STANDARD OPERATING PROCEDURE (SOP) FOR THE INSTITUTIONAL ETHICAL COMMITTEE (CLINICAL RESEARCH)

1. Purpose

To establish a transparent, independent, and systematic procedure for ethical review of all biomedical and clinical research involving human participants conducted under the aegis of Jamia Millia Islamia.

2. Scope

This SOP applies to all submissions involving:

- Human participants
- Human biological material
- Medical records
- Clinical trials
- Medical devices
- Diagnostic studies
- Public health research
- Artificial intelligence research involving identifiable human health data
- Behavioural and social science research involving patients

3. Composition of the IEC

The IEC shall consist of the following:

- Chairperson
- Members
- Convenor
- Invited subject expert, if required

4. Meetings

- Meetings shall ordinarily be held at least as and when required.
- The meeting schedule shall be notified in advance.
- Emergency meetings may be convened by the Chairperson.

5. Submission of Applications

Applications shall be submitted to the Chairperson on the prescribed application form along with all prescribed documents at least 15 working days before the scheduled IEC meeting.

Incomplete applications shall not be placed before the Committee.

6. Review Process

The review shall consider:

- Scientific validity
- Risk-benefit assessment
- Participant selection
- Informed consent
- Privacy and confidentiality
- Protection of vulnerable participants
- Data management
- Regulatory compliance

7. Decision of the IEC

The Committee may:

- Approve
- Approve with modifications
- Defer pending clarification
- Reject

All decisions shall be recorded in the minutes of the meeting, along with reasons where appropriate.

8. Communication of Decision

The Chairperson shall communicate the IEC decision to the Principal Investigator in writing within **15 working days** of the meeting.

9. Post-Approval Monitoring

The IEC shall monitor approved studies through:

- Annual progress reports
- Review of the final study report

10. Protocol Amendments

No amendment to the approved protocol shall be implemented without prior IEC approval, except where immediate changes are necessary to eliminate hazards to participants. Such changes shall be reported to the IEC at the earliest opportunity.

11. Serious Adverse Events (SAEs)

The Principal Investigator shall report all SAEs to the IEC promptly, in accordance with applicable regulatory timelines.

The IEC shall assess the event and recommend appropriate action, including continuation, modification, suspension, or termination of the study.

12. Suspension or Withdrawal of Approval

The IEC may suspend or withdraw approval if:

- the approved protocol is violated;
- participant safety is compromised;
- false or misleading information was submitted;
- required reports are not submitted; or
- any other serious ethical or regulatory non-compliance is established.

13. Record Keeping

The IEC shall maintain secure records of:

- applications;
- correspondence;
- meeting agendas and minutes;
- review comments;
- approval letters;

- amendments;
- adverse event reports; and
- final reports.

Records shall be retained for the period prescribed under applicable laws and institutional policies.

14. Confidentiality

All documents, deliberations, and decisions of the IEC shall be treated as confidential. Members shall not disclose information relating to research proposals except as authorised or required by law.

15. Conflict of Interest

Any IEC member with a financial, professional, or personal conflict of interest in a proposal shall disclose the conflict and recuse themselves from the review and decision-making process for that proposal.

16. Appeals

An applicant aggrieved by the decision of the IEC may submit a written appeal to the IEC within **30 days** of receipt of the decision. The appeal shall be considered in accordance with the University's prescribed procedure.