CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

General guidelines

1. Institutional Ethics Committee of Central University of Punjab (henceforth called as IEC-CUPB) is formulate to facilitate and regulate research related to human subjects and samples.
2. IEC-CUPB is Not Mandated to carry any clinical trials as Central University of Punjab is not a medical institution/hospital rather an Institute of higher learning.
3. Applications can be submitted throughout the year through office of Dean Research of the University.
4. Dean Research in consultation with research committee will forward the proposals, found suitable upon scrutiny, to member secretary of IEC-CUPB.
5. At least 01 meeting in every trimester (minimum 4 meetings in a year) should be held in periodical manner to review the newly submitted and earlier approved proposals
6. In case of emergency, separate meeting may be called anytime of the year with permission from the competent authority (Vice Chancellor of the University).
7. **Meeting procedure:** with consent from Chairperson of IEC-CUPB, member secretary shall request permission from the competent authority atleast 1 month before organizing the meeting. Dates of the meeting should be fixed in consultation with all the members of IEC-CUPB to ensure maximum attendance. Member secretary should notify the faculty about the upcoming IEC-CUPB meeting and give 2 weeks to submit new proposal with a strict deadline. Member secretary is responsible for making all the necessary arrangements for the meeting including meeting/conference hall, TA and honorarium and hospitality of the experts etc. member secretary should ensure that the submitted proposals along with agenda of the meeting are sent to members of the IEC-CUPB at least 7 working days before the meeting. On the day of meeting, member secretary should notify the applicants (or representatives) as they may be invited by IEC-CUPB

for any clarifications. Member secretary should record all the proceedings in detail apart from the minutes of the meeting. Any clarification sought from applicants; the answers should be submitted to IEC-CUPB in writing. After the review of the protocol, the committee should separate all the accepted proposals while appropriate reasons/remarks should be provided for the proposal which are either sent for revision or are rejected.

IEC-CUPB reserve the rights to decide and approve the submitted proposals based on (i) need and importance of the proposed study (ii) potential benefits to society (iii) funding sources (iv) harmful impacts on individuals/society. Chairperson and member secretary should ensure maximum consensus via due diligence and detailed discussions in the IEC-CUPB.

Member Secretary (IEC)

18.3.2024

Director, R&D Cell

Registrar,
Central University of Punjab

कुलसचिव/REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
Central University of Punjab, Bathinda-151401

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Terms of Reference Institutional Ethics Committee (IEC)

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the Terms of Reference of Institutional Ethics Committee (IEC) of Central University of Punjab are given below:

1. The IEC of Central University of Punjab is established to facilitate research related to human samples.
2. IEC should serve as an independent regulatory body.
3. The IEC of Central University of Punjab is non-clinical in nature.
4. The members of IEC shall be appointed by the Competent Authority (Vice Chancellor) of the University.
5. All the members of IEC should be aware of the latest policies related to Ethical Guidelines published by ICMR/DHR, Govt. of India.
6. The tenure of IEC should be 2 years.
7. The members of IEC should be appointed for a term of maximum Two Years with one extension (total 4 years). None of the member's tenure (except member secretary) should exceed maximum 4 years concurrently.
8. Member secretary of IEC can serve only one tenure of Two years. However, member secretary may be included as basic medical scientist for another tenure of maximum 4 years concurrently. There should be a minimum of 6 years gap between reappointment of faculty member as member secretary.
9. If any member of IEC is unable to continue due to their resignation or some other reasons, concerned member should submit resignation through member secretary to the Vice Chancellor. Upon acceptance of resignation, Vice Chancellor may appoint new members as per the ICMR policy. Vice Chancellor has the power to expel any member, in case of any misappropriations at any given time.
10. There should be minimum of two meetings of IEC 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 IEC are conducted.
11. It is the duty of Chairperson and member secretary to ensure IEC of Central University of Punjab is functioning as per guidelines issued by ICMR.
12. A minimum of FIVE members must be present to meet the quorum requirement for conduct of the IEC meeting. At least Two non-affiliated members (including the Chairperson and lay person) must be present during the meeting.
13. The proposals for IEC approval must be submitted through office of Director, research and Development Cell to ensure quality of research.

14. The IEC may invite expert members (internal/external) towards better understanding on need basis. However, such members shall not have decision making power.
15. Member secretary shall ensure record keeping including project copies, approved protocols, details of the meetings, approved minutes of the meetings.
16. Member secretary as well as Chairperson shall sign the certificate upon approval of proposals by the IEC committee.
17. IEC shall prepare detailed SOPs for preparation and submission of protocols for ethical approval as well as guidelines related to sample disposal as per ICMR policies.
18. To ensure responsible conduct of research, IEC may visit different laboratories and check the record related to approved protocols.
19. 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.

