMS

- **Annexure 1:** SOP Version History Record

7. REFERENCE

1. Indian Council of Medical Research (ICMR). National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

IHEC-CU

SOP Code: SOP 02/V1

Membership requirements of the ethics committee

Date: May 01, 2026

1. Purpose

The purpose of this SOP is to define the membership requirements, eligibility criteria, composition, roles, and responsibilities of members of IHEC-CU to ensure independent, competent, multidisciplinary, and ethical review of research involving human participants.

2. Scope

This SOP applies to all members appointed to the IHEC-CU.

3. Policy Statement

The IHEC-CU shall be constituted in accordance with applicable ethical guidelines and regulatory requirements and shall function independently to safeguard the rights, safety, dignity, and well-being of research participants.

The committee shall maintain multidisciplinary, multisectoral, and optimal gender- representation.

4. Composition of IHEC-CU

The chairperson of the IHEC will be from outside Chanakya University to maintain the independence of the Committee. The Member Secretary and alternate member secretary will belong to Chanakya University and will coordinate the actions of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the differed points of view. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism.

The members of the IHEC will include:

1. Chairperson (non-affiliated with Chanakya university)
2. One basic medical scientist (non-affiliated with Chanakya university)
3. One basic scientist (affiliated/ non-affiliated with Chanakya university)

4. One pharmacologist (not affiliated with Chanakya University)
5. One clinician (not affiliated with Chanakya University)
6. One legal expert (affiliated/ non-affiliated with Chanakya university)
7. One social scientist/ philosopher/ ethicist/ theologian (affiliated/ non-affiliated with Chanakya university)
8. One lay person from the community (non-affiliated with Chanakya university)
9. Member Secretary (affiliated with Chanakya University)
10. Alternate Member Secretary (affiliated with Chanakya University)

4.1. Dual role: Chairperson and Member Secretary can take up dual roles (clinician, basic scientist, lay person etc, if required).

5. Membership Requirements

5.1. Membership Composition of IHEC-CU

The Institutional Human Ethics Committee (IHEC-CU) shall be multidisciplinary and multisectoral and shall be constituted in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), Chapter IV, Section 4.3.

The committee shall ordinarily consist of 7–15 members representing both scientific and non-scientific disciplines. Members shall possess appropriate qualifications, experience, integrity, and independence to ensure objective ethical review.

5.2. Role-wise Membership Requirements

Member Category	**Essential Qualification/ Expertise**	**Primary Role in IHEC**
Chairperson (External)	Senior individual not employed by Chanakya University with experience in research, ethics, or administration	Provides independent leadership, chairs meetings, ensures impartial decision-making
Member Secretary	Senior faculty member from the institution with research and ethics experience	Coordinates committee activities, documentation, communication, regulatory

Member Category	Essential Qualification/ Expertise	Primary Role in IHEC
		compliance
Basic Medical Scientist	MD in basic medical sciences or equivalent expertise	Scientific evaluation of biomedical research
Clinician(s)	Medical practitioner(s) with clinical research experience	Evaluation of participant safety, risk-benefit assessment, and clinical aspects
Legal Expert	Person with legal expertise, preferably related to health or biomedical law	Advises on legal and regulatory compliance
Social Scientist/NGO Representative	Social scientist or NGO representative familiar with community issues	Assesses social and cultural implications of research
Philosopher/Ethicist/Theologian	Individual trained in ethics, philosophy, or theology	Provides ethical guidance and value-based perspectives
Lay Person	Literate member of the community with no scientific affiliation	Represents community interests and participant perspectives

5.3. General Membership Requirements

- The committee shall maintain an appropriate balance of scientific and non-scientific members.
- Both men and women shall be adequately represented.
- Members shall collectively possess expertise relevant to the types of research reviewed.
- External members shall ensure independence and minimize institutional bias.
- Additional subject experts may be invited whenever specialized expertise is required; however, they shall not participate in voting or be counted toward quorum.

5.4. Independence

The committee shall include independent members to minimize bias and ensure objective ethical review.

5.5. Diversity

The committee shall strive for: Gender balance, Multidisciplinary representation, Multisectoral participation and Community representation

5.6. Conflict of Interest

Members shall disclose any actual or potential conflict of interest, and refrain from review and decision-making for related protocols

6. Appointment of Members

The Registrar, Chanakya University will appoint the Chairperson of the IHEC, and all the committee members based on their competence, experience and integrity. An official request letter to join IHEC-CU will be send to the invitees. The members will give their acceptance letter to the IHEC secretariat by email **ihec@chanakyauniversity.edu.in**

7. Tenure of Membership

- Members shall ordinarily serve for a fixed tenure as determined by Chanakya University (two years).
- Members may be reappointed as per the university policy.

8. Roles and Responsibilities

Chairperson

- Preside over meetings
- Ensure independent and fair review
- Facilitate consensus and ethical decision-making

Member Secretary

- Coordinate committee activities
- Organize meetings and maintain records
- Communicate decisions to investigators

Alternate Member secretary

- Perform the duties of member secretary in their absence

Legal Expert

- Advises on applicable laws, participant rights, privacy, and regulatory compliance.

Social Scientist

- Reviews community engagement, social justice, and cultural sensitivity.

Lay Person

- Represents participant interests and ensures consent documents are understandable.

Basic Medical Scientist

- Evaluates scientific validity and biological rationale.

Clinician

- Assesses participant safety, clinical risks, and medical management.

Ethicist/Philosopher/Theologian

- Reviews ethical principles, autonomy, beneficence, justice, and non-maleficence.

9. Attendance Requirements

Members are expected to:

- Attend scheduled meetings regularly
- Review assigned documents before meetings
- Participate in discussions and decision-making

Repeated absence without valid justification may lead to review of membership status.

10. Training Requirements

Members shall undergo:

- Orientation training at induction

- Continuing education and refresher training in:
  - Bioethics
  - Good Clinical Practice (GCP)
  - Applicable regulations and guidelines

11. Confidentiality

All members shall maintain confidentiality regarding:

- Research protocols
- Participant information
- Committee deliberations and decisions

Members may be required to sign confidentiality agreements.

12. Special Invitees/Independent Experts

Subject experts may be invited for specific protocol review when required. Such experts:

- Shall provide technical/scientific opinion only, shall not participate in final voting
- Shall not count toward quorum

13. Resignation, Replacement, and Removal

Resignation, replacement, and removal of members shall be conducted as per IHEC-CU SOPs and applicable regulations.

