RESEARCH APPLICATION REVIEW

Registration No. 2000/026391/08

1. Application Review for Researchers

1.1. The HREC application form may be completed on the designated electronic platform.
1.2. All documents will be sent to HREC members at least 2 weeks prior to the meeting.
1.3. Application form:
  1.3.1. Answer all questions.
  1.3.2. Signed by investigator and supervisor/head of research.
1.4. Abridged CV including qualifications and expertise of the researcher.
1.5. Where applicants are from outside South Africa, there must be a South African-based co-investigator.
1.6. Protocol outlining the study aims, design, population and study risk assessment.
1.7. Data collection sheet or questionnaire (if applicable).
1.8. Participant information leaflet for prospective studies.
1.9. Informed consent for prospective studies
  1.9.1. For participants 18yrs or older.
  1.9.2. For parent of guardian.
  1.9.3. Child assent for child 7-17 years of age.
  1.9.4. Separate consent for DNA analysis/storage.
  1.9.5. Separate consent for control subjects.
  1.9.6. Separate consent for genetic studies.
  1.9.7. Motivation for waiver of consent from parents for minors.
  1.9.8. Separate consent for sample storage.
1.10. Human research ethics approval from applicant's institution, where applicable.
  1.10.1. E-mail evidence that the application has been submitted and/or is under review will be acceptable.
  1.10.2. Acknowledgement letter of the application should accompany the online application.
  1.10.3. Scientific review approval from the SANBS Scientific Review Committee.
1.11. Preapproval letter from SANBS operations indicating the requested study material/data can be supplied.
1.12. Declaration by the investigator.

2. Application review by secretariat

2.1. The application for review to the SANBS HREC will commence with the review by the Scientific Review committee at SANBS in accordance with the Scientific Review Committee Terms of Reference. This is outlined in the flow diagram below. In exceptional cases, the administrator may assume the role of the applicant and upload their application on an electronic platform.
2.2. **Meeting agenda**
  2.2.1. The Committee Secretariat prepares the draft meeting agenda together with Chairperson.
  2.2.2. The content of the agenda should include the following standing agenda items.
  2.2.3. Welcome and apologies.
  2.2.4. Attendance registers.
  2.2.5. Agenda adoption/notice.
  2.2.6. Declaration of conflict of interest.
  2.2.7. Minutes of previous meeting.
  2.2.8. Matters arising from previous meeting.
  2.2.9. Current applications for review.
  2.2.10. Progress reports of previously approved protocols.
  2.2.11. General and any other business.
  2.2.12. Date of the next meeting and closure.

3. HREC Meetings

3.1. HREC meetings are held every three months or as the need arises.
3.2. Meetings will be held in-person at the SANBS headquarters, or an alternative designated venue by the Chairman, or virtually using an appropriate virtual platform.

3.3. Proposed dates for the following years' meetings are discussed and agreed upon at the last meeting of the preceding year.
3.4. HREC members agree on dates of meetings for the following year as proposed by Chairperson.
3.5. The SANBS HREC Secretariat notifies all relevant persons of the proposed dates for the following year.

