SOUTH AFRICAN NATIONAL SERVICE HUMAN RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

Registration No. 2000/026390/08

1. Constitution

1.1. The South African National Blood Services (SANBS) Human Research Ethics Committee (HREC) ('The Committee') is an independent HREC registered with the National Health Research Ethics Council in terms of section 73(1) of the National Health Act No 61 of 2003 and was constituted upon request of the SANBS Executive Committee (EXCO).

1.2. The duties and responsibilities of the members of the Committee are as set out in these Terms of Reference ('The ToRs').

1.3. The purpose of the ToR is to establish the requirements for the Committee's constitution, membership, role and responsibilities, reporting and meeting procedures, as well as ensuring that the highest ethical standards are applied and maintained with respect to human dignity and respecting individuals and communities' rights to confidentiality and decision-making in all matters relating to the conduct of research on humans or biospecimens as well as related data by SANBS or any designated third party.

2. Reference

These TORs must be read and interpreted in conjunction with the following but not limited to:

2.1. Constitution of The Republic of South Africa No. 108 of 1996.

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

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

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

2.5. Ethics in health research: principles, processes and structures, second edition, 2015.

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

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

2.8. 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;

2.9. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2013);

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

2.11. International Conference on Harmonisation Good Clinical Practice Guideline, (10 November 2016);

2.12. 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

3. Method for Assessing Competency

3.1. N/A.

4. Rights and Powers of the Committee

The Committee:

4.1. Acts in terms of delegated authority of SANBS CEO as determined in these TORs.

4.2. Has the power to deliberate and report on any activity within the scope of its TORs.

4.3. Has reasonable access to SANBS's records, facilities, and other resources necessary to discharge its duties and responsibilities.

4.4. Can investigate any matter related to its duties and responsibilities in these TORs.

4.5. May obtain outside independent professional advice at the expense of SANBS, after following an approved process on any matter within its mandate.

4.6. Obtains reasonable resources required for the effective discharge of its responsibilities.

4.7. Is empowered to invite relevant persons to attend its meetings as and when required;
4.8. Is empowered to suspend or terminate studies that deviate from the approved protocol; or where statistically futility, efficacy, or harms outweigh benefits as demonstrated by the Data Safety and Monitoring Committee review; or where the magnitude of serious adverse events poses severe risks to participants' safety should the research continue.

5. Membership

5.1. SANBS CEO appoints the Chairperson of the Committee for three years, which may be extended for an additional 2 terms to a maximum of 9 years.
5.2. The committee will appoint the Vice-chairperson from the ranks of the Committee, for a term of three years, which may be extended for an additional 2 terms to a maximum of 9 years. The total membership of the Vice-chairperson on the HREC will not exceed 9 years.
5.3. The committee will appoint new members from time to time as required, and a member will have a tenure not exceeding 9 years.
5.4. The members must have skills, qualifications, and experience to fulfil their duties, including evaluating the research proposal's medical, social, legal, and ethical aspects.
5.5. The members should be independent, multi-disciplinary, multi-sectoral and pluralistic.
5.6. In general terms, membership should include as many disciplines, sectors, and professions as possible, appropriate to the remit of the particular HREC.
5.7. HREC membership should include senior experts and early career academics.
5.8. HREC composition should be ethnically and culturally diverse and an appropriate gender and age mix.
5.9. The Committee shall comprise a minimum of nine members, who, collectively provide for the following skills and experience matrix:
    5.9.1. Whose primary area of interest is non-scientific.
    5.9.2. Who is not currently involved in medical, scientific, or legal work and preferably from the community served by the Committee?
    5.9.3. With knowledge and experience in professional care, counselling, or health treatment of people;
        5.9.3.1.1. Who has professional training and experience in qualitative and quantitative research methodologies;
        5.9.3.1.2. With expertise in biostatistics;
        5.9.3.1.3. With expertise in research ethics; and
        5.9.3.1.4. Who is legally trained and has experience in health research.
5.10. The Committee will promote ongoing, relevant skills development and talent management.
5.11. The SANBS Senior Manager of Translational Research and Cellular Therapy will be a permanent ex officio member of the Committee.
5.12. The SANBS Medical Director will be an ex officio member of the Committee.
5.13. The Committee may invite non-members with expertise in particular areas to participate in a meeting or part of a meeting to assist with decision-making.
5.14. The Committee has the power, at any time to remove any member and to fill any vacancies created by such removal.
5.15. The Committee members identify a vacant position with its associated skills as part of the annual skills matrix assessment or when a member resigns.
5.16. Committee members, SANBS EXCO, and the Translational Research Department are given the specifications of the vacant post and asked to identify and notify the Chairperson of any suitable candidate they are aware of who is available to join the Committee.
5.17. The CVs of candidates who meet the vacant skill and expertise requirements are discussed at a regular sitting of the Committee and a decision is made on those who could be appointed.
5.18. The Chairperson sends an invitation letter to invite appointed candidates to join the next meeting of the Committee.

6. Role

6.1. The overarching role of the Committee is to ensure that:

6.2. The dignity, rights, safety, and well-being of all actual or potential research participants as well as those who may in the future be the recipients of the outcome of the research are safeguarded;

6.3. The health research goals do not override the research participants' health, well-being, and care.

6.4. Research conducted in or by SANBS as well as any external investigators or research collaborations which involve any SANBS data, staff, donors, recipients, patients, blood or blood products or any other SANBS materials or products complies with the national and international ethical guidelines;

6.5. A review process takes place on the ethics of any matter referred to the Committee for advice and consideration from within or outside of SANBS; and

6.6. Research protocols relating to research conducted in or by SANBS are reviewed.

6.7. Humans involved in research are treated with dignity and their well-being is not compromised.

6.8. Where applicable, informed consent is obtained.

6.9. Approval is granted when research proposals meet the accepted ethical norms and standards before the research commences.

