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Registration No. 2000/026390/08

## HREC Complaints Procedure

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### FRM-QMD-013

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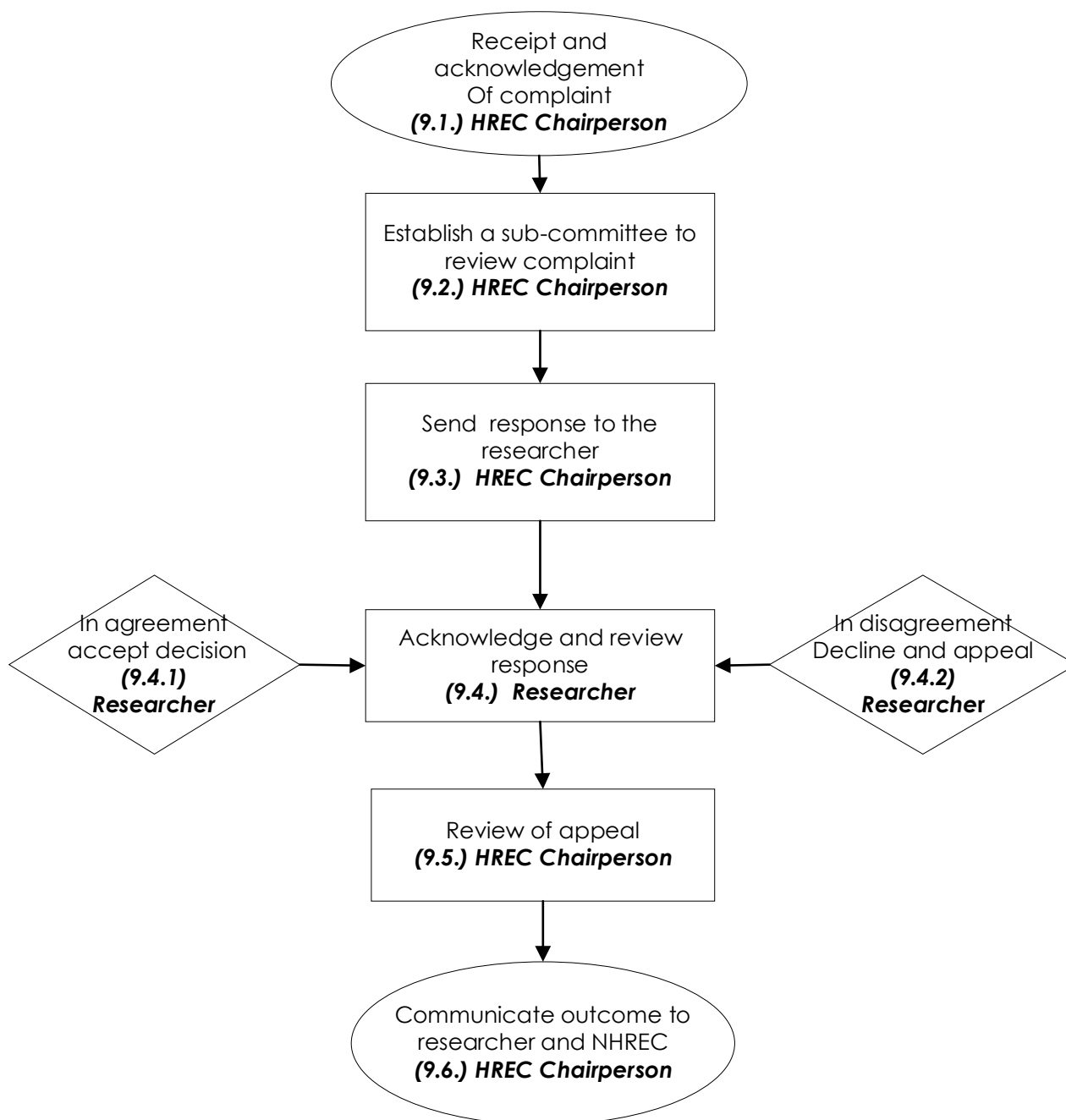
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| <b>HREC Complaints Procedure</b> |              |                 |             |                |   |

# 1. Process flow

(Include responsible position and step number in the process flow if not a swim lane flowchart)



|                                  |              |                 |             |                |   |
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## 2. Purpose

- 2.1. The purpose 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 regarding the research or researcher, and to maintain the integrity of the research.

## 3. Scope

- 3.1. This procedure applies to all SANBS HREC (Human Research Ethics Committee) 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 SANBS HREC.

## 4. Definitions

- 4.1. **Appeal:** escalation of a Complaint by a Complainant from SANBS HREC to HREC Chairperson, the chairperson can escalate the complaint to NHREC (National Human Research Ethics Committee).
- 4.2. **Complainant:** 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 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.
- 4.3. **Complaint:** A report by a Complainant that some aspects concerning the rights and welfare of a Research Participant/s, or SANBS HREC-related business or operations, is unsatisfactory, unacceptable or of concern.
- 4.4. **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.
- 4.5. **Research:** Any research that SANBS HREC considered, approved, rejected, or that is within the responsibility of SANBS HREC as captured in its Terms of Reference.
- 4.6. **Researcher:** Any person who does research that is within the responsibility of SANBS HREC as captured in its Terms of Reference.