Reviewed by:

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar
कुलसचिव / REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
Central University of Punjab, Bathinda-151401

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard Operating Procedures (SOPs) Institutional Ethics Committee (IEC)

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the general SOPs of Institutional Ethics Committee (IEC) of Central University of Punjab are given below:

1. Submission and review procedures: All the proposals must be submitted to member secretary through Director, R&D cell as per the format provided. Member secretary shall classify the proposals into exempt, expedited or full committee review.
2. Exempted proposals must be issued approval after consultations between member secretary and chairperson.
3. Expedited review can be conducted by Chairperson, Member Secretary and two other members.
4. 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.
5. All proposals including exempted or expedited approval must be ratified by the full committee meeting of IEC.
6. Agenda, record of attending members and other relevant details must be recorded by member secretary.
7. IEC may give full approval/minor revision/major revision/reject decision based on the deliberations.
8. IEC should ensure the relevant clinical documents including ethical approval from collaborating hospital/institute must be under process.
9. Studies requiring human samples must have onboard clinician with relevant expertise as PI or co-PI of the study.
10. Ongoing research should be reviewed at regular intervals, at least once a year

11. 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.

18.3.2024

Reviewed by:

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

कुलसचिव / REGISTRAR
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CENTRAL UNIVERSITY OF PUNJAB

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Institutional Ethics Committee

Membership requirements for Institutional Ethics Committee (IEC)

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the requirements to be member of Institutional Ethics Committee (IEC) of Central University of Punjab are given below:

1. **Chairperson** should be non-affiliated senior clinician (Preferable Professor rank) with previous exposure to serve on Ethical Committee within India.
2. **Member Secretary** should be faculty member of Central University of Punjab and must have experience in conducting research related to human samples.
3. **Basic Medical Scientists** should be from Central University of Punjab with prior experience working with human samples.
4. **Clinicians** from non-affiliated as well as from the Central University of Punjab (Medical Officer of University, if any) should serve as members of IEC.
5. **Legal expert** preferably non-affiliated should be appointed to be member of IEC.
6. **One faculty member** from relevant social sciences/languages department of the Central University of Punjab (social scientist/ philosopher/ ethicist/theologian) with knowledge of local culture and actively engaging with society should serve as member of the IEC.
7. **A local non-affiliated lay literate person** should serve as member of IEC.

Membership criteria is subject to changes as per the latest regulations issued by ICMR.

Reviewed by:

4.3.2024

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

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VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Criteria for selection of members of an EC

1. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC. See Table 4.1 for further details.
2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

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

Reviewed by:

18.3.2024

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

कुलसचिव / REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
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Institutional Ethics Committee

General requirements for all IEC members:

Every IEC member must:

1. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
2. either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. be aware of relevant guidelines and regulations;
5. read, understand, accept and follow the conflict of interest policy of the IEC and declare it, if applicable, at the appropriate time;
6. sign a confidentiality and conflict of interest agreement/s;
7. be willing to place her/his full name, profession and affiliation to the IEC in the public domain; and
8. be committed and understanding to the need for research and for imparting protection to research participants in research.

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

18.3.2024

Director, R&D Cell

Reviewed by:

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

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पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
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Institutional Ethics Committee

Quorum Requirements for meeting of CUPB-IEC

1. A minimum of five members present in the meeting room.
2. The quorum should include both medical/clinical, non-medical or technical or/and non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. No decision is valid without fulfilment of the quorum

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

Reviewed by:

14-3-2024

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

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Institutional Ethics Committee

Procedure for resignation, replacement or removal of members

1. If any member of IEC is unable to continue due to their resignation or some other reasons, concerned member should submit resignation through member secretary to the Vice Chancellor.
2. Chairperson/member secretary should submit resignation through Dean Research of the University to the Vice Chancellor.
3. Upon acceptance of resignation, Vice Chancellor may appoint new members as per the ICMR policy in consultation with Chairperson/member secretary.
4. Vice Chancellor has the power to expel any member, in case of any misappropriations at any given time.
5. For any reason, if any member is required to be replaced, a suitable replacement may be suggested by the IEC to Vice Chancellor. Vice Chancellor may accept the recommendation or may appoint new members independent of IEC recommendations.

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

Reviewed by:

18.3.2024

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

कुलसचिव / REGISTRAR
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Institutional Ethics Committee

Standard Operating Procedures (SOPs) for vulnerable populations

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the SOPs of Institutional Ethics Committee (IEC) of Central University of Punjab related to research carried out on vulnerable populations are given below:

1. Definition of Vulnerable populations - Individuals may be considered to be vulnerable if they are:
    a. *Socially, economically or politically disadvantaged and therefore susceptible to being exploited;*
    b. *incapable of making a voluntary informed decision for themselves of whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;*
    c. *able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or*
    d. *unduly influenced either but the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.*

2. Members of IEC should be aware of these populations and special care must be taken while evaluating such proposals.
3. Only the full committee should do accord approval and perform initial and continuing review of proposals involving vulnerable populations. No exception are allowed.
4. IEC must verify all the details including inclusion/exclusion criteria. Proposals recruiting only vulnerable populations must have meaningful outcome beneficial to the group.
5. Review of any such proposals shall be carried out every 3 months including periodic record verification.
6. In some cases, IEC may invite expert member(s) with special permission from Vice Chancellor. Such members shall have rights to vote in the final decision making process.

