पंजाब केन्द्रीय विश्वविद्यालय/ਪੰਜਾਬ ਕੇਂਦਰੀ ਯੂਨੀਵਰਸਿਟੀ
Central University of Punjab
A Central University established by an Act of Parliament

STANDARD OPERATING PROCEDURE
Institutional Ethics Committee (IEC)
Central University of Punjab

The Institutional Ethics Committee (IEC) is constituted by Vice-Chancellor, Central University of Punjab, in consultation with the existing Chairperson of Institutional Ethics Committee (IEC) and as the ICMR guidelines. The IEC, Central University of Punjab has been provisionally registered with NECRBHR, DHR for a period of 2 years with the **Registration No. EC/NEW/INST/2021/2130**. The registration was approved on 03 Mar 2022.

1. Purpose of IEC

The IEC is established to validate the University's commitment to promote ethical standards in research requiring clinical data and sampling and maintaining the confidentiality of the participating subjects

2. Responsibility of IEC

To ensure that the research projects that are carried out at Central University of Punjab

- Are sound in design, have statistical validity, follow the national and international ethical guidelines and are conducted according to the Indian Council of Medical Research guidelines
- Follows rigorous assessments of risk benefit ratio.
- Do not compromise right, safety and benefits of the patients or volunteers/ study participants.
- Include only those patients or participants who have given voluntary and informed consent.
- Are conducted in collaboration with trained medical / bio-medical persons with required expertise for clinical data collection and sample collection respectively.
- Education in research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for all categories of staff.

3. Composition of IEC

The Institutional Ethics Committee at Central University of Punjab is constituted for a period of 2 years and follows the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017. The IEC

members have to declare the conflict of interest (if any).

At present, IEC consists of 11 members

- 7 members are from Central University of Punjab
- 4 members are from outside of the university including chairperson from a reputed medical institution.
- Out of 11 members, 3 members are women

These members are as follows:

a) Outside Central University of Punjab

1. **Prof. Lajya Devi Goyal** — **Chairperson**
   Professor & Head, Department of Obstetrics & Gynecology — **Clinician**
   All India Institute of Medical Sciences, Bathinda
   Email- lajja.goyal@rediffmail.com

2. **Dr Tarun Goyal,** — **Clinician**
   Associate Professor, Department of Orthopaedics
   All India Institute of Medical Sciences, Bathinda
   Email- goyal.tarun@gmail.com

3. **Advocate Gurpreet Singh,** — **Legal Expert**
   Lawyers Chamber No.516, B-block, (Ground Floor),
   District Courts Complex, Bathinda
   Email- gurpreetadv81@gmail.com

4. **S. Raj Paul Singh** — **Socially active Lay member**
   Retired School Teacher
   Director, People's Forum Pb. (Regd.)

b) Inside Central University of Punjab

1. **Prof. Anjana Munshi** — **Basic Medical Scientist**
   Professor, Dept. of Human Genetics and Molecular Medicine
   Director, R&D Cell
   Central University of Punjab
   Email- anjana.munshi@cup.edu.in

2. **Prof. Ramakrishna Wusirika,** — **Basic Medical Scientist**
   Professor, Dept. of Biochemistry
   Dean Incharge Academics
   Central University of Punjab
   Email- dia@cup.edu.in

3. **Prof. Monisha Dhiman,** — **Basic Medical Scientist**

Professor, Dept. of Microbiology
Central University of Punjab
Email- monisha.dhiman@cup.edu.in

4. **Dr. Rajinder Kumar** — **Social Scientist**
   Associate Professor, Dept. of Hindi
   Central University of Punjab
   Email- rajinder.kumar@cup.edu.in

5. **Medical Officer,** — **Clinician**
   Central University of Punjab
   Email- mo@cup.edu.in

6. **Dr. Sandeep Singh**
   Associate Professor, Dept. of Human Genetics and Molecular Medicine — **Member Secretary**
   Central University of Punjab
   Email- sandeepsingh82@cup.edu.in

