CENTRAL UNIVERSITY OF KARNATAKA

Institutional Human Ethics Committee

1. Preamble

This document aims at supporting the efficient operation of Institutional Human Ethics Committee (Humans) IHEC at Central University of Karnataka, Kalaburagi-585367 and to establish a fair and consistent assessment process for proposals submitted to it for review. The IHEC will consider protocols involving research on human subjects, biological samples from human subjects, and data from human subjects.

2. Role of the Institutional Human Ethics Committee

As stated by the Indian Council of Medical Research (ICMR), the role of IHEC will be as follows: "all proposals for biomedical and health-related research will be subject to IHEC approval as a part of the IHEC's mandate. Proposals involving biological samples, vulnerable populations, and/or sharing of private information involving human subjects are also included in order to protect the rights, safety, and general welfare of all actual and potential participants in research that will be carried out by CUKarnataka researchers. No matter how essential the research's objectives are, the health and well-being of subjects must always come first".

The IHEC will make sure that the proposed approach/protocol complies with the four fundamental principles of research ethics: autonomy, beneficence, non-malfeasance, and justice.

The informed consent process, risk-benefit ratio, burden and benefit allocation, and provisions for suitable compensations will all be examined by the IHEC, as per the need.

IHEC will review proposals/protocols before the initiation of the study, and after the completion of the study through documented procedures. IHEC will not assess or approve a study retrospectively.

3. Purpose of IHEC

The purpose of IHEC at CUK is to ensure the quality and technical excellence, and ethical review of research proposals and ongoing studies in accordance with the ICMR guidelines, 2017. The IHEC will assess the study's scientific rationale, scope, and methodology, as well as its ethical aspects. The committee will consider the potential risks to participants and justify them, as well as the expected benefits to participants/community. The documentation required to ensure privacy will also be

reviewed.

4. Scope of IHEC

The scope of IHEC is to design SOPs, which cover the procedures for reviewing, writing, amending, and distributing SOPs. Relevant comments made during a study's discussion and deliberation will be recorded in minutes of meeting (MoMs). The IHEC's decision will be communicated to the principal investigator.

5. Composition of IHEC

a) IHEC will have a multidisciplinary composition, as per the norms laid down by the ICMR. The number of persons in the IHEC will be determined by the requirements and nature of the task.
b) The total number of members in an IHEC will be ideally between seven and 15 and at least five members will be present to meet the quorum requirements.
c) The IHEC will have both medical and non-medical members/technical and non-technical members.
d) Ideally, 50% of the members will be from outside the institution.
e) IHECs will be multi-sectoral and multi-disciplinary.

The composition of IHEC at CUK will be as follows:

i. **Chairperson**- the Chairperson of IHEC will be from outside CUK, with experience serving in an EC. He will be responsible for conducting EC meetings and their independent and efficient functioning. He will make sure that all members (particularly non-technical and non-affiliated) actively engage in all discussions. He will nominate a committee member as an acting chairperson in case of his and/or the vice-chairperson's absence at a meeting. He will seek a conflict of interest and assure fair decision-making. He will also address issues involving complaints against researchers and EC members and requests for the use of EC data.

ii. **Member Secretary/Alternate Member Secretary**-the member secretary will come from CUK. He will be responsible for a well-organised review of the proposal. He will have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. He is also responsible for scheduling EC meetings and their documentation. He will also make sure that SOPs are updated and respond to audits and inspections.

iii. **One or more scientists**, one or more biomedical scientists, will come from the departments/centres of CUK or from outside of CUK. They will engage in Scientific and ethical review with special emphasis on the intervention,

benefit-risk analysis, research design, methodology and statistics, continuing review process, serious adverse events (SAE), protocol deviation, progress and completion report.

iv. **One or more Clinicians**- one or more clinicians will come from hospitals/medical colleges/medical University/medical institutes inside or outside CUK. He will ensure the Scientific review of protocols, including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. They will also ensure ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report. They will review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation.

v. **Legal expert**- the legal expert will be from inside/outside CUK with a degree in law from a recognized university, with experience. He will be responsible for conducting an ethical review of the proposal, clinical trial agreement, MoU, informed consent documents (ICD), and its translations, researcher's undertaking, and protocols specific permissions. He should also interpret and notify EC members of any new regulations.