7. Minutes of such proposals shall be separate from rest of the proposals and all the record in such cases shall be maintained separately.
8. IEC shall a carefully determine the benefits and risks of the study and examine the risk minimization strategies.
9. Protection of privacy, confidentiality and rights of vulnerable populations is required at all times – during conduct of research and even after its completion.
10. Autonomy of such individuals is already compromised and researchers have to justify their inclusion. ECs have to satisfy themselves with the justification provided to include these participants and record the same in the proceedings of the EC meeting.
11. Additional safety measures suggested earlier in the guidelines should be strictly followed by the ECs.
12. The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalization.
13. The EC should also carefully determine the benefits and risks of the study and examine risk minimization strategies.

ICMR guidelines in such cases shall be binding and followed strictly. These criteria are subject to changes as per the latest regulations issued by ICMR.

Reviewed by:

18.3.2024

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

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Institutional Ethics Committee

Policy regarding conflict of interest of Institutional Ethics Committee (IEC) members

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the policy regarding conflict of interest of Institutional Ethics Committee (IEC) members of Central University of Punjab related to research carried out on vulnerable populations are given below:

1. Chairperson and Member secretary must ensure that none of the members of IEC have any conflict of interest related to the proposals submitted for approval.
2. All the members must declare conflict (if any) during review of individual proposals.
3. In case of any such interests, the respective members must excuse from the meeting.
4. In case of review of any proposal submitted by members of IEC, members must abstain from the meeting during review of their proposal.
5. In case of proposals submitted by Chairperson or member secretary, IEC with mutual consent shall appoint another member as chairperson or member secretary and shall discuss proposals in absence of the applicant.
6. Minutes of the meeting must have detailed description of such cases.
7. ICRM guidelines must be followed in case of discrepancies. Decision of Vice Chancellor shall be final in such cases.

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

18.3.2024

Reviewed by:

Director, R&D Cell

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

कुलसचिव / REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
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Institutional Ethics Committee

Policy for training of members of Institutional Ethics Committee (IEC)

As per the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" issued by Indian Council of Medical Research (ICMR) in 2017, the policy for training of members of Institutional Ethics Committee (IEC) of Central University of Punjab related to research is given below:

Training for New IEC Members:

1. **Orientation Program:** Before participating in any of the IEC meeting, the new members must attend an orientation program covering the following topics:
    - Overview of the IEC's role and responsibilities.
    - GCP Guidelines: Overview, Principles & Implications
    - Declaration of Helsinki.
    - ICMR National Ethical Guidelines (2017)
    - New Drugs and Clinical Trials Rules, March 2019
    - EC Functioning and Responsibilities

    The members must pass the examination and get a certificate of training in the above mentioned topics. The certificate shall be submitted to the member secretary
2. New members are paired with experienced IEC members during their initial period.
3. Hard copy of all SOPs must be provided to the newly inducted members of IEC. Member secretary should ensure to update records on DHR website.
4. All the members must read the latest ICMR guidelines and submit an undertaking in this regard.

Continued Training for Existing IEC Members:

1. Member secretary and Chairperson shall ensure periodic training by organizing specialized lectures for members of IEC.
2. The university will provide a separate budget to facilitate the periodic training program of IEC members by the experts.
3. The members will be encouraged to attend workshops or lectures covering the following topics:
    a. Updates to national and international ethical guidelines
    b. Principles of research ethics, including respect for persons, beneficence, and justice.

c. Procedures for obtaining and documenting informed consent.
d. Identifying and mitigating risks in research.
e. Ensuring confidentiality and privacy of research participants.

4. The members should submit certificates or proof of attending any training programs to the member secretary

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

Reviewed by:

31/10/2024
Director, R&D Cell

3-10-24
Member Secretary, IEC

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard Operating Procedure (SOP) for Categorization of Submitted Protocols for Ethics Review

This SOP establishes a standardized process for categorizing submitted research protocols to ensure efficient and ethical review by the Institutional Ethics Committee (IEC). The type of the categorization process is in accordance with the

After the protocols are submitted by the PI, the member secretary in consultation with chairperson categorizes the proposal based on the following criteria:

- **Exempt Review:** Proposals presenting less than minimal risk category can be exempted from review. For example surveys or observational studies without sensitive data. However there are some exceptions for example, if the studies can identify the human participant directly or indirectly, and any disclosure about his responses could subject the participant to the risk of psychological harm or any civil or criminal or financial liability.

- **Expedited Review:** The studies involving minor risks, such as non-invasive procedures or secondary use of data may be subjected to expedited review. The expedited review should be done only in the following scenarios:
  - There is minor deviations from originally approved research proposal and the revised proposal was earlier approved through full review by the IEC
  - If the approved proposals requires time extension where there is no additional risk or no new participant recruitment is done or the extension is only asked for data analysis.
  - The proposal involves research on disaster management after a sudden natural calamity. Such research studies would be considered for expedited review where the full review will take time and the research has the potential to provide immediate benefit to the affected participants and help frame governmental policies for the affected populations.

- **Full Board Review:** Studies involving more than minimal risk, vulnerable populations, or sensitive topics shall be subjected to full review by the IEC. The review should analyse the risk/benefit involved in the sample collection.

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

Reviewed by:

31/10/2024

Director, R&D Cell

3-10-24

Member Secretary, IEC

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard Operating Procedure (SOP) for Agenda Preparation, Meeting Procedures, and Minutes of IEC

This SOP establishes the administrative process to be followed for fixing the agenda for IEC meetings, meeting procedure, the recording of minutes, review and distribution of minutes among the IEC members.

