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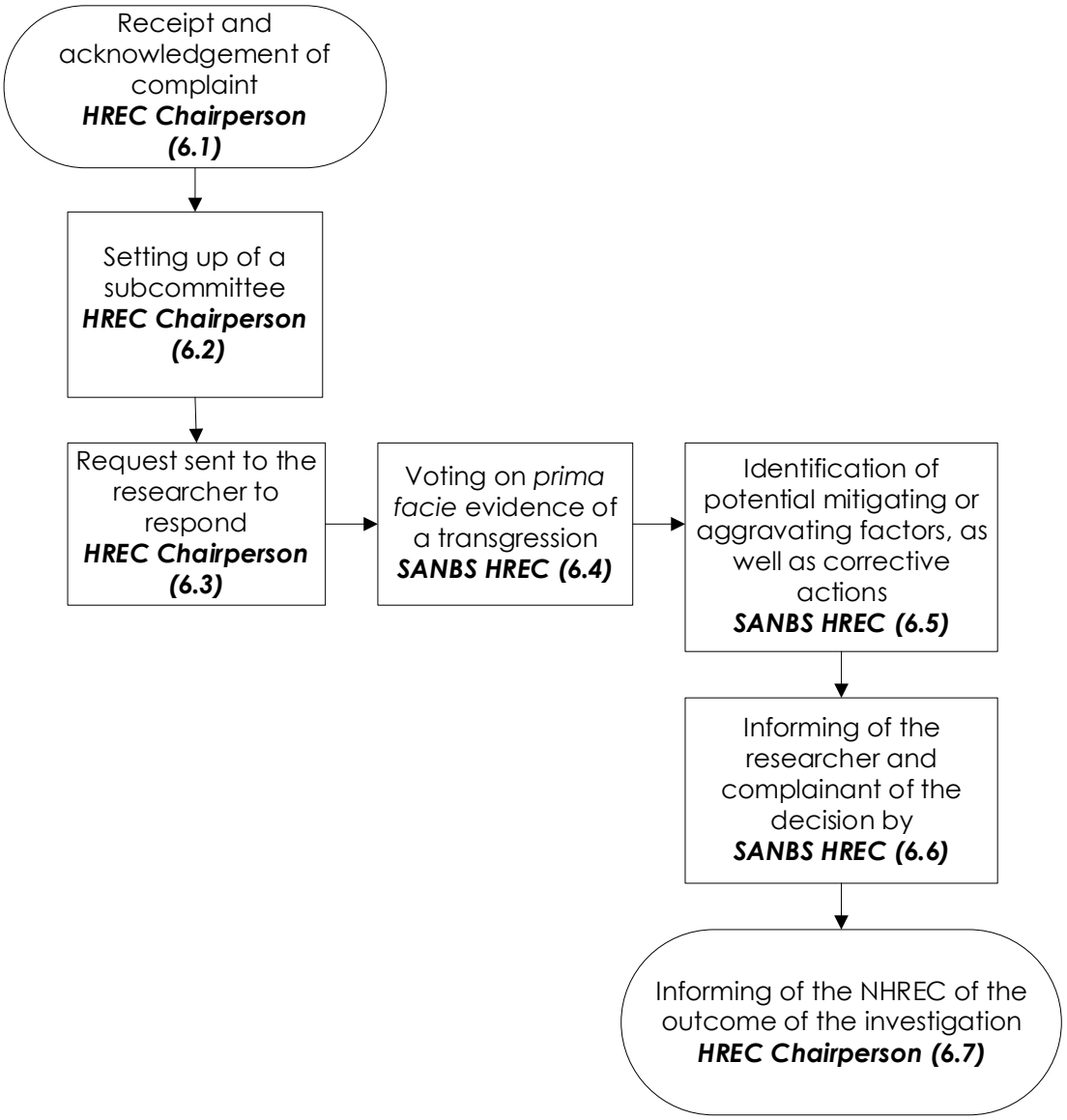
SANBS
Registration No. 2000/026390/08

HREC Complaints Policy

Contents

1. Process flow



1. Introduction and Purpose

1.1. SANBS conducts health research by means of the systematic collection, synthesis and analysis of information involving human participants.