vi. **One or more philosophers/social scientists/theologians/ethicists** will come from the Humanities and Social Sciences department of CUK and, if not available, will come from other institutes/universities. He will conduct an ethical review of the proposal and ICD (Informed Consent Document) and its translations. He assesses the impact on community involvement, socio–cultural context, religious or philosophical context, if any. He also serves as a patient/participant/ societal / community representative and brings in ethical and societal concerns.

vii. **Layperson**- Layperson will have no background in biomedical research. The layperson will also be a member of the local community. He will conduct an ethical review of the proposal, ICD, and its translations. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. He serves as a patient/participant/ community representative and brings in ethical and societal concerns.

The Member Secretary or Chairperson may invite subject matter experts, if needed, to hear their opinions.

6. Conditions of EC members' appointment

All EC members, including the chairperson, will be appointed by the head of the institution, the Vice Chancellor.

Guidelines for EC members

i. Name, gender, profession, and affiliation of IHEC members will be publicized.

ii. They will be required to undergo training to update their knowledge and skills.

iii. They will provide a recent CV and required training certificates.

iv. They will follow the conflict of interest (COI) policy of EC and declare it at an appropriate time.

v. They will sign a confidentiality and conflict of interest agreement/s.

vi. They will be committed to understanding the need for research and providing protection to research participants.

Training for EC members

EC members should have initial and continued research education related to science and ethics of biomedical research.

i. All IHEC members will be exposed to ICMR Guidelines for Research involving Human Subjects 2006, ICH-GCP guidelines and Schedule Y of Drugs and Cosmetics Act.

ii. IHEC members will also receive introductory training in IHEC SOPs and research bioethics, and will be made familiar with ongoing opportunities for increasing their efficiency for ethical review.

iii. A new member will be called about 1 month before his/her appointment and will be requested to observe during the first board meeting. An introductory training will be given by the Member Secretary.

iv. The IHEC members will also be required to get ongoing training by attending workshops at least once every year.

v. The IHEC will conduct workshops from time to time to train IHEC members and institutional faculty members.

vi. Members will be trained in EC functions and SOPs, human research protection, and relevant regulations of the country.

vii. EC members will have to undergo training in human research protection,

applicable EC SOPs and regulatory requirements related to them. All trainings must be documented.

viii. Any change in the relevant guidelines or regulatory requirements will be communicated to all EC members.

ix. EC members should be aware of social, cultural and local norms, including emerging ethical issues

x. The institute will make arrangements to ensure that members receive the initial training in EC functions, SOPs and relevant regulations of the country (new drugs and clinical trial rules, 2019), ICMR national ethical guidelines, and GCP. The institute will also ensure that the certificates of the IHEC members remain valid during their term as IHEC members.

7. Authority under which IHEC is constituted

Hon'ble Vice Chancellor of CUK will constitute IHEC. The IHEC will be serviced by the office of the Dean of Research and Development (R and D) with delegated authority from the Vice Chancellor.

8. Requirements for membership

i. The term of the members is for three years and renewable after the term.

ii. If a member is unavailable for a long time, a replacement can be found. A committee member may submit his/her resignation from the committee, stating the reasons to do so.

iii. Any change in the constitution of committee must be approved by the director.

iv. Each member is required to maintain absolute confidentiality regarding the deliberations of the committee.

v. All members must disclose any conflict of interest.

9. Quorum requirements and mode of meeting

The presence of at least five members will be required to meet quorum requirements and at least one representative from each of the following fields must be present to examine a proposal.

- Legal expert
- Clinician
- Social Scientist
- Basic Scientist
- Lay person

A minimum of one meeting will be held to consider each proposal/protocol that IHEC receives for review, and no decisions will be made without the proposal/protocol being discussed in a meeting. Proposals reviewed in expedited mode ("Expedited Review") may not be discussed in full board meetings. However, the committee will be kept informed of such a proposal and its status.

The committee meetings will be conducted in offline, online, or hybrid mode depending on the requirements.