Agenda preparation

1. Member Secretary in consultation with chairperson will prepare the agenda for the IEC meeting. The agenda may vary but would mostly include the following:
   - New protocol presentations, reviews, and discussions
   - Review of responses to previous queries.
   - Discussion of protocol amendments, continuing review reports, completion reports, and termination reports.
   - Declaration of conflicts of interest.
   - Any other matter referred for IEC opinion
2. At least one week prior to the meeting, the scanned copies of all the proposals will be shared with the IEC members so that the members get sufficient time to go through the proposals

Meeting procedure

1. A call for proposals requiring ethical approval will be made periodically. The IEC meetings will be held once every 3 months.
2. A minimum of five members besides the chairperson and member secretary are required to complete the quorum. Ideally, one social scientist, one lay person, one legal expert, one basic scientist and one clinician should be present. The meetings could be postponed if the IEC chairperson or member secretary is not available. In some cases, an internal IEC member from the university could assume the role of alternate member secretary with approval of IEC.
3. The PIs are informed of the IEC meeting in which their submitted proposal is to be reviewed. They may be asked to appear in person or in an online mode if the IEC needs some further clarifications regarding their proposed study.
4. The member secretary is responsible for organizing the meeting and communicating with all the concerned.

5. The chairperson calls the meeting to order and ask members to declare any potential conflict of interest with the agenda items. The members with conflict of interest may be asked to recuse from the meeting or leave the meeting when the concerned item is being discussed.
6. During the meeting, the agenda is followed as outlined and each agenda item is discussed, and decisions are made by consensus or voting.
7. The decisions of the meeting will include approval, disapproval, request for modifications in the proposal, termination or temporary suspension of an ongoing study

Documenting the minutes and record keeping

1. Member Secretary will record and draft the minutes of the meeting. The minutes will be disseminated to all the IEC members who will read and provide their approval. The chairperson will review and finally approve the minutes.
2. All the proposals received for IEC approval, the comments of IEC members, modifications by the PI and other documents related to IEC meeting will be maintained by the member secretary. The records are kept confidential.

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

Reviewed by:

31/10/2024

Director, R&D Cell

3-10-24

Member Secretary, IEC

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard Operating Procedure (SOP) for Continuing Review of study protocols

This SOP describes how continuing review of previously approved protocols should be managed by the IEC. The objective is the periodic monitoring of the reviewed studies and to continue ensuring the safety and welfare of the research participants.

1. All the PIs whose project has received ethical approval must submit yearly reports as per the format attached with this SOP.
2. The submission of the annual Report cum Continuing Review Application form should start exactly one year from the date of receipt of IEC certificate by the PI.
3. The member secretary should send periodic reminders to the PIs to submit the annual report for continuing review of their protocols
4. If the PI does not comply with the Continuing review process, the PI will be intimated by the member secretary to put recruitment of new research participants on hold and may be asked to explain the reasons for non-compliance. Other actions may be taken as deemed fit by the IEC.
5. The Annual Report cum Continuing Review Application form should include number & type of samples collected, brief update of the progress in the study, number of Serious Adverse Events (SAE) and whether they were reported.
6. The Continuing Review submission may undergo expedited review if there is no change in the protocol and there were no reported SAEs in the study
7. If there is any modification in the protocol or any SAE has been reported, the proposal may be put up for full review.

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

Reviewed by:

3.10.2024

Director, R&D Cell

3-10-24

Member Secretary, IEC

Institutional Ethics Committee
Central University of Punjab

Annual Report cum Continuing Review Application form

IEC Project No.:

IEC Certificate Ref. No. & Date:

Project Title:

1. Principal Investigator (PI):
   Designation/Affiliation:
2. Co-PI & Affiliation:
3. Co-PI & Affiliation:
4. Total no. & Type of samples collected:
5. Total no. of samples approved by the IEC for the study:
6. Duration of the study:
7. Brief update of the progress in the study:

8. No. of Serious Adverse Events (SAE)- if any:
9. Were all SAEs reported to IEC: Yes/ No (if no, reason for the same)

Signature of Principal Investigator: Date:

To be filled by IEC office only

Any remarks/observation:

Signature of Member Secretary with date:

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Undertaking regarding non-affiliate members in Institutional Ethics Committee (IEC)

The IEC may include any non-affiliate member as per the requirements from the list of 50 or more non-affiliate members recommended by the IEC. The list shall be prepared by IEC members and be finalized upon approval from the competent authorities.

15.3.2024

Director, R&D Cell

Reviewed by:

Member Secretary, IEC

Effective date: March 3, 2024 (With yearly review of the criteria)

Approved by:

Registrar

कुलसचिव / REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
Central University of Punjab, Bathinda-151401

Research Ethics Review Committee
Central University of Punjab (CUP), Bathinda

Name of Principal Investigator:

Name of Organization:

Name of Sponsor:

Name of Proposal and version:

This Informed consent for has two parts:

- Information sheet (to share information about the research with you)
- Certificate of Consent (for signature if you agree to take part)

You will be given a copy of the full Informed Consent Form

Note: Please attach 1 page CV of PI(s) along with the application.