14. Documentation

The following records shall be maintained:

- Appointment letters
- Member CVs and qualifications
- Training records
- Attendance records
- Conflict of interest declarations

- Confidentiality agreements

15. Office of IHEC-CU

The IEC Secretariat is located in the School of Biosciences, Chanakya University, and operates from 10:00 AM to 4:30 PM, Monday through Friday, excluding University holidays.

16. Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

IHEC-CU

SOP Code: SOP 03/V1

Terms of reference for IHEC-CU

Date: May 01, 2026

1. Purpose

The Institutional Human Ethics Committee of Chanakya University (IHEC-CU) is constituted to protect the rights, safety, dignity, and well-being of all research participants involved in biomedical and health research. The Committee shall ensure that all research involving human participants is scientifically sound, ethically acceptable, and conducted in accordance with the **ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)**, applicable national regulations, and institutional policies. The welfare of research participants shall always take precedence over the interests of science and society.

2. Scope

The IHEC-CU shall review, approve, monitor, and oversee biomedical and health research involving human participants conducted under the auspices of Chanakya University, irrespective of the funding source.

The scope includes research involving:

- Human participants
- Human biological materials (blood, tissue, body fluids, DNA, RNA, cells, etc.)
- Human biological data
- Medical records and identifiable health information
- Questionnaires, surveys, interviews, behavioural and observational studies
- Clinical, epidemiological, public health, social and behavioural research falling within biomedical and health research
- Student dissertations, postgraduate theses, doctoral research and faculty research involving human participants

The Committee shall review studies before initiation and continue ethical oversight through periodic review until study completion.

3. Types of Research Reviewed

IHEC-CU shall review the following categories of research:

- Investigator-initiated research
- Academic research projects
- Faculty research projects
- Undergraduate, postgraduate and doctoral student research involving human participants
- Institutionally funded research
- Extramurally funded biomedical and health research
- Collaborative multi-centre studies conducted by Chanakya University investigators

The Committee shall determine whether proposals qualify for exemption, expedited review, or full committee review in accordance with applicable ethical guidelines.

4. Terms of Reference

The IHEC-CU shall:

- Protect the rights, dignity, safety and well-being of research participants.
- Review scientific and ethical aspects of research protocols.
- Evaluate the risk-benefit ratio.
- Review participant information sheets and informed consent documents.
- Assess privacy, confidentiality and data protection measures.
- Ensure equitable participant selection, particularly for vulnerable populations.
- Review compensation and management plans for research-related injury wherever applicable.
- Monitor approved studies through continuing review, protocol amendments, annual reports, SAE reports and final reports.

- Review protocol deviations, violations and non-compliance.
- Ensure management of conflict of interest during ethical review.
- Maintain confidentiality of committee deliberations and research documents.
- Maintain documentation and records as required by applicable regulations.

5. External Research Proposals

IHEC-CU shall primarily review biomedical and health research conducted by investigators affiliated with Chanakya University. Research proposals from investigators outside Chanakya University may be considered only under the following circumstances:

- Collaborative projects in which Chanakya University is a participating institution;
- Research specifically referred by the competent authority of the University; or
- Other exceptional circumstances approved by the Chairperson and Member Secretary.

Such proposals shall comply with all applicable ICMR guidelines and institutional requirements.

Where applicable, an ethics review fee may be charged as approved by Chanakya University. The applicable fee schedule shall be notified separately by the University.

6. Ethical Principles

The IHEC-CU shall ensure that the principles of autonomy, beneficence, non-maleficence and justice are upheld throughout the planning, conduct, monitoring and reporting of all research. The Committee shall also ensure compliance with applicable regulatory requirements, national ethical guidelines and institutional policies.

IHEC-CU

SOP Code: SOP 04/V1

Conditions of appointment and the quorum required

Date: May 01, 2026

1. Purpose

The purpose of this SOP is to define the conditions for appointment of members to the IHEC-CU and to establish quorum requirements for conduct of IHEC meetings and ethical review activities.

2. Scope

This SOP applies to all members of the IHEC-CU.

3. Policy Statement

The IHEC-CU shall be constituted in accordance with applicable national ethical guidelines and regulatory requirements to ensure independent, competent, multidisciplinary, and unbiased ethical review of research involving human participants.

4. Conditions of Appointment of Members

4.1 Eligibility

Members shall be selected based on:

- Relevant qualifications and expertise
- Experience in research, ethics, law, social sciences, or community representation
- Ability to provide independent and unbiased opinion
- Willingness to uphold confidentiality and ethical standards

4.2 Appointment Authority

IHEC-CU members shall be appointed by the Head of Institution/Competent Authority through formal appointment orders.

4.3 Tenure

- Members shall ordinarily serve for a fixed tenure as decided by University (commonly 2 years), with eligibility for reappointment as per CU policy.
- The University may stagger appointments to maintain continuity of committee functioning.

4.4 Terms and Conditions

Members shall:

- Maintain confidentiality of all committee proceedings and documents
- Declare conflict of interest whenever applicable
- Participate actively in meetings and protocol review
- Adhere to applicable ethical guidelines and SOPs
- Attend orientation and continuing training programs

4.5 Honorarium/Compensation

Members may receive honorarium as per university policy.

5. Composition of IHEC-CU

The committee shall consist of multidisciplinary and multisectoral members including:

- Chairperson (external to Chanakya University)
- Member Secretary
- Basic medical scientist
- Clinician(s)
- Legal expert
- Social scientist
- Lay person
- Other members as required by regulations

The committee shall maintain appropriate gender balance and diversity.

6. Quorum Requirements

6.1 Definition of Quorum

Quorum refers to the minimum number and required representation of members necessary for valid conduct of IHEC-CU meetings and ethical review decisions.

6.2 Quorum Composition

The meeting requires the presence of at least 5 members to proceed and make decisions. Representation is required from essential categories such as:

- Medical/scientific member
- Non-scientific member
- Lay person
- Member from outside the University, where applicable

6.3 Quorum Maintenance

- Quorum shall be maintained throughout the meeting and decision-making process.
- Members with conflict of interest related to a protocol shall abstain from deliberation and voting and shall not contribute to quorum for that protocol.

6.4 Lack of Quorum

If quorum is not met, the meeting may discuss agenda items informally, but no final ethical review decision/approval shall be granted.

7. Special Invitees/Independent Experts

The Chairperson/member secretary of IHEC-CU may invite subject experts or consultants for specific protocol review. Such invitees:

✓Shall provide expert opinion only

✓Shall not participate in final decision-making or voting

✓Shall not count toward quorum

8. Documentation

The following shall be documented:

- ✓ Appointment letters
- ✓ Member CVs and qualifications
- ✓ Attendance records
- ✓ Quorum details in meeting minutes
- ✓ Conflict of interest disclosures

9. Responsibilities

Head of Institution/Competent Authority

- Approve constitution and appointment of members

Chairperson

- Ensure quorum requirements are met during meetings

Member Secretary

- Maintain membership records and attendance documentation

10. Record Retention

All records related to appointments, tenure, attendance, and quorum shall be securely maintained as per university policy and regulatory requirements.

11. Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
- Central Drugs Standard Control Organization applicable ethics committee regulations
- International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) Guidelines

IHEC-CU

SOP Code: SOP 05/V1

Procedure for resignation, replacement or removal of members

Date: May 01, 2026

1. Purpose

The purpose of this SOP is to define the procedure for resignation, replacement, and removal of members of IHEC-CU to ensure uninterrupted, independent, and effective functioning of the committee.

2. Scope

This SOP applies to all members of the IHEC-CU, including:

- Chairperson
- Member Secretary
- Basic medical scientists
- Clinicians
- Legal expert
- Social scientist/NGO representative
- Lay person
- External members/subject experts

3. Policy Statement

IHEC-CU membership shall be maintained in accordance with applicable ethical and regulatory requirements. Any resignation, replacement, or removal of members shall be documented appropriately to maintain transparency, quorum requirements, and committee functionality.

4. Procedure for Resignation of Members

Step 1: Submission of Resignation

A member intending to resign shall submit a written resignation letter addressed to: the Chairperson (for general members), or the Head of Institution/Competent Authority (for Chairperson or Member Secretary, where applicable)

The resignation letter shall include Reason for resignation (optional) and proposed effective date

Step 2: Acceptance of Resignation

The resignation shall be reviewed and formally accepted by the competent authority.

Step 3: Documentation

The Member Secretary shall record the resignation in committee records and meeting minutes and update the membership list and relevant regulatory records

5. Procedure for Replacement of Members

Step 1: Identification of Vacancy

Vacancies arising due to resignation, removal, death, completion of tenure, or prolonged non-availability shall be identified by the IHEC-CU.

Step 2: Selection of Replacement

Replacement members shall be selected based on:

- Required expertise/category
- Independence and eligibility
- Regulatory composition requirements

University shall ensure maintenance of multidisciplinary representation and quorum requirements.

Step 3: Appointment

The competent authority shall issue a formal appointment order specifying:

- Role/category of member
- Tenure period
- Responsibilities and confidentiality obligations

Step 4: Orientation and Training

Newly appointed members shall undergo orientation/training before participating in committee review activities.

6. Procedure for Removal of Members

A member may be removed under the following circumstances:

- Repeated absence from meetings without valid reason
- Breach of confidentiality
- Non-disclosure of conflict of interest
- Misconduct or unethical behaviour
- Actions affecting the integrity or functioning of the IHEC-CU
- Inability to perform assigned responsibilities

Step 1: Review of Concern

The Chairperson/ University shall review the issue and provide the concerned member an opportunity for explanation, where appropriate.

Step 2: Decision on Removal

Based on review findings, the competent authority may decide removal of the member.

Step 3: Documentation

The removal decision and reasons shall be documented in IHEC records and meeting minutes where applicable.

7. Maintenance of Quorum and Regulatory Compliance

Chanakya University shall ensure that:

- Committee composition remains compliant with applicable regulations
- Required quorum is maintained at all times
- Updated member details are communicated to relevant authorities where required

8. Record Retention

The following records shall be maintained securely:

- Resignation letters
- Appointment orders
- Removal records
- Updated membership lists
- Training/orientation records

9. Responsibilities

Chairperson

- Oversee proper implementation of the SOP

Member Secretary

- Maintain documentation and membership records
- Coordinate communication and updates

Competent Authority

- Approve appointments, resignations, and removals

10. Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
- Central Drugs Standard Control Organization applicable ethics committee regulations
- International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) Guidelines

IHEC-CU

SOP Code: SOP 06/V1

Standard operating procedures to be followed by the committee in general

Date: May 01, 2026

1. PURPOSE

The purpose of this SOP is to establish a standardized procedure for the submission, review, approval, monitoring, documentation, and archiving of research proposals involving human participants at Chanakya University.

2. SCOPE

This SOP applies to:

- All research involving human participants conducted under the auspices of Chanakya University.
- Faculty members, research scholars, students, investigators, co-investigators, and collaborators conducting human research.
- Research involving biological samples, questionnaires, surveys, interviews, observational studies, clinical studies, and other human participant-related investigations.
- Initial review, continuing review, amendments, protocol deviations, premature study termination, and study completion reports.
- Activities of the IHEC-CU

3. RESPONSIBILITY

3.1 Chairperson

- Preside over all IHEC meetings.
- Ensure impartial and ethical review of proposals.
- Approve recommendations arising from expedited review.
- Make final decisions where consensus cannot be achieved.

- Authorize constitution of expedited review subcommittees.

3.2 Member Secretary / Alternate Member Secretary

- Receive and scrutinize all applications and verify completeness of submitted documents.
- Communicate deficiencies to investigators.
- Categorize proposals for exempt, expedited, or full review.
- Circulate documents to committee members.
- Prepare meeting agendas and minutes.
- Communicate committee decisions to investigators.
- Maintain records, archives, and SOP documents.
- Coordinate inspections and audits.
- Review and update SOPs periodically.

3.3 Technical Advisory Committee (TAC)

- Review proposals for scientific validity and technical feasibility.
- Provide Technical Advisory Clearance certificates.
- Recommend scientifically sound proposals for ethics review.

3.4 Principal Investigator (PI)

- Submit complete applications within prescribed timelines.
- Provide accurate and complete documentation.
- Attend meetings when invited for clarification.
- Submit revisions, progress reports, deviations, amendments, and final reports.
- Conduct studies according to approved protocols.

3.5 IHEC Members

- Review assigned proposals.
- Identify ethical concerns and participant risks.

- Participate in discussions and decision-making.
- Maintain confidentiality of all submitted documents.

4. DETAILED INSTRUCTIONS

4.1 Submission of Applications

All proposals shall be submitted in English language only.

Submission Address

Hard Copy:
Member Secretary,
Institutional Human Ethics Committee (IHEC),
Chanakya University

Soft Copy:
ihec@chanakyauniversity.edu.in

Documents Required

The application package shall include:

1. Covering letter addressed to the Chairperson, IHEC-CU.
2. Technical Advisory Committee (TAC) clearance certificate.
3. Completed IHEC Application Form.
4. Detailed research proposal submitted to TAC.
5. Supporting documents:

   Consent forms, Questionnaires, University permissions (if any), Recruitment materials (if any)
6. Participant Information Sheet in:

   ○ English and Local/regional language understood by participants
7. Informed Consent Form in:

   ○ English and Participant's understandable language

Applications must be submitted at least **two weeks** prior to the scheduled IHEC meeting.

