



**Ethics Committee
RIRF's Ethics Committee
Rising India Research Foundation**

Standard Operating Procedures (SOP) for the Ethical Committee in General

- 1. Membership and Composition:** a. Clearly define the composition of the Ethical Committee, specifying roles, qualifications, and diversity. b. Establish procedures for the selection, appointment, and removal of committee members.
- 2. Training and Education:** a. Mandate ongoing training for committee members on ethical principles, relevant regulations, and emerging issues. b. Require comprehensive orientation sessions for new members.
- 3. Review Process:** a. Outline procedures for the submission, review, and approval/rejection of research proposals. b. Specify approval criteria based on participant welfare, scientific merit, and ethical considerations. c. Define the process for expedited and full committee reviews.
- 4. Informed Consent:** a. Provide guidelines for obtaining and documenting informed consent. b. Specify required information in the consent form. c. Address procedures for obtaining consent in special populations.
- 5. Risk Assessment:** a. Establish criteria for assessing and managing risks associated with research protocols. b. Outline procedures for monitoring ongoing studies for unanticipated problems.
- 6. Conflicts of Interest:** a. Implement procedures for disclosing and managing conflicts of interest among committee members and researchers. b. Define criteria for recusal in situations where a committee member has a conflict of interest.
- 7. Continuing Review:** a. Describe the process for ongoing monitoring of approved research to ensure compliance. b. Specify circumstances requiring further review or modification of an approved protocol.
- 8. Record Keeping and Documentation:** a. Establish guidelines for maintaining comprehensive records of committee activities, decisions, and communications. b. Specify the retention period for records in accordance with applicable regulations.
- 9. Reporting to Regulatory Authorities:** a. Define procedures for reporting adverse events, non-compliance, and serious breaches to regulatory bodies.
- 10. Communication and Transparency:** a. Implement clear communication channels between the committee, researchers, and stakeholders. b. Outline procedures for addressing concerns and complaints raised by researchers or participants.
- 11. Compliance with Regulations:** a. Ensure that all committee activities align with local, national, and international regulations governing research ethics. b. Regularly review and update SOPs to incorporate changes in regulations and best practices.



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12. Emergency Situations: a. Develop procedures for addressing ethical concerns in emergency situations, including protocol suspension if necessary.

13. Quality Assurance: a. Establish mechanisms for internal audits or quality assurance reviews to ensure effective committee processes.

14. Public Accountability: a. Promote transparency by outlining procedures for disclosing committee decisions and rationale when appropriate.