For Office Use:

Protocol number:

Date of protocol approval:

Part I: Information Sheet

Introduction

Purpose of the research

Type of Research Intervention.

Objectives of the study:

Duration of the protocol:
Start of the protocol: suggested by PI/ commencement of the project
End of the protocol: with conclusion of project/study or for maximum of 5 years (whichever is earlier)
Note: Whenever there is any change in protocol, fresh approval should be sought by referring to the earlier approved protocol.
Sample Collection:

Participant Selection

Inclusion Criteria

Exclusion Criteria

Voluntary Participation

Side effects:

Risks:

Expected outcomes and benefits of the study:

Reimbursements:

Confidentiality:

Sharing the Results:

Right to Refuse or Withdraw:

Who to contact: I

PI (Name, affiliation and Contact details)

Co-PI (Name, affiliation and Contact details)

Clinical Collaborators (Name, affiliation and Contact details)

Part II: Consent Form

Central University of Punjab

Declaration by PI regarding IEC approval for use of human samples in research

I _____ working as _____ in centre for _____ hereby declare that:

1. I/we am/are submitting research proposal entitled _____ ___ _____ ___for ethical approval in order to use human samples for research purposes.
2. I/we intend to use Human blood/ tissue samples solely for research purposes.
3. I/we shall be following the protocol as approved by Institutional Ethics Committee (IEC).
4. I/we shall ensure that only authorized technician/collaborating medical personnel will be drawing blood/ tissue sample.
5. I/we shall ensure that the proposal shall be duly approved by IEC of the host institute of collaborator(s).
6. I/we shall ensure that samples collected will be used only for research purposes.
7. I/we shall ensure that after use, left over bio-hazardous material will be disposed of properly as per guidelines of IEC.
8. I/we shall be responsible for proper conduction of the approved protocol.

Name and signature of the PI(s)

Date:

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard protocol for Collection of blood samples from healthy volunteers or patients.

- Individual PI/researcher has to get approval for the consent form duly signed by the donor..
- A trained staff (Technician/ Nurse) should be collecting using minimally invasive techniques.
- All the protective measures should be detailed by the applicant PI to be undertaken for the sample collection, handling, storage, experimentation and biohazard disposal.

Protocol for collecting blood samples:

1. Trained staff should give details to the selected individuals about the work they are undertaking and explain the consent form details in appropriate language.
2. Other necessary details of the donor should be collected at the same time.
3. After taking written consent from the donor, the person should prepare appropriate blood vessel for sample collection by venipuncture.
4. A cotton swab dipped in spirit alcohol should be used to wipe the target area skin for sterility.
5. A fresh (unopened) syringe needle should be used for drawing required amount of blood.
6. After drawing the blood a fresh alcohol dipped cotton swab should be placed on the site of venipuncture and pressed gently till the blood flow stops.
7. The donor should rest for some time (5-10 minutes before leaving).
8. The blood sample should be immediately transferred to collection tubes (EDTA, Heparin coated or uncoated) as per the needs of the experiment and stored in cold box).
9. The collection tube should be labelled as number (1,2 etc.) and date while the patient details should be entered in a register with respect to the same number as written on the tube.
10. The person collecting information and blood should sign in the record register.
11. The samples should be sent to the laboratory as early as possible and processed further for coding/decoding procedure.
12. The staff collecting samples should wear appropriate lab coat and gloves and practice all the sterile venipuncture precautions while doing the procedure.

CENTRAL UNIVERSITY OF PUNJAB

Consent Form

I have been explained the possible risks and benefits and have understood the purpose for which blood sample from me/my children is being sought by the centre for _____ Central University of Punjab, Bathinda.

I am free from any pressure whatsoever and herby give my own consent/consent of my children(who are under 18 years of age today) to: (i) withdrawal of sample of about .....ml blood by veni-puncture; and (ii) to all types of analysis of my blood for non-profit research purposes for acquisition of knowledge for the benefit of mankind by Centre for _____ or their collaborators.

I will have the right to know the analyzed results for my sample (samples) and I am not giving my consent for disclosure of any personal information either direct or derived from the analysis of my sample (samples) to any one without my further consent.

I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.

I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital. I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.

I have been informed that my consent will be sought prior to any for-profit (including filing of patents) that may be taken by the Centre for _____ or their collaborators on the basis of my blood sample.

Date:

Name: Sex: Age (Yrs):

Address:

Investigator Certificate

I certify that all the elements including the nature, purpose and possible risks of the above study as described in this consent document have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate,

Signature & Name of the Investigator: _____ Dated:_____

सहमति पत्र

_____, पंजाब केन्द्रीय विश्वविद्यालय द्वारा जिस उद्देश्य से मुझ से/मेरे बच्चों से रक्त के नमूने मांगे जा रहे हैं उसके संभावित जोखिम एवं लाभ की मुझे व्याख्या कर दी गई है और मैं उसे भलीभांति समझ चुका हूँ।

मैं मानव आनुवंशिकी केंद्र या इसके सहयोगियों द्वारा (i) वेनीपंचर (Venipuncture) विधि द्वारा मेरा/मेरे बच्चों का लगभग ..... मि.ली. रक्त निकालने; और (ii) मानवता के हित में ज्ञानार्जन के लिए अनुसन्धान के उद्देश्य से मेरे रक्त के सभी प्रकार के विश्लेषण करने की स्वयं मेरी / मेरे बच्चों (जिनकी आयु आज 18 वर्ष से कम है) की सहमती देता/देती हूँ; और मुझ पर किसी प्रकार का कोई दबाव नहीं है।