4.2 Preliminary Scrutiny

The Member Secretary/Alternate Member Secretary shall:

- Review applications for completeness.
- Verify adherence to submission requirements.
- Inform the PI within one week regarding:
  - Acceptance for processing, or Deficiencies requiring correction.

Incomplete applications not corrected before the prescribed deadline shall not be considered for review.

4.3 Categorization of Proposals

Following preliminary review, proposals shall be categorized into:

A. Exemption from Review

Applicable for studies involving less than minimal risk, including:

- Educational research
- Instructional methods
- Curriculum evaluation
- Classroom management studies

The Chairperson shall assess such studies, and the Member Secretary shall issue exemption letters.

B. Full Review

- Research involving more than minimal risk.
- Collection of biological samples.
- Vulnerable populations.
- Sensitive or stigmatizing topics.
- Studies not qualifying for exempt or expedited review.

All members shall review these proposals. The PI may be invited to provide clarification.

C. Expedited Review

- Revised proposals.
- Minor amendments.
- Nationally relevant urgent proposals.
- Studies specifically identified by the Chairperson.

An expedited review subcommittee may consist of:

Member Secretary, One Scientific Member and One Non-scientific Member

Recommendations shall be placed before the full IHEC meeting for ratification.

4.4 Conduct of IHEC-CU Meetings

Meeting Schedule

Regular meetings shall be conducted twice a year.

Meeting Procedure

1. Chairperson calls meeting to order.
2. Previous meeting minutes are presented.
3. Expedited review decisions are presented.
4. PIs present proposals or may be invited for clarification.
5. Ethical concerns are discussed.
6. Deliberations occur in a closed meeting.
7. Decisions are reached through consensus.
8. Chairperson's decision shall be final.
9. Minutes shall be prepared and signed by all members.

4.5 Decisions After Review

The IHEC may issue any of the following decisions:

- ***Approval:*** Unconditional Approval/ Conditional Approval
- ***Resubmission***

- ***Rejection***
- ***Expedited Review After Revision***
- ***Full Review After Revision***

Decision letters shall be communicated within **two weeks** of the meeting.

For conditional approvals, investigators shall submit revisions within **seven days** of communication.

4.6 Continuing Review and Monitoring

IHEC shall conduct annual review of approved studies by annual progress reports

For studies exceeding one year:

- First report: within 30 days after completion of first year.
- Subsequent reports: annually thereafter.

Investigators shall report:

- Progress updates
- Protocol deviations
- Amendments
- New safety information
- Change of investigators/sites
- Premature study termination

4.7 Study Completion

At study completion, investigators shall submit:

- Final Report
- Summary of Results
- Study Abstract

Prematurely terminated studies shall include:

- Reasons for termination

- Summary of data collected

4.8 Record Keeping, Archiving, Security

All documents shall be: Dated, Filed and Archived electronically

Access restricted to Member Secretary and Alternate Member Secretary

Retention Period

All records shall be retained for a minimum of **three** years following study completion or termination.

Documents to be Archived

- IHEC Constitution and Membership Records
- Member CVs
- Ethics Training Certificates
- SOPs
- Annual Reports
- Financial Records
- Study Protocols
- Progress Reports
- Meeting Agendas
- Signed Minutes
- Final Reports
- Relevant ICMR Guidelines

4.9 Inspection and Audit

IHEC shall remain open for inspections and audits by authorized agencies, including authorities designated by the Department of Health Research (DHR).

The Member Secretary shall facilitate inspections, provide required records, ensure compliance with: ICMR Guidelines and Indian Good Clinical Practice (GCP) guidelines.

5. FLOW CHART

Research Proposal Preparation

↓

Technical Advisory Committee (TAC) Review

↓

TAC Clearance Certificate

↓

Submission to IHEC

↓

Administrative Scrutiny by Member Secretary

↓

Complete?

→ No → Return to PI for Revision

→ Yes

↓

Categorization

(Exempt / Expedited / Full Review)

↓

IHEC Review

↓

Decision

(Approval / Conditional Approval / Rejection / Revision)

↓

Communication to PI

↓

Study Initiation

↓

Annual Monitoring & Progress Reports

↓

Study Completion Report

↓

Archiving of Records

6. ANNEXURES / FORMS

- IHEC Application Form
- Covering Letter Format
- Participant Information Sheet Template
- Informed Consent Form Template
- Progress Report Form
- Protocol Deviation Reporting Form
- Amendment Submission Form
- Study Completion Report Form
- Premature Termination Reporting Form
- IHEC Decision Communication Format

7. REFERENCES

1. Indian Council of Medical Research (ICMR). National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

2. ICMR Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2018.

3. Indian Good Clinical Practice (GCP) Guidelines.

4. Department of Health Research (DHR) Guidelines for Ethics Committees.

IHEC-CU

SOP Code: SOP 07/V1

Standard operating procedures to be followed by the committee for vulnerable population

Date: May 01, 2026

1. Purpose

The purpose of this SOP is to ensure adequate protection of the rights, safety, dignity, and well-being of vulnerable participants involved in biomedical and health research reviewed by IHEC-CU.

2. Scope

This SOP applies to all research proposals involving vulnerable individuals or populations submitted to the IHEC-CU for ethical review.

3. Definition of Vulnerable Population

Vulnerable persons are individuals or groups who may have limited autonomy, diminished capacity to provide informed consent, or increased likelihood of coercion or undue influence.

Examples include:

- Children/minors
- Pregnant women and foetus
- Elderly individuals
- Persons with cognitive impairment or mental illness
- Economically or socially disadvantaged individuals
- Prisoners/detainees
- Terminally ill or critically ill patients
- Students or employees under hierarchical influence
- Individuals with reduced decision-making capacity

4. Policy Statement

Research involving vulnerable individuals or populations shall receive enhanced ethical scrutiny to safeguard their rights, safety, dignity, autonomy, privacy, and well-being. Inclusion of vulnerable participants shall be scientifically necessary and ethically justified, and shall not be based on convenience.

The IHEC-CU shall ensure that additional safeguards are incorporated to prevent coercion, undue influence, discrimination, exploitation, or unnecessary risks. The rights and welfare of vulnerable participants shall always take precedence over the objectives of research.

In accordance with the ICMR National Ethical Guidelines (2017), all initial review, approval, and continuing review of research involving vulnerable populations shall be undertaken only by the Full Committee. Such proposals shall not be approved through expedited review or exemption mechanisms.

