

HEALTH RESEARCH ETHICS INFRASTRUCTURE

2024 Third Edition
Chapter Six

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Topics for discussion

Introduction

National Health Research Ethics
Council

Research ethics committees

Registration and audit of
committees

Statutory entities relevant to
research

Introduction

- Chapter 6 of the NHREC document focuses on the infrastructure and systems designed to regulate and oversee health research ethics in South Africa. It outlines the statutory framework, key entities, and processes involved in maintaining ethical standards in health research.

Key points

1. National Health Research Ethics Council (NHREC)

- **Establishment and responsibilities:** The NHREC, established under the National Health Act (NHA), sets ethical norms and standards, registers and audits research ethics committees (RECs), and promotes compliance.
- **Appointment of members:** The Minister of Health appoints 15 members with expertise in research ethics or law.
- **Operation:** The Council meets at least four times a year, supported by a secretariat, and maintains active relations with the research community.

2. Research ethics committees (RECs)



Role and responsibilities: RECs review research protocols to ensure that ethical standards are met, protecting the welfare of participants and animals.



Registration and audit: RECs must register with the NHREC and undergo regular audits to ensure compliance with ethical standards.

3. Quality assurance and capacity building

- **Assessment and audit:** The NHREC conducts quality assurance assessments and audits on a five-year cycle, providing guidance and recommendations for improvement.
- **Capacity building:** Emphasis on training, support, and feedback to enhance the capabilities of RECs.

4. Statutory entities relevant to research

South African Health Products Regulatory Authority (SAHPRA):
Ensures the safety, quality, and efficacy of pharmaceutical products and medical devices.

Provincial Health Research Committees: Coordinate health research at the provincial level, ensuring alignment with health priorities and managing access to health facilities.

National Health Research Committee (NHRC):
Determines national health research priorities and monitors research trends through the National Health Research Database.

Conclusion

- The chapter provides an overview of the health research ethics infrastructure in South Africa, highlighting the roles and responsibilities of various entities in maintaining ethical standards.
- The emphasis on regular audits, capacity building, and coordination among different bodies ensures a robust framework for ethical health research.
- This infrastructure aims to protect the welfare of research participants and animals, promoting high standards of ethical conduct in health 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/>