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HREC Overall Process

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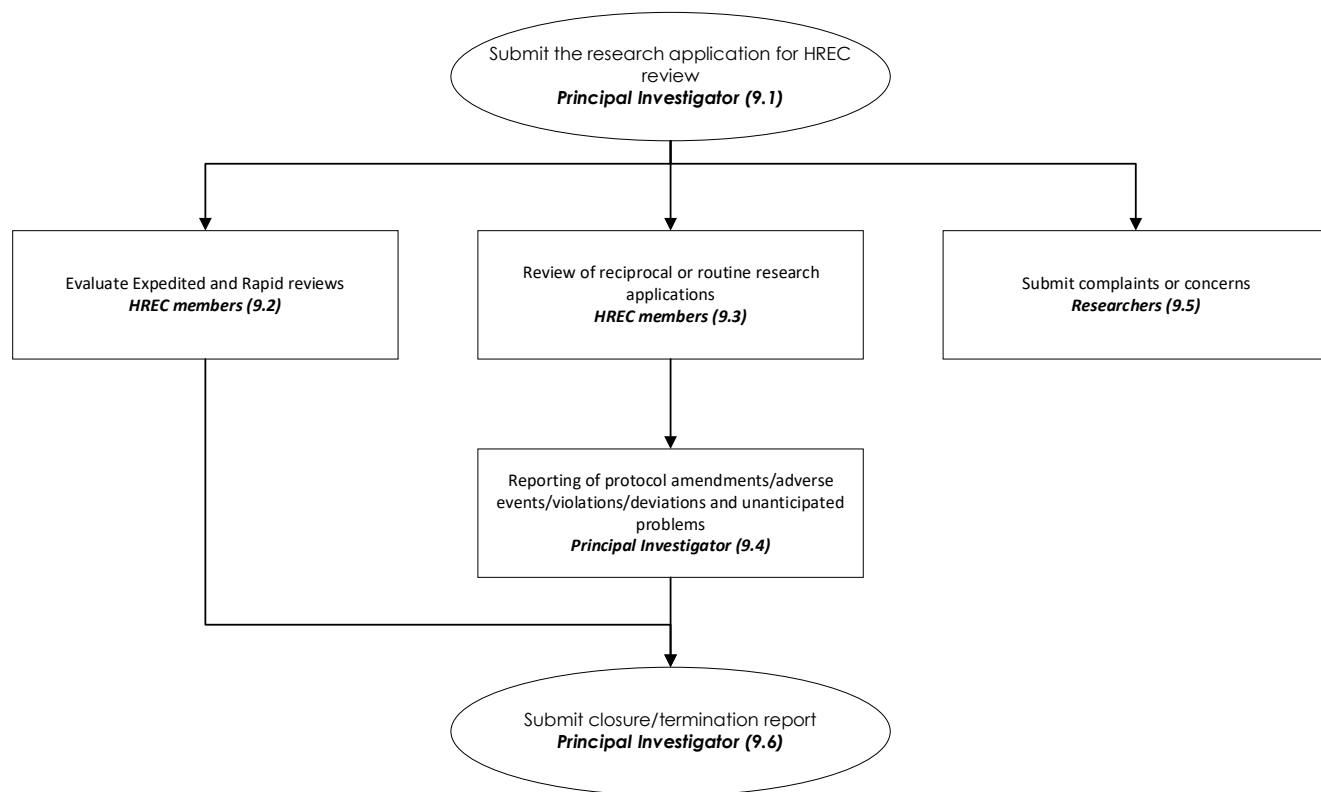
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1. Process flow

(Include responsible position and step number in the process flow if not a swim lane flowchart)



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2. Purpose

- 2.1. The purpose of this document is to describe, at a summary level, the processes followed by the South African National Blood Service (SANBS) Human Research Ethics Committee (HREC) from the point at which a research application has received Scientific Review Committee (SRC) approval through to study closure.
- 2.2. This document is intended to provide an overview of the HREC process for applicants and must be read together with the detailed HREC Standard Operation Procedures and related procedures, information documents and forms referenced herein.

3. Scope

- 3.1. This SOP applies to all research studies submitted to SANBS HREC following SRC approval.
- 3.2. It applies to Principal Investigators (PIs), co-investigators, students, collaborators and external applicants conducting research under SANBS auspices.
- 3.3. This SOP also applies to the SANBS HREC, its Secretariat, and any institutional governance structures involved in ethical review and oversight.

4. Definitions

- 4.1. **HREC:** Human Research Ethics Committee registered with the NHREC in terms of Section 73 of the National Health Act.
- 4.2. **SRC:** Scientific Review Committee responsible for scientific merit review.
- 4.3. **PI:** Principal Investigator responsible for the ethical conduct of the study.
- 4.4. **Expedited Review:** Ethics review process for minimal-risk studies as defined in NHREC guidelines.

5. Safety, Health, Environment and Risk

Hazards / Risks Identified	Risk Mitigation Controls
• Ethical non-compliance or participant risk • Absence of informed consent • Data privacy breaches	• Engineering Controls • Operational Controls ◦ HREC review, monitoring and mandatory reporting ◦ Review and approval of consent documents ◦ Data and Material Transfer agreements; POPIA compliance • Administrative Controls • Personal Protective Equipment and Clothing • Infection Prevention Control • Risk

6. Training and Competency

- 6.1. Training and competency requirements apply to SANBS HREC members and HREC Secretariat staff involved in the application of this SOP.
- 6.2. HREC members and Secretariat staff will participate in an interactive discussion of this SOP during a scheduled meeting, during which the ethics review and oversight processes will be considered. The discussion and any confirmations of understanding will be documented in the meeting minutes.
- 6.3. SANBS internal staff are required to complete a competency assessment to evaluate understanding of the processes and requirements outlined in this document. A minimum pass mark of 80% is required to be deemed competent. If an individual fails, they must seek clarity and re-attempt the assessment.
- 6.4. Records of attendance and competency assessments will be retained by the HREC Secretariat in accordance with SANBS document and training record requirements.