1.2. SANBS HREC ensures that the minimum national benchmark of norms and standards for conducting responsible and ethical research in SANBS and South Africa are complied with.

1.3. The purpose of the SOP is to outline the process for reporting research ethics violations, the procedures to follow once a complaint has been made, and to protect the confidentiality of the complainant or "whistle-blower" regarding the research or researcher, and to maintain the integrity of the research.

1.4. Usually, recruitment of participants focuses on the individual who chooses autonomously whether to participate. The balance of risk of harm and likelihood of benefit should favour Research Participants.

1.5. The HREC Complaints SOP provides overall direction for the SANBS HREC to receive and handle Queries and Complaints concerning the rights and welfare of Research Participants. SANBS HREC-related business and operations, in compliance with the minimum standards and statutory governance framework set out in the internal and external references mentioned below.

1.6. The informed consent may state that Research Participants may contact the researcher at the contact details provided if they have queries about the Research Project.

1.7. The SANBS HREC will document, address, and report to NHREC on its handling of Queries and Complaints.

2. Scope

2.1 This procedure applies to all SANBS HREC members, employees (including interns and learners), researchers, research participants, and any other individuals, whether affiliated with SANBS or not, who wish to raise concerns or complaints related to the ethical conduct of research approved by the SANBS HREC. It covers all research ethics-related complaints but does not apply to personal grievances, which should be addressed through internal HR policies.

2.2 This SOP should be interpreted within the Terms of Reference and SOPs of the SANBS HREC.

3. External and Internal References

3.1 External References

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

3.1.2 The National Health Act of 61 of 2003 and its regulations;

3.1.3 Protection of Personal Information Act 4 of 2013 and its regulations;

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

3.1.5 Health Professions Council of South Africa: General Ethical Guidelines For Health Researchers Booklet 13, 2016

3.1.6 South African Ethics in Health Research Guidelines: Principles, Processes and Structures 2024 Third Edition, NDOH 2024 ISBN 978-0-621-52027-9 https://www.health.gov.za/nhrec-guidelines/ ("NHREC" Guidelines)

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

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

3.1.9 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;

3.1.10 Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2024);

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

3.1.12 Operational Guidelines for Ethics Committees That Review Biomedical Research, WHO Geneva 2000

3.1.13 World Health Organisation Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)

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

3.1.15 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

3.2 Internal Referenced Documents

Document Number	SAP DIR Number	Document Title
CP-COS-002	1084274	Whistleblowing Procedure
GPI-CEO-003	1087385	Whistleblowing Response Plan
SP-CEO-013	1044384	Whistleblowing SOP
INF-HREC-007	1089124	SOP on Informed Consent

4. Abbreviations

4.1. HREC – Human Research Ethics Committee
4.2. NHREC – National Human Research Ethics Council
4.3. PI – Principal Investigator in SANBS HREC-approved research
4.4. SANBS – South African National Blood Service
4.5. SOP – Standard Operating Procedure
4.6. NDOH-National Department of Health

5. Definitions

5.1. **Appeal**: escalation of a Complaint by a Complainant from SANBS HREC to SANBS internal institutional processes for further consideration, before a Complaint may be escalated by a Complainant to NHREC;

5.2. **Complainant or "whistle-blower":** Any person or organisation that formally submits a Query or makes a Complaint concerning research or researcher or the rights and welfare of a Research Participant/s or SANBS HREC-related business or operations that fall within the mandate of the SANBS HREC. A complainant may be, but is not restricted to, SANBS staff, or its affiliated institutions, professional societies, affected organisations, and members of the public;

5.3. **Complaint**: A report by a Complainant that some aspect concerning the rights and welfare of a Research Participant/s, or SANBS HREC-related business or operations, is unsatisfactory, unacceptable or of concern;

5.4. **Query**: A question formally raised expressing doubts about, or to check the validity or accuracy of, the rights and welfare of a Research Participant/s, and/or SANBS HREC-related business or operations.

