Research Cell

Standard Operating Procedures (SOPS)

Institutional Review Board (IRB) with Technical Committee Functions

1. Purpose

This SOP outlines the procedures for the operation of the Institutional Review Board (IRB), which also performs the functions of a Technical Committee for research involving human subjects. The primary goal is to ensure the ethical conduct of research, the protection of participants, and the scientific rigor of the research proposals reviewed.

2. Scope

This SOP applies to all research proposals involving human subjects reviewed by the IRB, whether they are conducted by the institution or external collaborators. It also applies to the review and oversight of research protocols that require both ethical review and technical evaluation to ensure scientific validity.

3. Definitions

- Institutional Review Board (IRB): A committee responsible for reviewing and overseeing research involving human subjects to ensure compliance with ethical standards.
- Technical Committee: A sub-committee or integrated function within the IRB responsible for reviewing the scientific and technical aspects of research proposals.
- Research Protocol: A detailed plan that outlines the objectives, design, methodology, and potential risks of a research study.
- Principal Investigator (PI): The lead researcher responsible for the design and implementation of the study.

4. Structure and Composition

- The IRB is composed of members from diverse disciplines, including research, ethics, law, medicine, and the sciences.
- The Technical Committee, a sub-function of the IRB, is comprised of subject matter experts who assess the scientific and technical quality of the research.
    - IRB Chair: Oversees both ethical and technical reviews.
    - Members: Include experts in research methodology, clinical research, statistics, and other relevant fields.
    - Ad Hoc Experts: Called upon to review highly specialized areas when necessary.
    - Institutional Official (IO): The final authority on the IRB's decisions.

5. Roles and Responsibilities

- IRB Functions:
    - Review all research involving human subjects for ethical concerns, informed consent procedures, risk assessments, and privacy issues.
    - Ensure compliance with applicable laws and regulations (e.g., IRB regulations, Good Clinical Practice, HIPAA).
    - Make decisions regarding the approval, modification, or rejection of research proposals.
    - Monitor ongoing research for continued compliance and address any ethical concerns that arise during the study.
- Technical Review Functions:
    - Evaluate the scientific validity of research proposals.
    - Assess the methodology, sample size, statistical analysis, and overall research design for rigor and feasibility.
    - Provide feedback and recommendations on improving the quality of research, ensuring it is scientifically sound and capable of producing reliable data.
    - Advise on the adequacy of risk minimization strategies and ensure that technical aspects of the research design are aligned with ethical considerations.

6. Process for Review

The review process is divided into two primary phases: Technical Review and Ethical Review.

- Technical Review: The board will assess the scientific design, methodology, statistical approach, and overall feasibility of the research. This includes:
    - Research Design Review: Assessing the study's objectives, hypothesis, and methodology.
    - Sample Size and Statistical Power: Evaluating the appropriateness of the sample size and statistical methods.
    - Risk/Benefit Analysis: Analyzing whether the research is scientifically feasible and if the potential risks to participants are minimized.
- Ethical Review: The IRB evaluates the ethical aspects of the proposal, focusing on the protection of participants, informed consent, confidentiality, and compliance with applicable ethical guidelines.

Both reviews are conducted in parallel or sequentially, depending on the nature of the research.

7. Review Meeting Procedures

- Scheduling: IRB meetings are scheduled monthly, with additional meetings held as needed. Technical Committee reviews may occur in tandem with or independent of the full IRB meeting.
- Agenda: The meeting agenda includes discussion of research proposals, ethical concerns, technical and scientific validity.
- Documentation: Minutes of meetings must be recorded, including decisions made, discussions held, and reasons for approvals, rejections, or required revisions.
- Voting: A quorum (50% members attendance) is required for a decision to be made. Both ethical and technical components must receive approval for the research to proceed.
- IRB convenor reserves right to replace a member of IRB who will be absent from three IRB meetings consecutively.

8. Decision-Making

- Approval: If both the ethical and technical reviews are satisfactory, the proposal is approved.
- Conditional Approval: The proposal may be conditionally approved, subject to revisions, which may include further technical clarification or adjustments to ethical protections.
- Rejection: If the proposal fails to meet either ethical or technical standards, it is rejected. The researcher is informed of the reasons for rejection and given an opportunity for revision and resubmission.

9. Monitoring and Ongoing Review

- Post-Approval Monitoring: After approval, the IRB will monitor the research to ensure ongoing compliance with both ethical and technical standards.
- Adverse Events: Any adverse events related to the research must be reported to the IRB, which will reassess both the ethical and technical aspects of the study.
- Annual Reviews: Ongoing studies will be reviewed at least annually by the IRB to ensure continued compliance with both ethical and technical requirements.

10. Confidentiality

All members of the IRB and the Technical Committee must maintain confidentiality regarding the details of the research proposals reviewed. Information related to research protocols should not be disclosed to unauthorized persons.

11. Training and Education

- All IRB and Technical Committee members must undergo regular training on ethical guidelines, regulatory updates, research methodologies, and any other relevant topics.
- The institution will provide continuous education to ensure members are up-to-date with evolving ethical and scientific standards.

12. Record Keeping

- All documents related to the review process, including applications, minutes, correspondence, and approval letters, must be securely stored for at least five years.
- These records are accessible to authorized personnel but must be kept confidential to protect the privacy of the researchers and study participants.

13. Revision History

- This SOP will be reviewed annually for compliance with regulatory standards and updated as necessary.

This SOP ensures that both ethical and scientific standards are met in research involving human subjects, maintaining a high level of integrity and protection for participants while ensuring the quality of research conducted.