10. Offices

Each IHEC meeting will be led by the Chairperson, and if he or she is unable to attend the meeting, he or she will propose a co-chair for the meeting.

The Member Secretary will be in charge of setting up meetings, keeping track of agenda, and communicating with everyone concerned. The minutes of meeting (MoMs) will be written by the member secretary, and he will also send the comments to PIs after the meeting.

11. Application Procedures

i. CUK faculty will be given an advance notice by email about the dates for proposal submission and IHEC meetings.

ii. Submission guidelines will be available on the IHEC page, linked to Research and Development webpage. The guidelines and formats may be amended by the Member Secretary if required.

iii. The Principal Investigator (PI) will be required to turn in proposals in a specified format and by the specified deadlines.

iv. Each proposal will have a number assigned to it in the following format: CUK-IHEC/YYYY/Proposal No., where YYYY is the calendar year in which the proposal is submitted for review. The proposal No. will be assigned in the sequence it is received for IHEC's review.

v. The proposal will be emailed to the Member Secretary as a single PDF file, signed by the principal investigator (PI), and containing all relevant information, including attachments like the informed consent documents (ICDs) and their translations.

vi. The Member Secretary will forward the proposals to IHEC members by email for assessment and feedback.

vii. Members will express their opinions on the proposal and may ask for clarifications, as needed.

viii. Comments by members will be compiled by the Member Secretary and forwarded to the PI in advance so that PIs are ready to respond to requests for clarification.

ix. The PI is responsible for preparing the presentation for the IHEC meeting, and only co-PIs may attend.

x. The proposal will be presented by each PI, followed by discussions

xi. IHEC members will discuss the proposal, recommendation, and/or decision behind closed doors.

xii. The Member Secretary will email the PI with the recommendations and decisions of the IHEC regarding the proposal.

xiii. If revisions are required, the Member Secretary will communicate the same to PI, who will then carry out the revisions and prepare responses to comments. The PI will return the corrected proposal to the Member Secretary. The members will receive the updated version through email, and they will then take a final decision.

12. Documentation (as per ICMR guidelines)

All research proposals/protocols will be submitted with the following details:

i. The applicant's full name and designation- only CUK employees, who are permitted to be PIs as per the institute norms, can apply.

ii. Information on the location of the site, institute, hospital, or field, where the research will be done.

iii. A detailed protocol of the proposal that includes the information on the following:

a. The scientific justification, including the outcomes of prior animal and human studies.

b. The hypothesis.

c. The study designs.

d. The risks associated with the design of the study.

e. The statistical basis for the structure of the investigation.

f. Any potentially harmful effects that can be adequately detected, avoided, or treated.

iv. The principal investigator (PI) will classify study-related risks as one of the following:

i. Less than minimal risk

Research for which there is no known harm to one's health, well-being, or finances.
Examples:

- *Educational and classroom research (testing a new curriculum)*
- *Public observations (children are not involved, ie watching what shoppers buy*

at the local grocery store.

- *Analysis of existing dataset*
- *Taste and food evaluation studies*
- *Use of a database or a biobank*

ii. **Minimal risk**

The likelihood and potential severity of the harm or discomfort expected in the research are, taken alone, not larger than those typically encountered in daily life or when undergoing standard physical or psychological evaluations or tests. Examples of minimal risk studies include:

- *Blood collection via venipuncture, fingerstick, etc.*
- *Noninvasive collection of biological samples for research, such as hair, fingernails*
- *Noninvasive data collection, not using general anaesthesia or sedation, and part of routine clinical care (X-rays are excluded)*
- *Data collected for research purposes involving voice, video, or images*
- *Research involving individual or group behaviours or attributes, such as social and cultural beliefs, using surveys, interviews or focus groups.*

iii. **Greater than minimal risk**

Research procedures that may include danger above and beyond what subjects are typically exposed to under normal physical or psychological evaluations or tests. Examples include experimental drugs, maximal exercise testing, biologics or medical devices, stressful psychological testing, or use of special populations.

v. The ethical concerns in the proposal and measures to address them.

vi. Enclosures, such as the Informed Consent Document (ICD) and its translations in other languages, as required, questionnaires, etc.