मुझे अपने नमूने (नमूनों) से विश्लेषित परिणामों को जानने का अधिकार होगा और मैं अपने नमूने (नमूनों) के विश्लेषण से प्रत्यक्ष या इससे उत्पन्न कोई भी सूचना आगे की सहमती के बिना किसी को भी प्रकट करने की सहमती नहीं दे रहा हूँ।

मैं एतदद्वारा इस अध्ययन में भाग लेने के परिणामस्वरूप मुझ से प्राप्त सूचना(ओं) को आयोजकों, नियामक प्राधिकरणों, सरकारी एजेंसियों तथा नीतिशास्त्र समिति को प्रकट करने की अनुसंधानकर्ताओं को अनुमति देता हूँ। मैं भलीभांति समझता हूँ कि वे मेरे मूल अभिलेखों का निरीक्षण कर सकते हैं।

मैं जानता हूँ कि मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए अपनी सहभागिता समाप्त कर सकता हूँ; और इससे मेरे भविष्य में होने वाले ईलाज प्रभावित नहीं होंगे। मैं यह भी जानता हूँ कि अनुसंधानकर्ता किसी भी समय किसी भी कारण से मेरी सहमती के बिना इस अध्ययन में मेरी सहभागिता समाप्त कर सकते हैं।

मुझे सूचित किया जा चुका है कि _____ केंद्र या इसके सहयोगियों द्वारा मेरे रक्त नमूने के आधार पर किसी भी लाभ (पेटेंट पंजीकृत करवाने सहित) के लिए मेरी पूर्व सहमति ली जाएगी।

तिथि: _____

नाम: _____ लिंग: _____ आयु (वर्षों मे): _____

पता: _____

अनुसंधानकर्ता प्रमाण-पत्र

मैं प्रमाणित करता हूँ कि उपरोक्त अध्ययन की प्रकृति, उद्देश्य और संभावित जोखिम की व्याख्या संबंधित व्यक्ति को कर दी गई है। मेरी राय में इस अनुसन्धान में सहभागिता की सूचित सहमति प्रदान करने के लिए सहभागी कानूनी क्षमता रखता है और वह स्वैच्छिक रूप से और पूर्ण ज्ञान के साथ इसमें भाग लेने की सूचित सहमति दे रहा है।

अनुसंधानकर्ता के हस्ताक्षर एवं नाम: _____ दिनांक: _____

ਸਹਿਮਤੀ ਫਾਰਮ

ਮੈਨੂੰ ਸੰਭਾਵਤ ਖਤਰਿਆਂ ਅਤੇ ਫਾਇਦਿਆਂ ਤੋਂ ਜਾਣੂ ਕਰਵਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਂ ---------- ---------- ਕੇਂਦਰ, ਪੰਜਾਬ ਕੇਂਦਰੀ ਯੂਨੀਵਰਸਿਟੀ ਵਲੋਂ ਮੇਰੇ ਜਾਂ ਮੇਰੇ ਬੱਚਿਆਂ ਦੇ ਖੂਨ ਦੇ ਨਮੂਨੇ ਲਏ ਜਾਣ ਦਾ ਮੰਤਵ ਵੀ ਸਮਝ ਲਿਆ ਹੈ।

ਮੇਰੇ ਉਪਰ ਕਿਸੇ ਵੀ ਤਰ੍ਹਾਂ ਦਾ ਕੋਈ ਦਬਾਅ ਨਹੀਂ ਹੈ ਅਤੇ ਮੈਂ 1. ਨਾੜੀ ਵਿਚੋਂ ____ ਮਿਲੀਲੀਟਰ ਖੂਨ ਦਾ ਨਮੂਨਾ ਲੈਣ ਲਈ, ਅਤੇ 2. ---------- ਕੇਂਦਰ ਜਾਂ ਉਸਦੇ ਸਾਂਝੀਵਾਲਾਂ ਵਲੋਂ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਗਿਆਨ ਪ੍ਰਾਪਤੀ ਹਿੱਤ ਮੇਰੇ ਖੂਨ ਦੇ ਨਮੂਨੇ ਦੇ ਹਰ ਤਰ੍ਹਾਂ ਦੇ ਗੈਰ-ਮੁਨਾਫਾਕ੍ਰਿਤ ਖੋਜ ਅਧਿਐਨ ਲਈ ਆਪਣੀ ਸਹਿਮਤੀ/ਆਪਣੇ ਬੱਚਿਆਂ (ਜਿੰਨ੍ਹਾਂ ਦੀ ਉਮਰ ਅੱਜ ਦੇ ਦਿਨ 18 ਸਾਲ ਤੋਂ ਘੱਟ ਹੈ) ਦੀ ਸਹਿਮਤੀ ਦਿੰਦਾ ਹਾਂ।