5. Responsibilities

IHEC Responsibilities

The IHEC-CU shall:

- Ensure that inclusion of vulnerable participants is scientifically and ethically justified.
- Confirm that the research cannot be carried out equally well in a less vulnerable population.
- Assess whether anticipated benefits justify the risks.
- Ensure risks are minimized and are reasonable in relation to the expected benefits.
- Review the adequacy of additional safeguards to protect participants from coercion, undue influence, exploitation, and discrimination.
- Carefully evaluate the informed consent process, assent procedures where applicable, and consent from legally authorised representatives (LARs).
- Ensure that participant information sheets and consent forms are understandable and culturally appropriate.
- Ensure privacy, confidentiality, and protection of sensitive personal information.

- Determine whether additional monitoring of the research is required.
- Conduct **initial review, approval, continuing review, and monitoring only through the Full Committee** for all research involving vulnerable populations.
- Review protocol deviations, adverse events, and safety reports involving vulnerable participants promptly.
- Ensure continuing oversight until completion of the study.

Investigator Responsibilities

- Clearly justify the inclusion of vulnerable participants in the protocol.
- Describe all additional safeguards proposed.
- Obtain valid informed consent, assent, or consent from legally authorised representatives wherever applicable.
- Protect participants from coercion or undue influence during recruitment.
- Promptly report protocol deviations, adverse events, and safety concerns to the IHEC.
- Submit periodic progress reports as required by the Committee.

6. Procedure

Step 1: Identification of Vulnerable Population

The investigator shall clearly identify involvement of vulnerable participants in the protocol submission.

Step 2: Scientific and Ethical Justification

The IHEC shall verify:

- Necessity for inclusion of vulnerable participants
- Whether the research question can be answered using non-vulnerable populations
- Potential direct or indirect benefits to participants/population

Step 3: Risk-Benefit Assessment

The committee shall ensure that risks are minimized. The IHEC shall evaluate whether the level of risk is the minimum necessary to achieve the scientific objectives and whether the anticipated individual or societal benefits justify involving vulnerable participants. Where the research offers no direct benefit, the Committee shall ensure that risks remain minimal and are ethically acceptable.

Step 4: Review of Informed Consent Process

The IHEC shall evaluate:

- Simplicity and comprehensibility of Participant Information Sheet and Informed Consent Form
- Need for legally authorized representative consent
- Requirement for assent in case of minors
- Measures to avoid coercion or undue influence

Step 5: Additional Safeguards

Depending on the participant category, safeguards may include:

- Independent monitoring of the study.
- Appointment of an impartial witness during the consent process where appropriate.
- Community engagement or consultation for community-based research.
- Re-consent if participants regain decision-making capacity.
- More frequent safety reporting.
- Periodic review of recruitment practices.
- Enhanced protection of confidentiality and sensitive data.
- Additional counselling or psychosocial support wherever appropriate.

Step 6: Documentation

The following shall be documented:

- Justification for inclusion of vulnerable population

- Additional safeguards approved
- Consent/assent procedures
- Special monitoring recommendations

Step 7: Continuing Review

Research involving vulnerable populations shall undergo enhanced continuing review by the Full Committee. Depending on the level of risk, the IHEC may require:

- More frequent continuing review.
- Review of recruitment progress.
- Review of protocol deviations.
- Review of adverse events and serious adverse events.
- Periodic monitoring reports.
- Review of participant complaints.
- Site monitoring visits, where considered necessary.
- Reassessment of the risk-benefit ratio during the course of the study.

7. Special Considerations

Children/Minors

- Parent/legal guardian consent mandatory
- Assent from child wherever applicable

Cognitively Impaired Participants

- Consent from legally authorized representative
- Participant assent whenever feasible

Economically/Socially Disadvantaged Individuals

- Ensure absence of undue inducement or coercion

Pregnant Women

- Additional risk assessment for mother and fetus

Full Committee Review

- All research involving vulnerable populations shall undergo initial review, approval, continuing review, and any major protocol amendments by the Full Committee.
- Such studies shall not be approved through exempt or expedited review procedures. The Committee shall ensure that the required expertise is available during deliberations and may invite subject experts whenever necessary. Invited experts shall provide technical advice but shall not participate in voting or be counted towards quorum.

8. Record Retention

All records related to research involving vulnerable populations shall be securely maintained as per applicable regulations.

9. Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
- Central Drugs Standard Control Organization applicable ethics committee regulations
- International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) Guidelines

IHEC-CU

SOP Code: SOP 08/V1

Policy regarding training for new and existing committee members

Date: May 01, 2026

1. Purpose

The purpose of this policy is to ensure that all members of IEC-CU are adequately trained in ethical, scientific, and regulatory aspects of biomedical and health research involving human participants, enabling effective and competent ethical review.

2. Scope

This policy applies to:

- Newly appointed IHEC-CU members
- Existing IHEC members
- Member Secretary
- Chairperson
- External experts/consultants associated with IHEC activities

3. Policy Statement

Chanakya University shall ensure continuous capacity building and competency development of all IHEC members through orientation programs, refresher training, workshops, seminars, webinars, and continuing education activities related to research ethics and regulatory requirements.

Training shall be conducted in accordance with applicable national and international ethical guidelines.

4. Objectives of Training

Training programs shall aim to:

- Familiarize members with ethical principles governing human research
- Enhance understanding of applicable regulations and guidelines
- Strengthen protocol review and risk-benefit assessment skills

- Ensure proper functioning of the IHEC
- Promote participant safety, rights, dignity, and confidentiality

5. Training Requirements

A. Training for New Members

All newly inducted members shall undergo orientation training covering:

- Roles and responsibilities of IHEC members
- Ethical principles in human research
- ICMR National Ethical Guidelines
- Good Clinical Practice (GCP) guidelines
- Informed consent process
- Review procedures and SOPs
- Conflict of interest and confidentiality requirements

B. Continuing Training for Existing Members

Existing members shall participate periodically in:

- Refresher training programs
- Workshops/seminars/webinars on research ethics
- Updates on regulatory and guideline changes
- Specialized training relevant to ongoing research areas

6. Frequency of Training

- Orientation training: At the time of appointment
- Refresher training: At least once annually or as required

7. Documentation

The following records shall be maintained:

- Attendance records

- Training certificates
- Training schedules/materials
- Competency and participation records

8. Responsibility

- The Member / alternate Secretary shall coordinate training activities and maintain records.
- IHEC shall facilitate participation in relevant training programs.

9. Review of Policy

This policy shall be reviewed periodically and updated as per applicable ethical and regulatory requirements.

Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
- Central Drugs Standard Control Organization guidelines and applicable regulations
- International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines

IHEC-CU

SOP Code: SOP 09/V1

Policy to monitor or prevent the conflict of interest along with standard operating procedures

Date: May 01, 2026

Objective

To establish a standardized procedure for identification, disclosure, management, and documentation of conflict of interest in IHEC-CU functioning.

Policy Statement

All IHEC-CU members shall disclose any actual, potential, or perceived conflict of interest related to research proposals under review. Members with declared conflicts shall abstain from:

- Review of the concerned protocol
- Participation in discussion related to the protocol
- Voting/decision-making for the protocol

The conflicted member may provide clarification only if requested by the committee and shall leave the meeting during deliberation and decision-making.

Procedures for Monitoring and Prevention of conflict of interest (COI)

1. All IHEC-CU members shall sign a Conflict-of-Interest declaration at the time of appointment and annually thereafter.
2. At the beginning of every IHEC meeting, members shall disclose conflicts related to agenda items.
3. The Member Secretary shall record all disclosures in the meeting minutes.
4. Members with conflict shall recuse themselves from the review process of the concerned study.
5. The quorum requirement shall be maintained excluding the conflicted member.
6. Any undisclosed conflict identified later shall be reviewed by the Chairperson, and appropriate corrective actions shall be taken.

7. Confidentiality of disclosures shall be maintained by the committee.

Step 4: Maintenance of Quorum

- The Chairperson shall ensure that quorum requirements remain fulfilled after recusal.

Step 5: Monitoring

- The IHEC-CU shall periodically review compliance with COI procedures.

Step 6: Record Retention

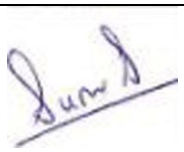
- COI-related documents shall be securely maintained.

Responsibility

- Chairperson: Oversight of COI management
- Member Secretary: Documentation and implementation
- IHEC-CU Members: Disclosure of conflicts

Reference Guidelines

- Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
- Central Drugs Standard Control Organization applicable ethics committee regulations

	Name	Designation	Signature	Date
Prepared by	Dr. Sumi. S	Member Secretary, IHEC-CU		12 June 2026
Reviewed by	Dr. Shilpee Jain	Alternate Member Secretary		15 June 2026
Approved by	Dr. Swarnarekha Bhat	Chairperson IHEC-CU		17 June 2026

Annexure 1: SOP version history record

Sl. No.	SOP Number	SOP Title	Version Number	Effective Date	Nature of Revision / Changes Made	Remarks
1						

Instructions:

- All modifications made to SOPs shall be documented in this record.
- Superseded SOP versions shall be archived by the IHEC-CU Member Secretary
- The effective date refers to the date from which the revised SOP becomes operational.
- "Nature of Revision" should briefly describe major updates, additions, deletions, or regulatory modifications incorporated into the SOP.

Annexure 2. Covering letter for initial IHEC Review

To,

The Member Secretary,

Institutional Human Ethics Committee,

Chanakya University, Bengaluru

Subject: Request for Exemption/Expedited Ethical/ Full Review (select one) of Research Proposal

Respected Sir/Madam,

I, ..., (designation) at School of ....., wish to submit my research proposal titled "....." for consideration under the Institutional Ethics Committee of Chanakya University. I kindly request an Exemption/Expedited Ethical/ Full Review (select one) under the applicable ethical framework. The study will be conducted at ..... (mention study site) and involves the collection of (mention samples).

Enclosed with this application are the following documents for your kind perusal:

1. Study Protocol
2. Participant information sheet and informed consent form (English & local language)
3. Questionnaire (if any)
4. Check List for Protocol Submission
5. Copy of approval letter from Technical advisory committee

I assure you that the study will be conducted in strict adherence to ethical guidelines and with utmost regard for participant safety and confidentiality.

Thank you

PI name and designation

Sign with date

PI Email:

PI Contact No.

Annexure 3: Application form for initial review

(Name of the Institution) **EC Ref. No.** *(For office use):*

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Principal Investigator:

(b) Designation: (c) School:

(d) Date of Submission:

(e) Title of the study:

(f) Acronym/ Short title, (If any):

(g) Details of Investigators:

Name	Designation and Qualification	School and Institution	Address for communication, Telephone, e mail ID
Principal Investigator/Guide			
Co-investigator/student/fellow			

(h) Duration of the study:

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget:

(b) Duration of the project:

(c) Funding agency:

Central government funding State government funding Institutional funding Private

Specify

(d) International Sponsor: Government Private UN agencies

(e) Industry: National Multinational

(f) Contact address of the sponsor:

SECTION B - RESEARCH RELATED INFORMATION

3.	**OVERVIEW OF RESEARCH**
(a)	Type of study: Basic Sciences — Clinical — Epidemiological Retrospective — Prospective Cross Sectional — Case Control *(Specify)* — Cohort Any others
(b)	Single center Multi-centric
4.	**METHODOLOGY**
(a)	Is there an external laboratory involved for investigations? [1] Yes ☐ No ☐ NA ☐
(b)	Overview of the research (Lay summary in 300 words)

[1] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.*

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Does the study involve:

New recruitment: Yes No

If Yes, skip to **b**.

Previously approved protocol by IHEC-CU: Yes No

Did previous approved protocol consent for future sample use, provide IHEC number:

If Yes, skip to **8.**

(b) Type of participants in the study:

Healthy volunteer		Patient		Vulnerable person/ Special groups	☐	Others *(Specify)*	

Who will do the recruitment?

Participant recruitment methods used:

Posters / leaflets / Letters	☐	TV/Radio ads/social media/Institution website		Patients / Family/Friends visiting hospitals	☐	Telephone	
Others *(Specify*							

(c)

Children under 18 yrs	Pregnant or lactating women
Differently abled (Mental/Physical)	Employees/Students/Nurses/ Staff
Elderly	Institutionalized

	Economically and socially disadvantaged Terminally Ill (stigmatized or rare diseases) Refugees/Migrants/Homeless Any other *(Specify)*: i. Will there be vulnerable person/special groups involved? Yes No NA ii. If yes, type of vulnerable person /special groups
(d)	iii. Provide justification for inclusion/exclusion criteria iv. Are there any additional safeguards to protect research participants?