vii. All significant pre-clinical animal data and clinical trial data from other centers within the country or from abroad, if available for any drug or device trial.

viii. CVs for every researcher along with their recent publications during the last five years.

ix. Any need for regulatory clearances.

x. The project's funding source and necessary funds.

xi. Additional monetary concerns, particularly insurance-related ones. xii. A commitment to inform IHEC of Serious Adverse Events (SAE).

xiii. Statement of potential conflicts of interest.

xiv. Agreement to adhere to the relevant international and national regulations. xv. A statement outlining the following:

a. payment to research participants as compensation for their time (including reimbursement for travel costs and access to healthcare).

b. a description of indemnity plans, if any (in the event of injuries related to the study)

c. a statement of the insurance coverage arrangements for research participants, if any, and all major prior choices (such as those resulting in an adverse determination or a changed protocol) by ECs or the planned study's regulatory bodies (whether in the same place or elsewhere) and a description of any changes made to the created on that account via protocol. The justifications for negative decisions should be provided.

xvi. Plans for publishing findings, whether positive or negative, while protecting the participants' privacy and confidentiality.

xvii. Additional data relevant to the study.

xviii. Proposals will not be taken up for review by IHEC until all the information is provided

13. SOP for Terms of reference of the committee

The IHEC will be constituted for a term of three years. The office of IHEC, CUK will maintain the terms of reference, which include

1. The IHEC of Central University of Karnataka is established to facilitate research related to human samples. It will have a fair and consistent assessment process for proposals submitted to it for review. The IHEC will consider protocols involving research on human subjects, biological samples from human subjects, and data from human subjects.
2. IHEC should serve as an independent regulatory body.
3. The IHEC of Central University of Karnataka is non-clinical in nature. Proposals involving biological samples, vulnerable populations, and/or sharing of private information involving human subjects are included to protect the rights, safety, and general welfare of all actual and potential participants in research that will be carried out by CUKarnataka researchers. No matter how essential the research's objectives are, the health and well-being of subjects must always come first". ***Currently, outside/other Institutions' proposals will not be allowed for review.***
4. The members of IHEC shall be appointed by the Competent Authority (Vice Chancellor) of the University.
5. All the members of IHEC should be aware of the latest policies related to Ethical Guidelines published by ICMR/DHR, Govt. of India.
6. The tenure of IHEC should be 3 years.

7. Member secretary of IHEC can serve only one tenure of three years. However, a member secretary may be included as a basic medical scientist for another tenure of a maximum of six years concurrently. There should be a minimum of 6 years' gap between the reappointment of a faculty member as a member secretary.
8. If any member of IHEC is unable to continue due to their resignation or other reasons, the concerned member should submit their resignation through the member secretary to the Vice Chancellor. Upon acceptance of resignation, the Vice Chancellor may appoint new members as per the ICMR policy. The Vice Chancellor has the power to expel any member in case of any misappropriation at any given time.
9. There should be a minimum of two meetings of IHEC every year. However, the number of meetings may be increased as per the needs of the institute. It shall be the responsibility of member secretary to ensure that periodic meetings of IHEC are conducted.
10. It is the duty of the Chairperson and the member secretary to ensure IHEC of Central University of Karnataka is functioning as per the guidelines issued by ICMR.
11. A minimum of Six members must be present to meet the quorum requirement for the conduct of the IHEC meeting. At least two non-affiliated members (including the Chairperson and lay person) must be present during the meeting.
12. The proposals for IHEC approval must be submitted through the office of the Director, Research and Development Cell, to ensure the quality of research.
13. The IHEC may invite expert members (internal/external) on a need basis. However, such members shall not have decision-making power.
14. Member secretary shall ensure record keeping, including project copies, approved protocols, details of the meetings, and approved minutes of the meetings.
15. Member secretary as well as the Chairperson, shall sign the certificate upon approval of proposals by the IHEC committee.
16. Research requiring clinical trials, medical interventions, and drug trials involving administering any kind of drug-related interventions, bioavailability, or bioequivalence studies will not be reviewed in the Department of Health Research registered IHEC.
17. IHEC shall prepare detailed SOPs for the preparation and submission of protocols for ethical approval, as well as guidelines related to sample disposal as per ICMR policies.
18. Latest guidelines issued by ICMR shall be consulted and considered final in case of any discrepancies.