7. **Dr Ravindresh Chhabra** — **Alternate Member Secretary**
   Assistant Professor, Dept. of Biochemistry
   Central University of Punjab
   Email- ravindresh.chhabra@cup.edu.in

4. **IEC sub-committee:** Constitution and functioning of Internal Research Advisory Committee (IRAC)

The purpose of IRAC is to expedite the review of the submitted proposals. All the members of IRAC are familiar with IEC guidelines. The members of IRAC are mentioned below:

1. **Prof. Ramakrishna Wusirika,**
   Professor, Dept. of Biochemistry
   Dean Incharge Academics
   Central University of Punjab
   Email- dia@cup.edu.in

2. **Prof. Vinod Kumar Garg**
   Professor, Dept. of Environmental Science and Technology
   Dean Students Welfare
   Central University of Punjab
   Email- dsw@cup.edu.in

3. **Prof. Anjana Munshi**
   Professor, Dept. of Human Genetics and Molecular Medicine
   Director, R&D Cell
   Central University of Punjab
   Email- anjana.munshi@cup.edu.in

4. **Prof. Monisha Dhiman,**
   Professor, Dept. of Microbiology
   Central University of Punjab
   Email- monisha.dhiman@cup.edu.in

5. **Dr. Puneet Kumar Bansal**
   Associate Professor, Department of Pharmacology
   Central University of Punjab
   Email- puneet.bansal@cup.edu.in

6. **Prof. Aklank Jain**
   Professor, Dept. of Zoology
   Central University of Punjab
   Email- aklank.jain@cup.edu.in

7. **Dr Manju Jain** **Convenor**
   Assistant Professor, Dept. of Biochemistry
   Central University of Punjab
   Email- manju.jain@cup.edu.in

5. IEC approval process at Central University of Punjab

1. The IEC committee calls for proposal submission for ethical approval at regular intervals. The faculty members are notified of the same through an email by member secretary of IEC.

2. Proposals are submitted to Member Secretary, IEC through Director, Research & Development Cell (R&D cell) before the deadline.

3. From R&D cell, the proposals are forwarded to Internal Research Advisory Committee (IRAC).

4. IRAC screens the proposal (as per the prescribed format) and evaluates the scientific aspects of the proposal and if required, seeks the clarification from the Principal Investigator (PI).

5. The proposals recommended by IRAC are forwarded to IEC which scrutinizes if all the forms and requisite documents are attached. In case of any discrepancies, the PIs are informed and requested to rectify.

6. Once approved by the IEC committee, ethical clearance/approval certificate is issued to the PI.

Fig. 1 Steps followed for IEC approval process at Central University of Punjab

All submissions should be made in the prescribed Format of the Institute Ethics Committee with signatures of all the investigators (PI as well as Co-PIs) on the hard copy. The PIs should submit the research proposal along with the IEC and IRAC forms which are attached below for your reference. In addition, the PIs must keep the following points in mind before submitting:

1. Number of samples must be clearly mentioned for both the control and patient groups.
2. CV of all the investigators must be attached.
3. The performa which will be used for the collection of the clinical and demographic data must be included.
4. The research proposal must include the references.
5. Instead of stating “no risk” in the risk assessment column, “minimal risk” or

"less than minimal risk" should preferably be written.

6. Please include the name of the Ph.D. students who will be working in the proposed study (if it has already been decided).
7. The PI will be responsible for submitting a brief progress report of the project to IEC, annually in the prescribed format.
8. PI will have to submit a compliance certificate at the end of the study along with the conclusion report.
9. PI must intimate the IEC about any significant change in the project and the reason for that change, including an indication of ethical implications. The IEC will determine if requested protocol changes alter the risks. In some cases, investigator may be asked to resubmit the study protocol and related documents for fresh review by IEC.
10. A delay of more than 12 months in the commencement of the project should be informed by the PI to IEC.

Please note that no research project shall be started in Central University of Punjab unless ethics clearance from IEC is obtained. Please note that no retrospective / post facto IEC certificate will be issued to research projects which were neither submitted nor vetted by the Institute Ethics Committee.