ਮੈਨੂੰ ਆਪਣੇ ਨਮੂਨੇ (ਨਮੂਨਿਆਂ) ਦੇ ਅਧਿਐਨ ਦੇ ਨਤੀਜੇ ਜਾਣਨ ਦਾ ਹੱਕ ਹੋਵੇਗਾ ਅਤੇ ਮੈਂ ਅਗਲੇਰੀ ਅਗਾਉਂ ਸਹਿਮਤੀ ਹਾਸਲ ਕੀਤੇ ਬਗੈਰ ਸਿੱਧੀ ਜਾਂ ਨਮੂਨੇ (ਨਮੂਨਿਆਂ) ਦੇ ਅਧਿਐਨ ਰਾਹੀਂ ਹਾਸਲ ਕੀਤੀ ਗਈ ਕੋਈ ਵੀ ਨਿੱਜੀ ਜਾਣਕਾਰੀ ਜਨਤਕ ਕਰਨ ਦੀ ਸਹਿਮਤੀ ਨਹੀਂ ਦੇ ਰਿਹਾ।

ਮੈਂ ਖੋਜ ਕਰਤਾਵਾਂ ਨੂੰ ਇਸ ਅਧਿਐਨ ਵਿਚ ਮੇਰੀ ਸ਼ਮੂਲੀਅਤ ਸਦਕਾ ਮੇਰੇ ਤੋਂ ਪ੍ਰਾਪਤ ਜਾਣਕਾਰੀ ਸਪਾਂਸਰਾਂ, ਨਿਯਮਕ ਸੰਸਥਾਵਾਂ, ਸਰਕਾਰੀ ਏਜੰਸੀਆਂ ਅਤੇ ਸਦਾਚਾਰ ਕਮੇਟੀ ਨਾਲ ਸਾਂਝਾ ਕਰਨ ਦੀ ਇਜ਼ਾਜਤ ਦਿੰਦਾ ਹਾਂ। ਮੈਨੂੰ ਪਤਾ ਹੈ ਕਿ ਉਹ ਮੇਰੇ ਅਸਲੀ ਦਸਤਾਵੇਜ਼ਾਂ ਦੀ ਜਾਂਚ ਕਰ ਸਕਦੇ ਹਨ।

ਮੈਂ ਇਸ ਤੱਥ ਤੋਂ ਜਾਣੂ ਹਾਂ ਕਿ ਮੈਂ ਕਿਸੇ ਵੀ ਸਮੇਂ ਬਿਨ੍ਹਾਂ ਕੋਈ ਕਾਰਨ ਦੱਸੇ ਇਸ ਅਧਿਐਨ ਕਾਰਜ ਨੂੰ ਛੱਡ ਸਕਦਾ ਹਾਂ ਅਤੇ ਹਸਪਤਾਲ ਵਿਚ ਹੋਣ ਵਾਲੇ ਮੇਰੇ ਸੰਭਾਵੀ ਇਲਾਜ ਤੇ ਇਸਦਾ ਕੋਈ ਅਸਰ ਨਹੀਂ ਪਵੇਗਾ। ਮੈਨੂੰ ਇਹ ਵੀ ਜਾਣਕਾਰੀ ਹੈ ਕਿ ਖੋਜ ਕਰਤਾ ਕਿਸੇ ਵੀ ਸਮੇਂ, ਬਿਨ੍ਹਾਂ ਕੋਈ ਕਾਰਨ ਦੱਸੇ ਅਤੇ ਮੇਰੀ ਸਹਿਮਤੀ ਬਗੈਰ ਇਸ ਅਧਿਐਨ ਕਾਰਜ ਵਿਚ ਮੇਰੀ ਸ਼ਮੂਲੀਅਤ ਖਤਮ ਕਰ ਸਕਦੇ ਹਨ।

ਮੈਨੂੰ ਜਾਣਕਾਰੀ ਦੇ ਦਿੱਤੀ ਗਈ ਹੈ ਕਿ ਮੇਰੇ ਖੂਨ ਦੇ ਨਮੂਨੇ ਦੇ ਅਧਾਰ ਤੇ ਕਿਸੇ ਵੀ ਲਾਭ ਵਾਲੇ ਕਾਰਜ (ਪੇਟੇਂਟ ਫਾਈਲ ਕਰਨ ਸਹਿਤ) ਨੂੰ ਕਰਨ ਤੋਂ ਪਹਿਲਾਂ ---------- ਕੇਂਦਰ ਜਾਂ ਉਸਦੇ ਸਾਂਝੀਵਾਲਾਂ ਵਲੋਂ ਮੇਰੀ ਸਹਿਮਤੀ ਹਾਸਲ ਕੀਤੀ ਜਾਵੇਗੀ।

ਮਿਤੀ:

ਨਾਮ: ਲਿੰਗ: ਉਮਰ (ਸਾਲ):

ਪਤਾ:

ਖੋਜਕਰਤਾ ਵਲੋਂ ਪ੍ਰਮਾਣ-ਪੱਤਰ

ਮੈਂ ਇਹ ਪ੍ਰਮਾਣਿਤ ਕਰਦਾ ਹਾਂ ਕਿ ਇਸ ਸਹਿਮਤੀ ਪੱਤਰ ਵਿਚ ਦਰਜ ਉਪਰੋਕਤ ਅਧਿਐਨ ਕਾਰਜ ਨਾਲ ਜੁੜੇ ਹੋਏ ਲੱਛਣਾਂ, ਮੰਤਵਾਂ ਅਤੇ ਸੰਭਾਵਿਤ ਖਤਰਿਆਂ ਸਮੇਤ ਸਾਰੇ ਤੱਥਾਂ ਤੋਂ ਭਾਗੀ ਨੂੰ ਜਾਣੂ ਕਰਵਾ ਦਿੱਤਾ ਗਿਆ ਹੈ। ਮੇਰੇ ਵਿਚਾਰ ਅਨੁਸਾਰ ਭਾਗੀ ਇਸ ਖੋਜ ਵਿਚ ਸ਼ਾਮਲ ਹੋਣ ਲਈ ਜਾਗਰੂਕ ਸਹਿਮਤੀ ਦੇਣ ਦੇ ਕਾਨੂੰਨੀ ਰੂਪ ਵਿਚ ਸਮਰਥ ਹੈ ਅਤੇ ਸਵੈਇੱਛਾ ਨਾਲ ਅਤੇ ਜਾਣਦੇ ਹੋਏ ਜਾਗਰੂਕ ਸਹਿਮਤੀ ਦੇ ਰਿਹਾ ਹੈ,

ਖੋਜਕਰਤਾ ਦੇ ਦਸਤਖਤ ਅਤੇ ਨਾਮ: _____ ਮਿਤੀ: _____

CENTRAL UNIVERSITY OF PUNJAB

VPO Ghudda 151401, Dist. Bathinda

Institutional Ethics Committee

Standard protocol for Coding/ decoding of the sample.

1. **Coding/ decoding of the sample details:**

- Coding of the human sample is required to safeguard the identity of the donor.
- A committee comprising of coordinator of same centre (or senior faculty) and coordinator/senior faculty from another centre will be involved in coding of the sample. In case of CoC is the PI, senior faculty from same centre and CoC/senior from another centre will be involved in coding/decoding)
- Each sample will be assigned a random number (as mentioned in serial number 2 under heading of sample numbering).
- Personnel information like name etc. shall be kept confidential and required information may be released to the researchers like age and sex of the donor, clinical features etc.

2. **Sample numbering**: A number than may be given to the sample; eg. Human sample collected in March 2014 can be coded as CUPB/HSB/14/03/----, where CUPB stands for the university, HSB for human sample blood (or others like HSP for human sample prostate etc.), 14 is the year 2014, 03 is the month March followed by 4 digit serial number for the sample.
3. **Criteria and procedure for disclosing the patient's confidential record**: Donor's confidential details shall not be revealed under any circumstances for the study or any other gains. In case of any emergency, committee set up by the competent authority shall decide whether to reveal the identity or any other details. Once the details are revealed the particular sample should be immediately excluded from the study.
4. **Emergency measures:** if in case of any leakage of donor information the PI or the concerned person should immediately inform the office regarding the information leakage and work should be stopped immediately. The committee will find out the source of information leakage and the guilty should be penalized as per the University regulations.

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Institutional Ethics Committee

Standard protocol for Disposal of biohazard waste generated from blood samples.

1. Personnel responsible for disposing of human samples must be appropriately trained and qualified, and demonstrate due care and respect for the material at all time.
2. All human samples to be disposed of should be autoclaved (at 131°C for 30 minutes) prior to disposal using a separate clear autoclave bag designated solely for human samples. ***The only exception to this is the disposal of formalin-fixed blood which must not be autoclaved***.
3. A record of the autoclaving should be kept by the personnel responsible for undertaking the procedure. These records should then be retained as part of the provision of an audit trail of the fate of samples.
4. Samples for disposal, once autoclaved, or formalin-fixed blood samples which should not be autoclaved, should be placed into a thick gauge biohazard waste bag for storage until subsequent disposal. If the material is hazardous, including formalin-fixed blood, this should be separated from normal clinical waste and disposed of using appropriate procedures for hazardous material
5. When samples require disposal if there is no regular collection of clinical waste (e.g. routine weekly collection), a clinical waste collection should be requested.

CENTRAL UNIVERSITY OF PUNJAB

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Institutional Ethics Committee

Mechanisms of reporting of Serious Adverse Events (SAE)

1. In case of any injury or serious adverse events during procurement of human samples, immediate and appropriate medical aid by a qualified doctor should be ensured by principal investigator.
2. Since IEC-CUP is not mandated to approve clinical trial protocols, SAE in such cases should be handled by the collaborating medical institute.
3. It is the responsibility of Applicant (Principal Investigator) to notify the member-secretary and chairperson of IEC-CUPB immediately in case of any such event.
4. Vice Chancellor and IEC-CUP should also be provided with detailed incident report and analysis.
5. IEC-CUPB should discuss such events in detail and advice applicant accordingly to avoid any such future incidences.
6. Strict compliance with ICMR/DHR and DCGI guidelines is responsibility of the principal investigator (applicant) of the study.

Member Secretary (IEC)

18.3.2024

Director, R&D Cell

Registrar,
Central University of Punjab

कुलसचिव / REGISTRAR
पंजाब केन्द्रीय विश्वविद्यालय, बठिंडा-151401
Central University of Punjab, Bathinda-151401