These criteria are subject to changes as per the latest regulations issued by ICMR.

14. SOP for vulnerable population

Individuals are considered vulnerable if they are economically and socially deprived, and are not capable of making a voluntary decision, or their autonomy is compromised and, hence, more prone to being exploited.

i. People in vulnerable populations will have an equal right to participate in research.
ii. Involvement of a legally authorised representative (LAR) is necessary when the participant is unable to provide consent.
iii. The privacy of participants will be ensured.
iv. Additional data relevant to the study.
v. Proposals will not be taken up for review by IHEC until all the information is provided
vi. Only the full committee will accord approval and conduct initial and ongoing reviews of proposals involving vulnerable populations.

15. SOP for handling and mitigation of conflict-of-interest (COI)

COI can affect the research questions, recruitment of participants, publications, and ethical review of research. The following steps will be taken for identifying, managing, and mitigating COI.

i. Development of procedures and policies to address COI and training of personnel on how to use them.
ii. Ensuring the accuracy and objectivity of the study by keeping an eye on it or examining the results.
iii. Researchers will make sure to disclose any COI (financial or non-financial).
iv. Researchers will make sure that they do not examine grants and papers filed by close colleagues, family, and/or students to avoid intellectual and interpersonal disputes.
v. IHEC will assess each study in light of disclosed COI and make sure that appropriate mitigation measures are taken.
vi. IHEC will also propose suitable management recommendations if COI is found at the institutional or researcher level.
vii. COI within the EC will be declared and managed in accordance with the standard operating procedures (SOPs) of that EC
viii. If an IHEC member has some COI, she/he will inform to the member secretary/ chairperson and will not participate in the discussion/decision making when that particular research project is discussed in the meeting. The member will neither participate in the discussion nor vote on that project. This will be noted in minutes.
ix. In case of conflict, the decision of the local EC based on relevant facts/guidelines/law of the land shall prevail.

16. Review procedures (as per ICMR guidelines)

i. The IHEC meeting will take place on the dates set forth in the calendar of IHEC meeting dates, and the schedule will be provided to PIs in advance through email.
ii. Proposals will be submitted by the deadline and will be considered for review in

the order they have been received. The protocols submitted after the deadline will be considered in the next meeting.

iii. Before the meeting, one to two committee members (principal reviewers) will read the proposal and provide their feedback. The PI will receive these remarks in addition to a list of clarifications before the meeting. PIs will be required to be present at the IHEC meeting when their proposal is being considered.

iv. After thorough consideration and discussion, decisions will be made (only members present).

v. PIs will be asked for explanations/revisions, if necessary.

vi. If required, outside consultants and experts will be contacted to provide their insight on certain aspects of the proposal.

vii. Decisions will be recorded in minutes of meeting (MoMs), confirmed electronically by the Chairperson and members, and ratified at the following meeting.

viii. Any deviation in the review procedure must have the approval of the Chairperson.

17. Elements of review

i. The scientific rationale, hypothesis, design, and execution of the study. ii. If required, approval from competent scientific review committees.

iii. Analysis of expected risks and damages.

iv. A review of potential advantages.

v. The process of choosing subjects, including the inclusion/exclusion criteria, the withdrawal criteria, and other factors, like the details of the advertisement.

vi. When required, the management of accidents, bad events, etc., related to research.

vii. Provisions for compensation.

viii. ICD and its translation in other languages, as required, and participant information sheet

ix. Privacy and confidentiality protection.

x. Plans for reporting and data analysis.

xi. Compliance with legal requirements and regulations

xii. Competence of PIs.

xiii. Infrastructure and facilities at study sites, where appropriate.

xiv. Requirements for patient withdrawal, study suspension, or study termination.

