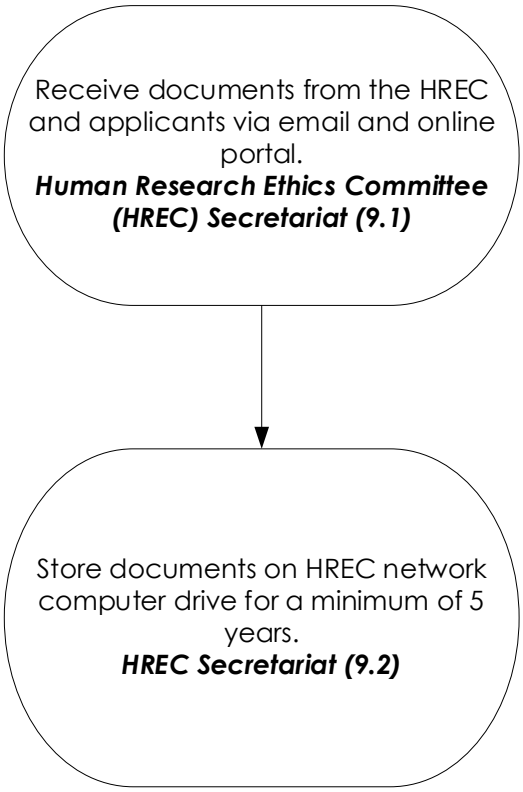
Department Code	SOP-HREC-001	Document Number	1089126	Version Number	0
Document Owner	C Nyoni		Final Approver	A Swarts	
Date Issued		Document and Record Controller		Effective Date	

SANBS
Registration No. 2000/026390/08

Archiving of Human Research Ethics Documents

Contents

1. Process flow



2. Purpose

2.1. This procedure describes the process to be followed by the SANBS Human Research Ethics Committee (HREC) for archiving of documents of the committee to ensure that the process complies with the following requirements and below mentioned references:

2.1.1. SA document retrieval of archive boxes.

2.1.2. SANBS document retention of records.

2.1.3. Archiving of documents.

3. Scope

3.1. This document applies to the HREC office in Translational Research Department.

4. Definitions

4.1. **Archive**: a collection of historical records relating to a place, organization.

4.2. **Archiving documents**: Putting information you no longer use regularly into a secure storage for a period of time.

5. Safety, Health, Environment and Risk

Hazards / Risks Identified	Risk Mitigation Controls
Documents not archived.	• Engineering Controls: N/A. • Operational Controls: N/A. • Administrative Controls: N/A. • Personal Protective Equipment and Clothing: N/A. • Infection Prevention Control: N/A. • Risk: Create storage for traceability purposes.

6. Training and Competency

6.1. Staff will be trained by the Clinical Trial Manager (CTM)/ Translational Research Administrator (TRA) experienced with HREC requirements before access given to the HREC drive.

6.2. All employees to whom this procedure is applicable have to be found competent through a demonstration and observation method. This will be done three times to ensure competency.

6.3. A *Records of Training* and Competency (FRM-QMD-028) form must be signed to confirm completion.

6.4. File the proof of competency in employees personal file or electronically.

6.5. Reassessment will be with each revised version of the procedure.

7. Responsibilities

7.1. It is the responsibility of the Clinical Trial Manager to ensure that the document is reviewed and updated biennially.

7.2. The Secretariat of the HREC is responsible for documentation with regards to storage and archiving of submission, application, reports and decisions of the HREC.

8. Additional Information

8.1. HREC chair, Secretariat and Translational Research and Cellular Therapy Senior manager will have access to off-site stored committee documents.

8.2. Under exceptional circumstances and accompanied by a court order access will be granted to legitimate other parties.

8.3. Documents stored will be inclusive of electronic and hard copies.

8.4. Offsite storage will be for a period of at least fifteen years.

9. Procedure

9.1. Receive documents from HREC and applicants via email and online portal.

9.2. Store documents on HREC network computer drive for a minimum of 5 years.
- 9.2.1. Create files on the network drive.
- 9.2.2. Name all the files according to HREC functions.
- 9.2.3. Save received documents in a specific files.

10. Limitations / Measurement of Uncertainty

10.1. If documents are not stored on the restricted network drive, HREC office will not be able to access them.

11. Record Documents

Document Number	Document Title	Initial On Site Retention Period	Off Site Retention Period	Total Retention period
FRM-QMD-028	Record of Training and Competency	In employees file	N/A	Employment period of employee

12. Internal Referenced Documents

Document Number	SAP DIR Number	Document Title
N/A	N/A	N/A

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. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3ed 2020).
13.6. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268;
13.7. 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.
13.8. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS.
13.9. 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).
13.10. Ethics in health research: Principles, structures and procedures (SA DOH 2015;).
13.11. Ethical principles for medical research involving humans: Declaration of Helsinki (WMA, 2022).
13.12. Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2020).
13.13. 21 Code of Federal Regulations Part 50 – Protection of Human Participants.
13.14. 21 Code of Federal Regulations (CFR) Part 56 – Institutional Review Boards.
13.15. International Conference of Harmonization Good Clinical Practice, 10 November 2016.

14. Revision Summary

Version Number	Revision Details
0	• New Document.