4. Meeting proceeding:

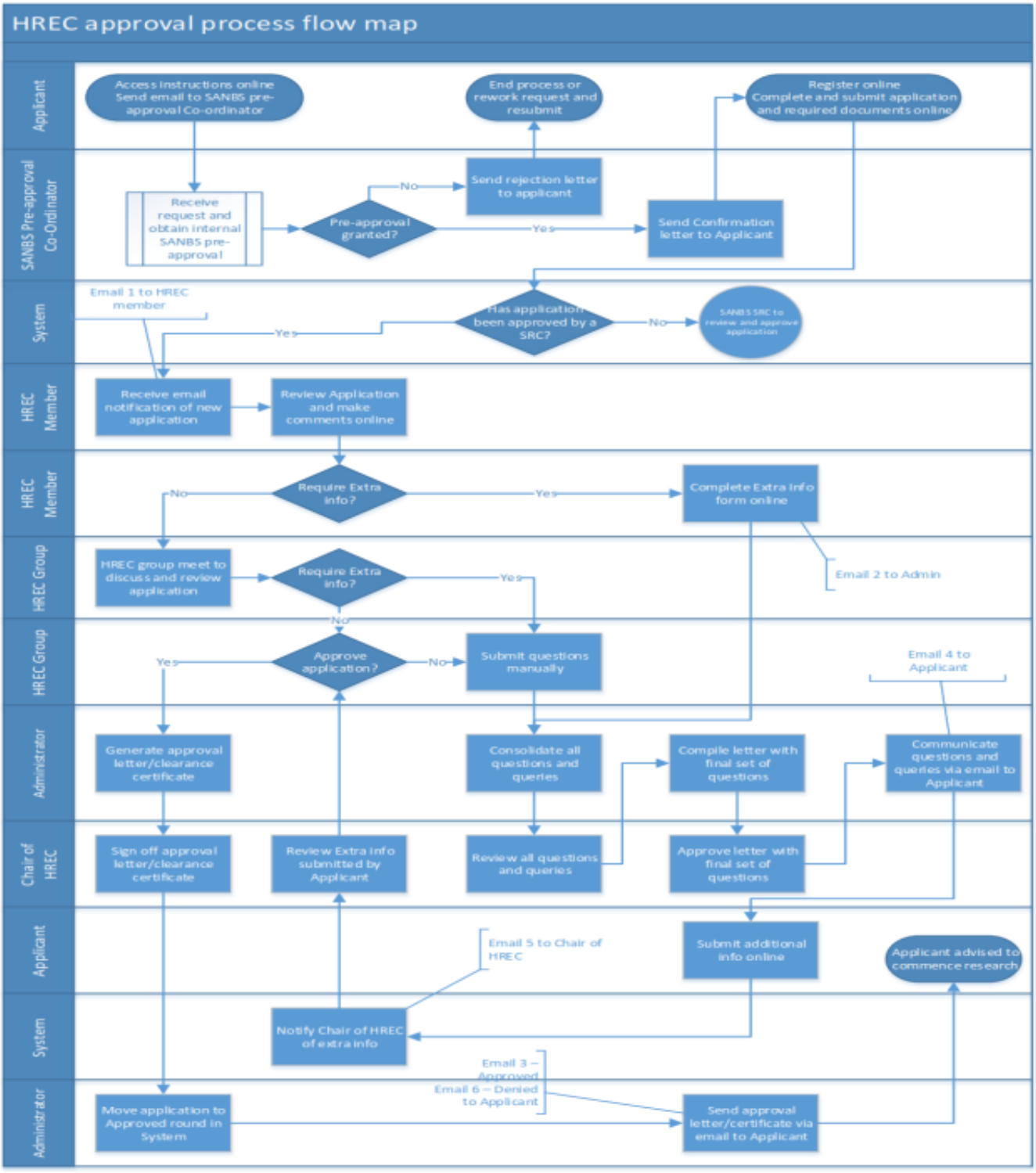
4.1. Completed applications are viewed & assessed by the HREC member.
4.2. All HREC members review the protocol and other documents prior to the meeting. Where required, the secretariat may assume the role of the HREC member, and upload reviews done on hard or soft copy, onto an electronic system.
4.3. The Consent/Patient Information Leaflet is to be checked for compliance with reference to section 2 of this document.
4.4. The application should be reviewed from an ethical perspective, which includes the regulatory, scientific, clinical and participant safety perspective.
4.5. All members discuss concerns, recommendations and queries relating to the presented protocol. If queries are unresolved at the meeting, the Secretariat will address these with the investigator and/or sponsor after the meeting.
4.6. The chairperson calls for the Committee decision of approval or non-approval of the protocol. Decisions of the Committee are made by consensus if all issues relating to the protocol are resolved during the meeting. If a decision is not reached by consensus, Committee members may be asked to vote and the majority decision is binding on members.
4.7. Only an appropriate quorate Committee may approve research applications. The decision of approval must be based on the criteria for approval of research, with reference to section 2 of this document.
4.8. The amount of risk to patients is considered and discussed by the committee with regard to benefit to the patient, potential risk due to the study drug, study procedures, concomitant therapy, concurrent diseases and the potential effect of the study thereon, and implications in terms of vulnerable populations, including social risks.
4.9. Secretariat prepares draft minutes of meeting within 7 days of the meeting date, which should contain the following information:
    4.9.1. Actual attendance at meeting.
    4.9.2. Results of voting or consensus by members.
    4.9.3. Actions taken by the HREC.
    4.9.4. Written summary of discussion of controversial issues.
    4.9.5. Resolution of these issues.
4.10. Secretariat or subcommittee address unresolved queries with the investigators and/or sponsors and gives feedback to HREC chairperson.
4.11. Secretariat prepares draft clearance certificates and forward to Chairperson within 3-5 days of all issues or queries being resolved on the application.
4.12. Secretariat ensures that all documentation is archived appropriate.

5. References

5.1. Constitution of The Republic of South Africa No. 108 of 1996;
5.2. The National Health Act of Act 61 of 2003 and its regulations;
5.3. Protection of Personal Information Act 4 of 2013 and its regulations;
5.4. Material Transfer of Human Biological Materials (National Health Act, 2003 - Act No. 61 of 2003);
5.5. Ethics in health research: principles, processes and structures, second edition, 2015;
5.6. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3ed 2020);
5.7. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268;
5.8. 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;
5.9. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2013);
5.10. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS;

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

5.12. 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).



Revision Summary

VERSION NUMBER	REVISION DETAILS
0	New document.