

RESEARCH ETHICS COMMITTEES

2024 Third Edition
Chapter Five

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Topics for discussion



- Introduction
- Government framework
- Role of research ethics committees
- Education and training in research ethics
- Standard operating procedures
- Compliance reporting to the NHREC

Introduction

- This chapter outlines the governance framework, roles, and responsibilities of research ethics committees (RECs).
- It covers the composition, training, and operational procedures of RECs, emphasising their critical role in ensuring ethical standards in health and health-related research.

Governance framework

- **Statutory framework:** Institutions conducting health research must have RECs registered with the National Health Research Ethics Council (NHREC).
- **Terms of reference (ToR) and standard operating procedures (SOPs):** RECs must have ToR and SOPs to guide their operations, ensuring transparency and adherence to legal and ethical standards.
- **Expectations of institutions:** Code of conduct for RECs, administrative support and resources, indemnification of REC members, and well-being of people involved in institutional animal care and use.

Role of Research Ethics Committees

- **Primary role:** Protect the rights and welfare of research participants and animals used in research.
- **Independence:** RECs must operate independently within their institutional governance systems, free from external interference.



REC membership composition

Diversity: RECs should be multidisciplinary, multisectoral, and pluralistic, including members from various disciplines, sectors, and backgrounds.

Appointment of chairperson and members: Chairpersons should have experience in research and ethics, and members should be appointed for renewable terms to ensure continuity and institutional memory.

Education and training in research ethics

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Training requirements: REC members, administrators, researchers, and students must complete theoretical research ethics training, including assessments to ensure competence.

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Training outcomes: Members should understand ethical principles, research integrity, and REC governance.

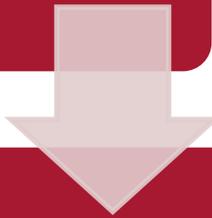
Standard operating procedures (SOPs)

Purpose: SOPs detail the steps for achieving review or administrative objectives, ensuring standardised best practices and compliance with ethical and regulatory requirements.

Examples: SOPs should cover institutional operations, REC administrative procedures, complaints handling, and monitoring processes.

Applications for ethics review

Review process: RECs must develop an ethics review application form to capture essential ethical elements and standardise the review process.



Decision-making: RECs should approve, require amendments to, or reject research protocols based on thorough deliberation and feedback.

Monitoring and compliance



Monitoring types: Active (site visits) and passive (paper-based) monitoring to ensure adherence to approved protocols.



Annual reporting: RECs must submit annual reports to the NHREC, detailing their activities, membership, and compliance with ethical standards.

Handling complaints and queries

- **Complaints process:** Accessible procedures for handling complaints about REC-related business, escalating unresolved issues to the NHREC if necessary.

Conclusion

- Research ethics committees play a vital role in safeguarding the rights and welfare of research participants and animals. By adhering to rigorous ethical standards and governance frameworks, RECs ensure the integrity and societal value of health research. Continuous training, transparent procedures, and effective monitoring are essential to maintaining high ethical standards and fostering public trust in research.

National Health Research Ethics Council (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH.

Available from: <https://www.health.gov.za/nhrec-home/>