18. Expedited review

An expedited review may be conducted without a full board meeting in the following situations:

i. Such proposals will be considered by a few members (1-2 members, with permission from the Chairperson) only if the proposals involve minimal risks or less than minimal risks. The PI will provide a basis for an expedited review. The

primary reviewer(s), depending on the contents of the proposal, may decide to review and approve it in an expedited mode or assign it for review by the full board.

ii. For proposals that have been approved in principle but are subject to minor changes, the following procedure will be followed:
   a. The Member Secretary will send an email to PIs regarding the IHEC's recommendations.
   b. The Member Secretary will receive the revised document electronically from PIs.
   c. The updated document will be sent to the members by email.

iii. Members will give their feedback on the updated document, and, if necessary, their consent for the approval of the proposal will be collected by email.

iv. Expedited review will not be allowed for proposals that are required to be resubmitted to the committee for a subsequent meeting.

19. Making decisions (as per ICMR guidelines)

The following decision-making procedure shall be used:

i. Before concluding by consensus, the IHEC members will discuss numerous issues.

ii. Members who might have conflicts of interest will abstain from voting. Before the application assessment and recording of minutes of meeting (MoMs), the Chairperson must be informed of any such conflicts of interest.

iii. Decisions will be made only at meetings with a full quorum.

iv. The decision will be made by members only, and the experts/consultants will only provide their insights and cannot take part in making a decision.

v. A proposal/protocol may be approved, revised, or rejected. Reasons for rejection and revisions recommended will be provided.

vi. In cases of conditional decisions, clear suggestions for revision will be provided.

vii. The process for getting the proposal re-evaluated either as expedited review or resubmission to a subsequent meeting will be outlined. After receiving IHEC recommendations, the request for re-review will be presented within 180 days.

viii. Any appeal of the IHEC's decision must be submitted first to the IHEC Chairperson, who has the authority to reevaluate, affirm, or reject the recommendations while taking the PI's input into account.

ix. If the IHEC turns down a request, an appeal may be made to the Director of CUK. The Director may determine himself/herself or appoint a committee to decide on the request, after seeking clarification from the Member Secretary. In such circumstances, the decision by the Director will be final.

x. The IHEC at CUK will grant approval for research projects. For IHEC approval of regulatory studies, PIs should contact ethical committees that are registered with the DCGI. In the latter scenario, an official letter of IHEC permission will be sent to IHEC at CUK.

20. Communicating the decision

i. The Member Secretary will email PIs' recommendations for revision and re-review, as well as any other decision.
ii. The PI will be provided with reasons for rejection.
iii. The Member Secretary will prepare the acceptance letter based on the members' agreement to approve a proposal, either during the IHEC meeting or after reviewing a revised document received after the IHEC meeting.
iv. The Member Secretary will sign the approval letter on behalf of the IHEC Chairperson.
v. The PI will receive both the original approval letter and a soft copy of it.

21. Follow-up procedures

i. The PI must monitor the study.
ii. All SAEs and the interventions undertaken should be intimated.
iii. Protocol deviations, if any, must be disclosed to the IHEC before the divergence and must be properly justified. The protocol must then be presented again for new approval.
iv. The study's new information should be communicated.
v. A summary of the data collected so far and reasons for the study's premature discontinuation should be provided.
vi. Changes in investigators or study locations must be reported. vii. After the study, a final report is required.

22. Archiving and record-keeping

i. The curriculum vitae (CV) of every IHEC member.
ii. Copies of all study protocols, progress reports, and SAEs with attached documents. iii. Minutes of all meetings (Moms).
iv. A copy of the current, relevant national and international regulations and ethical standards for research.
v. Copy of all correspondence with members, researchers and other regulatory bodies.
vi. Final report on the projects that were approved.
vii. The soft copy documents will be archived at IHEC for a period of five years after the study is approved.

23. Updating IHEC members

The IHEC members will be regularly updated about new guidelines, and they will be encouraged to take part in national and international training programs in research ethics to uphold the standard of the review process and stay aware of the latest developments in the area.

24. Reference

Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics

Committee for Human Research, Indian Council of Medical Research.

25. Nomenclature CV: Curriculum Vitae
ICD: Informed Consent Document
ICMR: Indian Council of Medical Research IHEC: Institutional Ethics Committee (Humans) MoM: Minutes of Meeting
PI: Principal Investigator
R&D: Research and Development SAE: Serious Adverse Events

Effective date: 01 January 2026 (with yearly review of the criteria)

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