INFORMED CONSENT AND PARTICIPANT INFORMATION MANAGEMENT

Registration No. 2000/026390/08

1. Introduction

1.1. This document guides the HREC members to review and evaluate the informed consent documents submitted with the application for conducting research on human subjects.

2. Definitions

2.1. **Informed consent**: Is a legal and ethical process to ensure that the participant knows and understands what participating in the study entails. The elements of informed consent include informing the participant of the nature of the study, the procedures, the potential risks and benefits of participating in the study, and that they can withdraw at any time after enrolling. For informed consent to be considered valid, the participant must be competent and the consent must be given voluntarily.

2.2. **Vulnerable population**: This is defined as a disadvantaged community or subgroup who cannot make informed choices, protect themselves from inherent or intended risks, or safeguard their interests.

2.3. **Assent**: This is an agreement given by a child (7-18 years) who is not legally empowered to consent. The agreement is given after all information regarding the research project has been made known in age-appropriate language.

3. References

3.1. Constitution of The Republic of South Africa No. 108 of 1996.
3.2. The National Health Act of Act 61 of 2003 and its regulations;
3.3. Protection of Personal Information Act 4 of 2013 and its regulations;
3.4. Material Transfer of Human Biological Materials (National Health Act, 2003 - Act No. 61 of 2003);
3.5. Ethics in health research: principles, processes and structures, second edition, 2015.
3.6. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3ed 2020)
3.7. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268;
3.8. 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;
3.9. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2013);
3.10. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS.
3.11. International Conference on Harmonisation Good Clinical Practice Guideline, (10 November 2016);
3.12. 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).

4. General Principles

4.1. Members of the SANBS HREC are required to check the participant information leaflet and informed consent documents for the presence of the following elements:
4.2. A statement that the study involves research.
4.3. An explanation of the purposes of the research.
4.4. The expected duration of the subject's participation.
4.5. A description of the study's procedures to be followed.
4.6. Identification of any experimental procedures.
4.7. Describe any reasonably foreseeable risks or discomforts to the participant.
4.8. A description of any benefits to the participant or society that might reasonably be expected from the research.
4.9. A disclosure of appropriate alternative methods that might be available to participants if they decline to participate in the study.

4.10. A statement describing the extent to which the data will be kept confidential.
4.11. For research involving more than minimal risk, an explanation as to whether any treatments and / or insurance are available if injury occurs.
4.12. An explanation of whom to contact for questions about the research.
4.13. An explanation of whom to contact for questions about research participants' rights.
4.14. A statement that participation is voluntary.
4.15. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
4.16. A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
4.17. Passive assent, including group assent (with consent given by a gatekeeper), should be avoided wherever possible, and every effort should be made to develop methods of seeking consent that is appropriate to the groups studied, through community consultation and engagement, expert advice, support and training where necessary.
4.18. In cases where research involves potential vulnerable groups, for example children, older persons or adults with learning disabilities or indigent people, a process should be followed to secure freely given first-person informed consent from the participants.
4.19. Vulnerability should be considered on a case-by-case basis; many groups or individuals not traditionally considered vulnerable could be exposed to issues as a result of participating in research that makes them vulnerable.

Revision Summary

VERSION NUMBER	REVISION DETAILS
0	New document.