6. BENEFITS AND RISKS

(a)

i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes No

If yes, categorize the level of risk[2]:

Less than Minimal risk (non – identified data samples from public domain)	Minimal risk (obtaining body fluids without invasive intervention, eg: hair, saliva or urine samples)
Minor increase over minimal risk or Low Risk (minimally invasive procedures, such as obtaining blood sample)	More than Minimal Risk or High Risk (Invasive procedure such as biopsy, endoscopy procedures, lumbar puncture, intravenous sedation etc.)

ii. Describe the risk management strategy: (if applicable)

(b)

What are the potential benefits from the study?	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐

[2] *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1*

	For the society/community	☐	☐		☐	☐
	For improvement in science	☐	☐		☐	☐
	Please describe how the benefits justify the risks : (If minimal / high risk)					
(c)	Are Adverse Events expected in the study? Yes No NA Are reporting procedures and management strategies described in the study? Yes No If Yes, Specify					
7. INFORMED CONSENT						
(a)	Are you seeking waiver of consent? Yes No If yes, please specify reasons					
(b)	Type of consent planned for : Signed consent / Verbal/ oral consent / Witnessed consent / Audio-Video (A/V) consent Consent from LAR (If so, specify from whom) / For children<7 yrs parental/LAR consent / Verbal assent from minor (7-12 yrs) along with parental consent / Written Assent from Minor (13-18 yrs) along with parental consent Other *(specify)*					
(c)	Who will obtain the informed consent? PI/Co-I Nurse/Counsellor Research Staff Other *(Specify)*					
(d)	Participant Information Sheet (PIS) and Informed Consent Form (ICF) English Local language other (*specify*) List the languages in which translations were done					
8. STORAGE AND CONFIDENTIALITY						
(a)	Identifying Information: Study Involves samples/data. If Yes, Specify Yes No NA If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)					

(b)	Do you propose to use stored samples/ data in future studies? Yes No May be If No, when and how will you discard the samples?
(c)	Who will be maintaining the data pertaining to the study?
(d)	Where will the data be analyzed and by whom?
(e)	For how long will the data be stored?
9	**PAYMENT/COMPENSATION**
	(a) Who will bear the costs related to participation and procedures? PI or Institution or Sponsor or Other agencies (specify) ..... (b) Is there a provision for free treatment of research related injuries? Yes or No If yes, then who will provide the treatment? ..... (c) Is there a provision for compensation of research related SAE? If yes, specify. (d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes or No .....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES	
(a)	Will the results of the study be reported and disseminated? If yes, specify. Yes No NA
(b)	Will you inform participants about the results of the study? Yes No NA
(c)	Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details Yes No NA

(d)	If commercial product is developed, is there any plan for post research benefit sharing with participants? If yes, specify Yes No NA
(e)	Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide the details. Yes No

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.

☐	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.
Name of PI: Signature: Date	

Annexure 4. Participant information sheet template

Title of the study:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation. Please give your consent to participate in this study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant. Your participation in this study is voluntary.

- **Purpose of the study**

Briefly state the background and rationale for undertaking this study in layman friendly language.

- **Expected duration of the study and number of research participant**

You will be one of the approximately XXX people who will participate in this study. (If multicentric study – mention that the study is also being carried out at XXX other centres across the country/ state.

- **Study procedures**

Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organize this section. Do not use scientific / technical terms. Use language appropriate to the population. If applicable, specify the subject's assignment to study groups, length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done. Describe any invasive procedures or biological sampling.

- **Potential risk and discomfort**

In addition to physiological risks/discomforts, describe any reasonably foreseeable psychological, social, legal, or financial risks or harms that might result from participating in the research.

- **Potential benefit**

Describe benefits to subjects expected from the research. If the subject will not benefit directly from participation, clearly state this fact. State the potential benefits, if any, to science or society expected from the research.

- **Compensation for participation**

You will not be compensated for participating in this study. However, in the event of any injury during the study, due care will be taken care of by the investigators.

- **Confidentiality**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of *describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc. The results of the study will be published in the journals; however, your identity will not be revealed*.

- **Participation and withdrawal**

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. Your decision will not affect your further treatment at this institute.

- **Contact for further information**

Thank you for your time to read (or have read to you) the information about this study. We undertake to maintain complete confidentiality regarding the information obtained from you during the study. The information obtained from you will be used for research only. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during and after the study. If you have any questions about the study or wish to report any medical problem related to study, please contact the study investigator XXX, designation, department XX, telephone number. If you have any questions or concerns about your rights as a research participant, or complaints regarding the research study, you may call xxxxxxxx who is the Member Secretary of the Institutional Human Ethics Committee-Chanakya University on telephone xxxxxxxxxx (Monday to Friday: 9am to 04.30pm)

Annexure 5. Informed consent form template

Informed Consent Form

a. I have read or have had read to me the information given in the informed consent document for the study entitled "XXXX".
b. I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of the information sheet.
c. I understand that my participation in the study is voluntary and that I may withdraw from the study at any time, without any loss of benefits to which otherwise entitled.
d. I understand and accept that my biological samples may be used for **xxxxxx** in the future research.

☐ Yes ☐ No

_____

Name of research participant

_____ _____

Signature/ thumb impression of participant **Date**

Signature of the impartial witness

_____ _____

Signature of PI: .....date .....

Annexure 6. IHEC decision communication format

IHEC Reference No.: _____ **Date:** _____

To,
Dr. _____
Principal Investigator
Department of _____

Subject: Communication of IHEC Decision

The Institutional Human Ethics Committee reviewed your proposal entitled:

Title: _____ Date: _____ at its meeting held on _____.

Decision

☐ Approved

☐ Approved with modifications

☐ Resubmission

☐ Rejected

Comments / Recommendations

_____

_____

Required Modifications (if any)

_____

_____

Please submit the revised documents for re-review, if applicable.

Sincerely,

Member Secretary
Institutional Human Ethics Committee **(Signature & Date)**

Annexure 7. Application form for expedited review

.....

(Name of the Institution) **EC Ref. No.*** ***(For office use):***

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation):

.....

.....

1. **Choose reasons why expedited review from EC is requested?**
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records).
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)).
   iv. Revised proposal previously approved through expedited review, full review or continuing review approved proposal.
   v. Minor deviation from originally approved research causing no risk or minimal risk.
   vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis.

   Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.

   vii. For multicentre research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full

committee common review.

viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).

ix. Any other (please specify)

.....

.....

.....

2. Is waiver of consent being requested? Yes No

3. Does the research involve vulnerable persons? Yes No

If yes give details:

Signature of PI: .....date .....

Comments of EC Secretariat:

.....

Signature of Member Secretary: .....date .....

Version 1.0

Annexure 8. Application form for exemption from review

.....

(Name of the Institution) **EC Ref. No. *(For office use):***

Title of study:

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. **Choose reasons why exemption from ethics review is requested?**
   i. Research on data in the public domain/ systematic review s or meta-analyses
   ii. Observation of public behaviour/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person
   iii. Quality control and quality assurance audits in the institution
   iv. Comparison among instructional techniques, curricula, or classroom management methods
   v. Consumer acceptance studies related to taste and food quality
   vi. Public health programmes by government agencies
   vii. Any other (please specify in 100 words):

.....

