EXPEDITED REVIEWS AND RAPID REVIEWS

1. Purpose and Scope

This procedure describes the process to be followed by the SANBS HREC for expedited approval of Research on Human Participants' applications to ensure that the approvals provided by the SANBS HREC comply with the below-mentioned references.

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. International Conference on Harmonization Good Clinical Practice Guideline, (10 November 2016);
2.11 Research Ethics Policy, South African Medical Research Council, 2018 and
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

3. Definitions

3.1 **Expedited review**: Review of studies that pose no more than minimal risk of harm or post-approval passive monitoring documents by the Chairman and another designated member of HREC or a subcommittee of the REC without an entire sitting of the Committee.
3.2 **Rapid review:** A fast-track review process during a public health emergency or major incident to allow for research to be conducted in a judicious and well-timed manner. Rapid review does not mean lowering ethical safeguards; the review process must be rigorous and robust.
3.3 **Major Incident:** any sudden event with constrained local resources, making urgent response difficult. Unusual and sudden demands on local resources could have ethical implications for patient care. Research in these contexts could be critical for advancing emergency healthcare interventions and treatments (s3.4.1 of NHREC Guidelines). The ethics clearance process must occur rapidly with related research proposals being rapidly processed without compromising rigor. For example, minimal risk studies could undergo rapid expedited review, while more than minimal risk studies could undergo rapid full committee review.

4. Responsibility

4.1 the HREC is responsible for ensuring that the document is updated accordingly.

5. Procedure Expedited Review

5.1 Eligibility for Expedited Review:
Types of research that may undergo advancement include:

- Research classified as no higher than minimal risk, depending on the details of the study. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not higher in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
- Full Review of Annual renewals of studies where there are no substantive ethical problems, will be at the Chair's discretion.
- Minor amendments to previously approved research where changes to the study protocol or consent documents do not result in significantly increased risk to participants. NB – major amendments carry the risk of significant harms to participants and must be reviewed at a full sitting of the HREC.
- When, in the Chair's opinion, using an expedited procedure would be in the public interest.
- Additional categories of minimal risk research as defined by a convened Committee meeting.

5.2 In general, research with the potential to cause physical or psychological harm should not be considered for expedited review. This includes:
- Drug trials, research involving invasive procedures and research involving sensitive personal or cultural issues.
- Studies done on minors or vulnerable populations.

5.3 Review Procedure Expedited Review:
The Chairperson reviews the submitted application and gives written input to the secretariat electronically.
- The Chairperson may appoint a subcommittee or call a round-robin teleconference meeting of available HREC members to get additional input if required.
- A response is sent to the applicant as soon as possible: within 3-5 days, if possible.
- The decision of the expedited process is to be ratified at the next full HREC Committee meeting.

6. Review Procedure Rapid Review

The Chairperson determines whether the application qualifies for a rapid expedited or full committee review.
- Minimal risk research will undergo perted reviews in line with procedures outlined in section 5 above.
- More than minimal risk research will require urgently convening a full committee meeting and fast-tracking the administrative processes. The rights and interests of research participants must be safeguarded in line with national and international standards and norms. Added protections will be required due to vulnerability increasing during infectious disease outbreaks and significant incidents.

Revision Summary

VERSION NUMBER	REVISION DETAILS
0	New document.