6. As per ICMR guidelines there are following types of reviews

6.1 Exemption from review process

- Proposals which present "**less than minimal risk**" fall under this category.
- Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research on use of educational tests, survey or interview procedures.
- Interviews involve direct approach or access to private papers.
- Research conducted on data available in the public domain for systematic reviews or meta-analysis
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
- Quality control and quality assurance audits in the institution
- Consumer acceptance studies related to taste and food quality
- Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

6.1.2 Exempt Process:

The IEC will review the brief summary of the project and the Exemption Form.

- If the protocol and related documents satisfy the criteria listed in **Exemption from review**

(section 6.1) the Member Secretary in consultation with the Chairperson along with one or two members will review the brief summary of the project and the Exemption Form.

- The Proposals exempted from review need not submit continuing review reports. However, once the study is complete completion reports need to be submitted for Ethics records.

6.2 Expedited Review:

Proposals which present no more than minimal risk to the research participants will be subjected to expedited review.

The member secretary and the chairperson of the IEC or the designated member of the committee or sub-committee of the IEC will do expedited review if the proposals involve:

- Minor deviations from originally approved research during the period of approval usually of one-year duration Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- Research involving clinical materials like data, records, documents or specimens that have been collected for non-research or clinical purposes.
- When in emergency situations like serious outbreaks or disaster the full review is not possible, prior written permission of IEC may be taken before use of the test intervention. However, such research will be approved only for pilot study or preliminary work.

6.2.1 Examples of the research that may be eligible for expedited review are:

- Collection of hair or baby teeth.
- Collection of external secretions, including sweat and saliva.
- Recording of data from adults using noninvasive procedures that are routinely employed in clinical practice (not including exposure to electromagnetic radiation outside the visible range, for example, x-rays or microwaves.)
- Collection of blood samples by venipuncture.
- Voice recordings made for research purposes, such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- Study of existing data, documents, records, pathological specimens, or diagnostic specimens etc.

6.3 Full Review:

- All other studies which do not fall under **Exemption from review or Expedited Review** will go for the full review as per the procedure described in section 5

7. General rules for the IEC meeting

i. The IEC proposals are circulated to members a week before the meeting.

ii. A quorum is required for all meetings (6 members out of 11 make a quorum). Approval of a project is made by consensus of members present at the meeting.

iii. In case a member is absent from IEC meeting and if no objection / comments are obtained from that member, the proposal is considered to be approved by that member.

iv. If a member is unable to attend a meeting, his/her opinion on the projects to be discussed

in the said meeting may be submitted in writing to the Chairperson of the IEC before the date of the meeting.

8. Brief overview of IEC procedure

i. Proposals are submitted to Member Secretary, IEC through Director, Research & Development Cell (R&D cell) and Member secretary shall classify the proposals into exempt, expedited or full committee review.

ii. Exempted proposals must be issued approval after consultations between member secretary and chairperson.

iii. Expedited review can be conducted by Chairperson, Member Secretary and two other members.

iv. All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting.

v. All proposals including exempted or expedited approval must be ratified by the full committee meeting of IEC.

vi. Agenda, record of attending members and other relevant details must be recorded by member secretary.

vii. IEC may give full approval/minor revision/major revision/reject decision based on the deliberations.

viii. IEC should ensure the relevant clinical documents including ethical approval from collaborating hospital/institute must be under process.

ix. Studies requiring human samples must have onboard clinician with relevant expertise as PI or co-PI of the study.

x. Ongoing research should be reviewed at regular intervals, at least once a year

xi. All documentation and communication of an EC should be dated, filed and preserved according to written procedures. All active and inactive (closed) files should be appropriately labelled and archived separately in designated areas. All records must be archived for a period of at least 3 years after the completion/ termination of the study.

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

PS: This Standard Operating Procedure is effective from 02-03-2021

Dr. Ravindresh Chhabra
Alternate Member Secretary
Institutional Ethics Committee
Central University of Punjab