5.5. **Research** Any research that the SANBS HREC considered, approved, rejected, or that is within the responsibility of the SANBS HREC as captured in its Terms of Reference.

5.6. **Researcher:** Any person who does research that is within the responsibility of the SANBS HREC as captured in its Terms of Reference.

5.7. **Research or researcher misconduct:** That research activity or conduct that the Research Ethics Committee considers to be misconduct, includes but is not restricted to the following:

5.7.1. Failure to obtain ethics approval before commencing with research
5.7.2. Failure to obtain ethics approval for amendments to research
5.7.3. Conducting research without a valid ethics approval certificate
5.7.4. Conducting research outside the terms and stipulations of the documents considered by the ethics committees in their approval of the study
5.7.5. Failure to suspend research activities when so instructed by the ethics committee
5.7.5 Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research
5.7.6. Substantive deviation from or failure to adhere to the approved study protocol without prior formal approval from the ethics committee
5.7.7. Any misrepresentation of data/or interests, and/or involvement
5.7.8. Any falsification of credentials
5.7.9. Any deception in documentation or in publication
5.7.10. A false claim that ethics approval would have been granted
5.7.11. Piracy of materials
5.7.12. Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research personnel
5.7.13. Failure to obtain voluntary and informed consent in writing unless this requirement has been waived by the ethics committee.
5.7.14. A breach of confidentiality
5.7.15. Negligent management of data security.
5.7.16. Conducting research in a way that is malicious or harmful to research participants
5.7.17. Conducting research that is negligent as a researcher and/or professional
5.7.18. Conducting research that violates the standard codes and regulations of the researcher's profession.
5.7.19. Any research activity that violates the South African Constitution or is in violation of a South African law.

5.8. **Research Participant/s:** Person/s recruited or selected for, excluded from, or included in, research

6. Reporting Procedure

6.1 Receipt and acknowledgement of complaints within 2 business days, for complaints made in writing to the chairperson of the SANBS HREC.

6.2 Setting up of a subcommittee by the chairperson, which may request further information from the complainant, researcher, or others. The sub-committee, chaired by the Chairperson, may consult confidentially with experts in the field. The subcommittee will report its findings to the SANBS HREC.

6.3 Request sent to the researcher within a reasonable time period after receipt of the complaint, to respond to the complaint in writing within 5 business days. The SANBS HREC will take all reasonable steps to prevent the disclosure of the complainant's identity unless there is a compelling reason for its disclosure.

6.4 Voting on *prima facie* evidence of a transgression by the HREC, on whether there is a case to answer, once sufficient information has been obtained. The SANBS HREC will formulate an opinion on the nature of the alleged ethical misconduct.

6.5 Identification of potential mitigating or aggravating factors, as well as corrective actions by the SANBS HREC, and suggestions regarding disciplinary action, if any, if a simple majority vote supports *prima facie* evidence of a transgression. The SANBS HREC will not participate in disciplinary processes other than providing the available documentation in

the matter or expressing an opinion or explanation on whether a specific action is unethical. All members of the SANBS HREC must keep information regarding the complaint and its processing confidential.

6.6 Informing the NHREC of the outcome of the investigation by the HREC Chairperson.

7. Approaches to Implementation: Training and Complaints Reporting

7.1 For existing SANBS HREC members, training will be through reading, understanding and discussion of this Queries and Complaints SOP/procedure/response plan SOP where relevant.

7.2 After induction and research ethics training, new SANBS HREC members are expected to understand:

7.2.1 Available structures within the SANBS administration for research Queries and Complaints

7.2.2 The relationship with the NHREC and relevant statutes.

7.3 The SANBS HREC must report annually to NHREC on Complaints received and action taken. Information collected by NHREC from the SANBS HREC annual reports is used to maintain a record of the SANBS HREC activities, queries, and complaints.

7.4 The SANBS HREC should ensure that the SOP on informed consent and Participant Information contains a provision referring the Research Participant or Complainant to the contact details of the SANBS HREC for queries and complaints.

8. Revision Summary

VERSION NUMBER	REVISION DETAILS
0	• 03 September 2025