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Registration No. 2000/026390/08

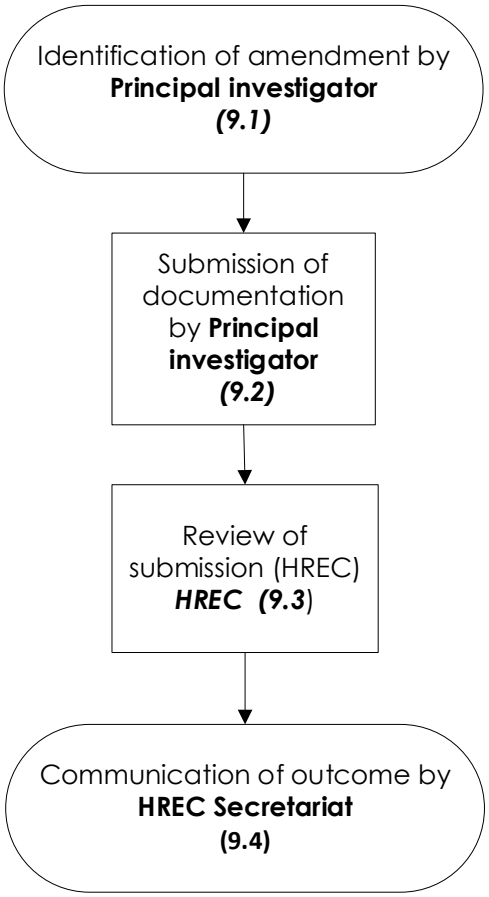
Protocol Amendment Process

Contents

Protocol Amendment Process

1. Process flow

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



2. Purpose

2.1. The purpose of the Standard Operating Procedure is to explain the procedure for requesting the amendment of a South African National Blood Service (SANBS) Human Research Ethics Committee (HREC)-approved research protocol.

3. Scope

3.1. The HREC has the discretion to decide whether or not a proposed amendment is minor, major or requires a full ethical review. Principal investigators and sponsors should seek advice from the HREC if in doubt.

3.2. The HREC must be notified of all amendments, and approval for these must be granted before any change is implemented.

3.3. Amendments may not be implemented without HREC approval unless patient safety is at stake and the issues have been discussed with the HREC Chair.

4. Definitions

4.1. SANBS: South African National Blood Service

4.2. HREC: Human Research Ethics Committee

4.3. PI: Principal Investigator

4.4. Minor amendment:

- 4.4.1. Does not change the risk category of the study
- 4.4.2. Includes minor, non-material changes in the informed consent
- 4.4.3. Includes additional investigators or study sites
- 4.4.4. Includes the extension of the study period
- 4.4.5. Includes changes that do not affect the study design or study outcomes
- 4.4.6. Includes stricter inclusion and exclusion criteria

4.5. Major amendment:

- 4.5.1. Changes the risk category of the study
- 4.5.2. Includes changes in study aims, objectives or design
- 4.5.3. Includes changes in the study methodology or procedures
- 4.5.4. Includes slackening off of the inclusion and exclusion criteria
- 4.5.5. Includes major material changes in the informed consent
- 4.5.6. Includes additional study procedures

5. Safety, Health, Environment and Risk

Hazards / Risks Identified	Risk Mitigation Controls
Research performed that deviate from the HREC-approved protocol	• 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: Research not approved by HREC conducted

6. Training and Competency

6.1. Read and understand

7. Responsibilities

7.1. The principal investigator (PI) must seek approval from the SANBS HREC prior to implementing any changes to the protocol.

7.2. The HREC, under the guidance of the HREC Chair, will review the requested amendment to the protocol and inform the applicant of the outcome via the HREC Secretariat.

7.3. It is the responsibility of the Senior Manager: Translational Research and Cellular Therapy to ensure the document is reviewed and revised.

8. Additional Information

8.1. N/A

9. Procedure

9.1. Identification of amendment (PI)

9.1.1. The PI must identify the need to amend the protocol changes that will be requested

9.2. Submission of documentation (PI)

9.2.1. The PI must submit a cover letter explaining the reasons for the requested changes.

9.2.2. The cover letter must include the HREC approval number and the title of the research protocol.

9.2.3. The cover letter must address the impact of the amendment on participant safety.

9.2.4. All documents must be submitted with the changes highlighted, as well as clean versions.

9.2.5. If site changes or additions are requested, a site approval letter must be included

9.2.6. If the research team changes, the CVs and proof of research ethics training of new members must be included

9.2.7. FRM-HREC-002 must be completed and included

9.2.8. Submissions must be directed to the HREC Secretariat (HRECAdmin@sanbs.org.za)

9.3. Review of submission (HREC)

9.3.1. The HREC secretariat will inform the HREC Chair of the amendment request

9.3.2. For minor amendments, the HREC Chair will determine if the request can be reviewed by the Chair or whether a sub-committee needs to be convened for the review.

9.3.3. All major amendments will be sent to the full HREC for review.

9.4. Communication of outcome (HREC Secretariat)

9.4.1. The outcome of the amendment review will be communicated to the PI by the HREC Secretariat.

9.4.2. The amendment will be ratified and documented in the minutes of the next HREC meeting.

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

12. Internal Referenced Documents

Document Number	SAP DIR Number	Document Title
1097325	FRM-HREC-002	Human Research Ethics Committee Application for Ethics Approval of Amendments

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 Harmonisation Good Clinical Practice Guideline, (10 November 2016);
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	03 September 2025