.....

Signature of PI: .....date .....

Comments of EC Secretariat:

.....

Signature of Member Secretary: .....date .....

Annexure 9. Continuing review / Annual report format

.....

(Name of the Institution) **EC Ref. No.** ***(For office use):***

Title of study:

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: Validity of approval:

2. Date of Start of study: Proposed date of Completion

Period of Continuing Report:

3. Does the study involve recruitment of participants

If yes, Total number expected..... Number Screened: .....

Number Enrolled: ..... Number Completed:.....

Number on follow up:.....

(a) Enrolment status – ongoing / completed/ stopped

(b) Any other remark.....

(c) Have any participants withdrawn from this study since the last approval? Yes No

If yes, total number withdrawn and reasons: .....

.....

.....

4. Is the study likely to extend beyond the stated period ? Yes No

If yes, please provide reasons for the extension. .....

.....

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

If No, skip to item no. 6 Yes No

(a) If yes, date of approval for protocol and ICD :

(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes No If yes, when / how:

.....

.....

(c)Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes No

If yes, discuss in detail:

.....

.....

6. Have any ethical concerns occurred during this period? Yes No

If yes, give details. ....

.....

7. (a) Have any adverse events been noted since the last review? Yes No

Describe in brief: .....

(b) Have any serious adverse events (SAE)'s occurred since last review? Yes No

If yes, number of SAE's :..... Type of SAE's:

.....

.....

(c) Is the SAE related to the study? Yes No

Have you reported the SAE to EC? If no, state reasons Yes No

.....

.....

8. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations

..... Have you reported the deviations to EC? If no, state reasons Yes No

.....

.....

9. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ?

10. Are there any publications or presentations during this period?

If yes give details

.....

...

Any other comments:... .....

Signature of PI: .....date .....

Annexure 10. Application/notification form for amendments

.....

(Name of the Institution) **EC Ref. No.** ***(For office use):***

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: Date of start of study
2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD

3. Impact on benefit-risk analysis Yes No

If yes, describe in brief:

.....

4. Is any re-consent necessary? Yes No

If yes, have necessary changes been made in the informed consent? Yes No

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants)

Full review by EC (There is an increased alteration in the risk to participants)

6. Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI: .....date .....

Version 1.0

Annexure 11. Protocol violation/deviation reporting form (Reporting by case)

.....

(Name of the Institution) **EC Ref. No. *(For office use):***

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval Date of start of study
2. Participant ID: Date of occurrence
3. Total number of deviations /violations reported till date in the study:
4. Deviation/Violation identified by:

   Principal Investigator/study team Sponsor/Monitor SAE Sub Committee/EC
5. Is the deviation related to (Tick):

Consenting

Enrollment

Laboratory assessment

Investigational Product

Safety Reporting

Source documentation

Staff

Participant non- compliance

Others *(specify)*

6. Provide details of Deviation/Violation:

.....

7. Corrective action taken by PI/Co-PI:

.....

8. Impact on (if any): Study participant Quality of data

9. Are any changes to the study/protocol required? Yes No

If yes, give details

.....

.....

Signature of PI: .....date .....

Version 1.0

Annexure 12. Serious adverse event (SAE) reporting format (Biomedical Health Research)

.....

(Name of the Institution) **EC Ref. No. *(For office use):***

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation):

.....

1. Participant details:

Initials and ID	Age at the time of event	Gender	Weight:.....(Kgs)
.....	.....	Male Female	Height:.....(cms)
.....	.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: Date of reporting SAE:

4. Describe the event

5. Details of suspected intervention causing SAE

.....

.....

6. Report type: Initial Follow-up Final

If Follow-up report, state date of Initial report

7. Have any similar SAE occurred previously in this study? If yes, please provide details.

   Yes No

.....

8. In case of a multi-centric study, have any of the other study sites reported similar SAEs?

   (Please list number of cases with details if available)

.....

.....

9. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process) (Tick)

A. Expected event unexpected event

B. Hospitalization	Increased Hospital Stay	Death	Congenital anomaly/ birth defect
Persistent or significant disability/incapacity	Event requiring intervention (surgical or medical) to prevent SAE	Event which poses threat to life	Others

10. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

11. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much and to whom

.....

.....

12. Outcome of SAE

Resolved Ongoing Death Others *(specify)*

.....

13. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

.....

14. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

Signature of PI: ..... Date .....

Version 1.0

Annexure 13. Premature termination/Suspension/ Discontinuation report format

.....

(Name of the Institution) **EC Ref. No. *(For office use):***

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Date of EC approval: Date of start of study:
2. Date of last progress report submitted to EC:
3. Date of termination/suspension/discontinuation:
4. Tick the appropriate

   Premature Termination Suspension Discontinuation

   Reason for Termination/Suspension/Discontinuation:

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any):

   .....
   ...
5. Plans for post study follow up/withdrawal (if any):

   .....
   ...
6. Details of study participants:

   Total participants to be recruited: .....

   Enrolled:..... Consent Withdrawn:.....

Reason (Give details):

Withdrawn by PI:..... Reason (Give details):

Participants lost to follow up: .....

Any other: .....

Number of drop outs:.....

Reasons for each drop-out:

7. Total number of SAEs reported till date in the study:

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes No

8. Have there been participant complaints or feedback about the study?

Yes No If yes, provide details

9. Have there been any suggestions from the SAE Sub Committee? Yes No If yes, have you implemented that suggestion? Yes No

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes No . If Yes, provide details

11. Summary of results (if any):

Signature of PI:.....date .....

Annexure 14. Study completion report form

IHEC proposal number:

Title of study:

Principal Investigator (Name, Designation and Affiliation)

Date of IHEC Approval:

Date of Start of Study: **Date of study completion**:

Duration of the study:

1. Provide details of:

a) Total no. of study participants approved by the IHEC for recruitment:

b) Total no. of study participants recruited:

c) Total number of participants withdrawn from the study (if any):

Provide the reasons for withdrawal of participants1:

2. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

3. Describe the main Ethical issues encountered in the study (if any)

4. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

5. Describe in brief Plans for archival of records / Record Retention:

6. Is there a plan for post study follow-up

7. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

8. Describe results (summary) with Conclusion:

9. Number of SAEs that occurred in the study:

10. Have all SAEs been intimated to the EC:

11. Is medical management or compensation for SAE provided to the participants?

Signature of PI:.....date .....