



## 1. General

The South African National Blood Service (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). The purpose of the Committee is to facilitate sound ethical conduct in all research practices.

## 2. References

- 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>); and
- 2.13. Other relevant legislation, company documents and policies.

## 3. Definitions

- 3.1. **Non-compliance:** Failure or refusal to comply with some requirement.

## 4. General Principles

All members of the SANBS HREC are responsible for the following:

- 4.1. Diligently performing all responsibilities arising from their membership of the HREC.
- 4.2. Regularly and punctually attending meetings.
- 4.3. Maintaining confidentiality regarding the research studies reviewed by the HREC, and the deliberations at HREC meetings.
- 4.4. Considering and declaring any prior interest and/or involvement in any matter being considered at an HREC meeting to avoid actual or potential conflict of financial or personal interest. This includes perceptions of conflicts of interest.
- 4.5. Reviewing accountably and reliably the research studies assigned to them.
- 4.6. Acting constructively and with integrity in all HREC activities.
- 4.7. Making decisions and conducting their oversight responsibilities in an independent manner, free from bias and undue influence.
- 4.8. Abiding by decisions by the HREC on how such a declared actual or potential conflict of interest should be managed.
- 4.9. Familiarizing themselves with relevant policies of the SANBS HREC, as well as national and international research ethics guidelines.
- 4.10. Maintaining their HREC responsibilities in accordance with national and international regulatory requirements and within provisions of South African laws.
- 4.11. Providing the Research Ethics Committee's administrative office with an abbreviated CV regarding their ethics training and experiences at the beginning of their term and attending

regular research ethics training, in line with NHREC requirements to maintain their knowledge and keep abreast of the latest developments in the field.

4.12. Remaining impartial and objective when reviewing protocols.

4.13. Respecting all committee members' views and the deliberative process.

4.14. Responding within 48 hours to emails and correspondence regarding SANBS HREC-related matters between meetings. Non-compliance will result in consequence management in line with the SANBS policies.

## **5. Conduct of the Chairperson**

The Chair is responsible for the following:

### **5.1. Chairing meetings**

- Reviewing amendments, serious adverse event (SAE, adverse event (AE) reports, protocol deviations, protocol violations, responding to general, non-administrative queries from researchers as well as renewals between meetings as required, together with a subcommittee where appropriate.
- Assigning tasks to members regarding HREC-related matters between meetings
- Performing expedited reviews of minimal risk research with 1 other member of the REC.
- Participating in non-compliance investigations.
- Participating in active monitoring.
- Assisting the administrative officer in ensuring that suitable and proportionate review teams are set up.
- Representing the SANBS HREC at the Department of Health National Health Research Ethics Council (NHREC) meetings
- Signing approval letters and minutes and authorizing proxy signature where required.
- Reviewing and updating SOP's annually.
- Reviewing of anonymous tip -offs from researchers or participants.

### **5.2. Responsibilities of the Deputy Chairperson**

- Chairing of meetings in absentia of the Chairperson.
- Performing functions delegated by the Chairperson, including expedited review.
- Participating in non-compliance investigations.
- Representing the SANBS HREC at NHREC meetings in the absence of the Chair.

### **5.3. Responsibilities of the Secretariat**

- Communicating the meeting schedule for the year ahead, including posting it on the SANBS website.
- Receiving applications.
- Checking that applications are complete and signed.
- Compiling the agenda packs for approval by the Chairperson.
- Distributing application packs to HREC members, including applications and supporting documents, at least two weeks before each meeting.
- Attending the HREC meetings and compiling detailed minutes of the discussions and evaluation of applications.
- Providing written feedback to applicants within two weeks of each HREC meeting.
- Being in frequent contact with the Chairperson regarding the assignment of protocols to members for reviewing, following up on revisions to applications, applications for expedited review, applications that qualify for exemption from ethics review, and related matters.
- Providing feedback to applicants on the approval process.
- Administering requests for renewals and amendments by referring them to the chairperson.
- Informing the HREC Chair of protocol deviations and violations within 24 hours of these being submitted.
- Assisting the Chairperson with the annual NHREC report.
- Assisting the Chairperson with compiling the HREC component of the Annual SANBS Report.
- Keeping records: Ensuring that all HREC documentation is dated, filed and archived. All records (electronic and hard copies) are stored securely to safeguard the information and ensure confidentiality.
- Assisting applicants and REC members on the online system when required.

**6. Conflicts of interest**

- 6.1. All HREC members are required to declare any real or perceived conflict of interest at the commencement of each meeting or this may be in writing to the Chairperson prior to the meeting.
- 6.2. The HREC will consider the declaration of conflict and make a determination as to whether they should recuse themselves from the HREC meeting while the issue is being discussed or the application is being discussed/reviewed by the Committee.
- 6.3. Where the Chair of the HREC discloses a real or perceived conflict of interest, the HREC will make a determination as to whether the Chair should recuse her/himself from that aspect of the meeting. The Deputy Chair will lead the discussion on the matter where the HREC deems it necessary for the Chair to be recused.

**5. Revision Summary**

VERSION NUMBER	REVISION DETAILS
0	New document.