7. Functions and Responsibilities

7.1. Responsibilities of the Chairperson of the Committee are to:

7.1.1. Lead the Committee and ensure that the Committee is functioning effectively;

7.1.2. Chair committee meetings in accordance with the standard operating procedures and relevant regulations.

7.1.3. Review and accept revisions made per the committee recommendation, pending protocol approval.

7.1.4. Together, with an appropriate member of the HREC, perform an expedited review of research that meets the expedited review criteria.

7.1.5. Execute, together with the HREC, rapid reviews when required.

7.1.6. Assign responsibilities and duties to other members of the Committee.

7.1.7. In the event that the Chairperson is unable to attend a committee meeting, the Deputy Chair will execute his or her responsibilities and duties.

7.1.8. Evaluate final reports and outcomes.

7.1.9. Review, discuss, and consider research protocols and amendments submitted for evaluation to safeguard the rights and well-being of the study participants.

7.1.10. Review progress reports and monitor ongoing studies as and when required.

7.1.11. Support the administrator in the discharge of duties when called upon.

7.1.12. Maintain the confidentiality of documents and deliberations of the Committee meetings.

7.1.13. Participate and facilitate continuing education activities in biomedical ethics and research.

7.1.14. Report and provide feedback on the decisions of the Committee to relevant stakeholders including principal investigators and the National HREC.

7.1.15. Perform responsibilities detailed in the specific sections of these TORs.

7.1.16. Appoint subcommittees as required to advance any activity of the HREC.

7.1.17. The chair will attend the National NHREC meetings, or delegate attendance to another member of the HREC.

7.1.18. The Chair, along with the Secretariat, will collate information for the NHREC Annual Report.

7.2. Responsibilities of the Committee:

7.2.1. Review, discuss, and consider research protocols and amendments, submitted for evaluation, to safeguard the rights and well-being of the study participants.

7.2.2. The Committee must ensure that information regarding compensation to participants, including the method, amounts, and schedule of compensation to participants and any other information to be provided, is set out in the written informed consent form. The way payment will be prorated must be specified.
7.2.3. The Committee must perform its functions according to written operating guidelines and comply with good clinical practice with the applicable regulatory requirements.
7.2.4. The Committee must conduct reviews in compliance with the established South African and international guidelines for research.
7.2.5. Ensures that no research deviates from the SANBS Research Policy unless the SANBS Medical Director approves such deviation.
7.2.6. Maintain the confidentiality of documents and deliberations of the Committee meetings.
7.2.7. Declare conflicts of interest. Participate in continuing education activities in biomedical ethics and research.

8. Meetings

8.1. Meetings of the Committee are held as and when required and not less than four times in a year.
8.2. The Senior Manager of Translational Research and Cellular Therapy or her/his designated representative will be the Committee Secretary.
8.3. The Committee must establish an annual work plan for each year to ensure that all responsibilities are covered by the agendas of the meetings planned for the year;
8.4. The dates for meetings must be set in the prior year, and the notice, together with the agenda and meeting papers, must be distributed at least two weeks in advance of each scheduled meeting.
8.5. In the special meetings, notice must be provided in accordance with the instruction of the Chair;
8.6. The Chairperson leads the setting of the agenda of the meeting;
8.7. The quorum for the meeting and taking decisions is 50% of the members of the Committee;
8.8. If the Chairperson is absent from a meeting or is conflicted in the matters to be discussed, the Deputy Chairperson will act as Chairperson.
8.9. The proceedings of all meetings must be minutes and the minutes must be completed as soon as possible, but no later than fourteen days after the meeting and circulated to the Chairperson for first review and then to the members for final review thereof;
8.10. The Committee must formally approve the minutes at its next scheduled meeting;
8.11. All minutes are available for inspection by any member of the EXCO;
8.12. Each member of the Committee has one vote. The Chairperson will have a casting vote.
8.13. Members of the Committee will declare any conflict in respect of matters on the agenda before the start of the meeting and such declarations will be managed as deemed necessary, including possible recusal from the discussion and decision-making of the meeting;

9. Attendance at Meetings

9.1. Committee members must attend all scheduled meetings of the Committee, including meetings called on an ad-hoc basis for particular matters, unless a prior apology, with reasons, is submitted to the Chairperson or Committee Secretary.
9.2. The Chairperson has the right to exclude from the whole or part of a meeting any person if, in the opinion of the Chairperson, there is or might be an evident or potential conflict of interest.
9.3. Members and/or invited attendees of the Committee may participate in and at any meetings by means of telephone video-conference or other communication equipment provided that all persons participating in the meeting can communicate with one another.
9.4. Participation in such meetings will constitute attendance and presence by the persons participating.

9.5. Non-attendance of two meetings without legitimate reason will result in termination of membership. Each member should actively engage in meetings and contribute meaningfully to review discussions.

10. Remuneration

10.1. The Board's Directors and Officers Indemnity and Insurance process applies to the members of the Committee.

10.2. Members of the Committee, who are not SANBS employees, are to be remunerated in accordance with the non-Executive Director Remuneration Policy and in line with SANBS remuneration policies and practices and the quantum as approved by the SANBS National Council from time to time.

11. General

11.1. All deliberations of the Committee will remain confidential and may be privileged.

12. Record Documents

Document Number	Document Title	Initial On Site Retention Period	Off Site Retention Period	Total Retention period
N/A	N/A	N/A	NA	N/A

13. Revision Summary

Version Number	Revision Details
0	• New Document.