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- 6.5. External applicants are not required to complete formal competency assessments; however, applicants are expected to familiarise themselves with this SOP and the referenced documents prior to submission.
- 6.6. Re-training and re-assessment will be required following any substantive revision of this SOP

7. Responsibilities

Key responsibilities of personnel involved in HREC processes are as follows:

- 7.1. **HREC Chairperson**
 - 7.1.1. Oversee ethical review and signs approval letters.
- 7.2. **HREC Members**
 - 7.2.1. Conduct independent ethical reviews and declare conflicts of interest.
- 7.3. **HREC Secretariat staff**
 - 7.3.1. Coordinates submissions, reviews, communication, record-keeping and monitoring.
 - 7.3.2. Ensures documents are reviewed and revised.
- 7.4. **Principal Investigator**
 - 7.4.1. Ensures accurate submissions, ethical conduct, reporting, and compliance with HREC decisions.

8. Additional Information

- 8.1. Ethics approval is time-limited and subject to ongoing compliance with HREC requirements.
- 8.2. No research activities may commence prior to written HREC approval and institutional authorization.

9. Procedure

- 9.1. Submit the research application for HREC review
 - 9.1.1. Submit the SRC-approved research application and all required supporting documents to the SANBS HREC Secretariat in accordance with the *Research Application Review (INF-HREC-005)*.
 - 9.1.2. Applications are reviewed through the appropriate HREC review pathway including full committee review, expedited review or rapid review depending on the level of risk and regulatory requirements.
- 9.2. Evaluate Expedited and Rapid Reviews
 - 9.2.1. Conduct review in accordance with *Expedited Reviews & Rapid Reviews (INF-HREC-003)*.
 - 9.2.2. Provide feedback to applicant on outcome of review
 - 9.2.3. Issue clearance letter once PI has addressed all comments/concerns
 - 9.2.4. Distribute the *Data Transfer Agreement (DTA) (FRM-PRU-006)* or *Material Transfer Agreement (MTA) (FRM-PRU-002)* following the signing thereof in the following order PI, Medical Director (MD) and HREC Chairperson respectively.
 - 9.2.5. Re-certify research project on an annual basis as per *Annual Progress Report Renewal (FRM-HREC-001)*
- 9.3. Review of reciprocal and routine research applications
 - 9.3.1. Conduct the review and ensure compliance with *Informed consent and Participant Information (INF-HREC-007)* where applicable
 - 9.3.2. Provide feedback to applicant on outcome of review
 - 9.3.3. Issue clearance letter once PI has addressed all comments/concerns
 - 9.3.4. Distribute the DTA and/or MTA where applicable following the signing thereof in the following order PI, MD and HREC Chairperson respectively.
 - 9.3.5. Re-certify research project on an annual basis as per *Annual Progress Report Renewal (FRM-HREC-001)*.
 - 9.3.6. Monitoring of research projects will be conducted at the discretion of HREC as described in the *Active and Passive Monitoring (SOP-HREC-004)*.
- 9.4. Reporting of protocol amendments/adverse events/violations/deviations and unanticipated problems

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9.4.1. Prepare and submit a protocol amendment application where applicable as per *Protocol Amendment Application (SOP-HREC-003)*.

9.4.2. Prepare and submit reports of Adverse Events and Unanticipated Problems in accordance with the *Adverse Events (INF-HREC-008)*.

9.5. Submit complaints or concerns

9.5.1. Complaints are managed in accordance with the *HREC Complaints (SOP-HREC-002)*.

9.6. Submit closure/ termination report

9.6.1. Submit report as per *Annual Progress Report Renewal (FRM-HREC-001)*.

10. Limitations / Measurement of Uncertainty

10.1. N/A

11. Record Documents

Document Number	Document Title	Initial On-Site Retention Period	Off Site Retention Period	Total Retention period
FRM-PRU-006	Data Transfer Agreement	5 Years	25 Years	30 Years
FRM-PRU-002	Material Transfer Agreement	5 Years	25 Years	30 Years
FRM-HREC-001	Annual Progress Report	5 Years	25 Years	30 Years

12. Internal Referenced Documents

Document Number	SAP DIR Number	Document Title
INF-HREC-005	1089122	Research Application Review
INF-HREC-003	1089119	Expedited Reviews & Rapid Reviews
INF-HREC-007	1089124	Informed Consent & Participant Information
SOP-HREC-004	1108246	Active and Passive Monitoring
SOP-HREC-003	1108636	Protocol Amendment
SOP-HREC-002	1089131	HREC Complaints
INF-HREC-008	1108209	Adverse Events

13. External References

13.1. Constitution of The Republic of South Africa No. 108 of 1996;

13.2. The National Health Act of Act 61 of 2003 and its regulations;

13.3. Protection of Personal Information Act 4 of 2013 and its regulations;

13.4. Material Transfer of Human Biological Materials (National Health Act, 2003 - Act No. 61 of 2003);

13.5. Ethics in health research: principles, processes and structures, third edition, 2024.

13.6. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3rd ed. 2020);

13.7. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268;

13.8. Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes, R181 of 2012, Gazette No 35099, 2 March 2012;

13.9. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2024);

13.10. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS.

13.11. International Conference on Harmonization Good Clinical Practice Guideline, (6 January 2025);

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13.12. International Committee of Medical Journal Editors (ICMJE) guidelines for authorship (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>); and

13.13. Other relevant legislation, company documents and policies.

14. Revision Summary

Version Number	Revision Details
0	New Document