## 5. Safety, Health, Environment and Risk

| Hazards / Risks Identified                                                                                                                                                                                                          | Risk Mitigation Controls                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Researcher does not follow the prescribed procedure for reporting and managing research-related queries and complaints.</li> <li>Reputational damage to SANBS and the SANBS HREC.</li> </ul> | <ul style="list-style-type: none"> <li>Engineering Controls: N/A.</li> <li>Operational Controls: N/A.</li> <li>Administrative Controls: <ul style="list-style-type: none"> <li>To ensure that researchers understand and comply with the prescribed complaints procedure, with appropriate corrective action where non-compliance is identified.</li> </ul> </li> <li>Personal Protective Equipment and Clothing: N/A.</li> <li>Infection Prevention Control: N/A.</li> <li>Risk: <ul style="list-style-type: none"> <li>Clearly defined complaints procedures, roles and responsibilities, confidentiality requirements, and escalation pathways.</li> </ul> </li> </ul> |

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## 6. Training and Competency

- 6.1. Training and competency requirements apply to personnel involved in implementing this SOP, as applicable to their roles.
- SANBS HREC members and Secretariat staff will receive appropriate training on the processes and requirements outlined in this SOP.
  - Competency assessment will be conducted where applicable, with a minimum pass mark of 80%.
  - External applicants must provide proof (certificate) of valid research ethics training and familiarise themselves with this SOP and the referenced documents prior to submission.
  - If the competency is not achieved, it must be repeated until employee is found competent.
  - FRM-HCM-019 and certificate obtained must be filled employee personal file or electronically.
  - Training and competency must be completed every two years and/or at major revision.

## 7. Responsibilities

- 7.1. **HREC Chairperson**  
Oversee the management and resolution of queries and complaints. Ensures appropriate review, action and escalation of complaints were required.
- 7.2. **NHREC**  
Provides oversight and guidance on research ethics complaints and queries in accordance with applicable national requirements.  
Receive reports from SANBS HREC on the management of complaints, where required.
- 7.3. **HREC Sub-Committee**  
Review complaints referred to the HREC and provide independent ethical advice.
- 7.4. **Researcher**  
Comply with the complaint's procedure and HREC requirements. Provides information and responds to complaints relating to their research, and Implements required corrective actions arising from complaints.

## 8. Additional Information

- 8.1. SANBS HREC will document, address, and report to NHREC on its handling of Queries and Complaints.
- 8.2. It covers all research ethics-related complaints but does not apply to personal grievances, which should be addressed through internal HR policies.
- 8.3. This SOP should be interpreted within the Terms of Reference and SOPs of the SANBS HREC
- 8.4. 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:
- 8.4.1. Failure to obtain ethics approval before commencing with research.
  - 8.4.2. Failure to obtain ethics approval for amendments to research.
  - 8.4.3. Conducting research without a valid ethics approval certificate.
  - 8.4.4. Conducting research outside the terms and stipulations of the documents considered by the ethics committees in their approval of the study.
  - 8.4.5. Failure to suspend research activities when so instructed by ethics committee.
  - 8.4.6. Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research.
  - 8.4.7. Substantive deviation from failure to adhere to the approved study protocol without prior formal approval from the ethics committee.
  - 8.4.8. Any misrepresentation of data/or interests, and/or involvement.
  - 8.4.9. Any falsification of credentials.
  - 8.4.10. Any deception in documentation or in publication.

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- 8.4.11. A false claim that ethics approval would have been granted.
- 8.4.12. Piracy of materials.
- 8.4.13. Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research personnel.
- 8.4.14. Failure to obtain voluntary and informed consent in writing unless this requirement has been waived by the ethics committee.
- 8.4.15. A breach of confidentiality.
- 8.4.16. Negligent management of data security.
- 8.4.17. Conducting research in a way that is malicious or harmful to research participants.
- 8.4.18. Conducting research that is negligent as a researcher and/or professional.
- 8.4.19. Conducting research that violates the standard codes and regulations of the researcher's profession.
- 8.4.20. Any research activity that violates the South African Constitution or is in violation of a South African law.
- 8.5. Research Participant/s: Person/s recruited or selected for, excluded from, or included in, research

## 9. Procedure

- 9.1. Receipt and acknowledgement of complaint
  - 9.1.1. The HREC Chairperson receives complaints submitted in writing concerning research ethics violations or concerns regarding the rights, safety, dignity or welfare of Research Participants.
  - 9.1.2. The HREC Chairperson acknowledges receipt of the complaint in writing within 2 business days.
  - 9.1.3. The complaint and related information must be treated as confidential, with reasonable measures are being taken to protect the identity of the complainant.
- 9.2. Establish a sub-committee to review complaints.
  - 9.2.1 The HREC Chairperson establishes an HREC Subcommittee to review the complaint.
  - 9.2.2 The Subcommittee may request additional information from the complainant, researcher or other relevant people.
  - 9.2.3. Where required, the Subcommittee may seek confidential advice from an appropriately qualified expert.
  - 9.2.4. The Subcommittee documents its findings and recommendations and submits these to SANBS HREC.
- 9.3. Send responses to the researcher.
  - 9.3.1. The researcher is given an opportunity to respond in writing within 5 business days of receiving the request.
  - 9.3.2. The HREC considers the researcher's response and available evidence before reaching a decision.
  - 9.3.3. The HREC considers the researcher's response and available evidence before reaching a decision.
  - 9.3.4. The HREC Chairperson communicates the decision and any required corrective actions to the researcher in writing.
- 9.4. Acknowledge and review response
  - The researcher acknowledges receipt of the HREC decision and reviews the findings and required actions.

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9.4.1. In agreement – accept- where the researcher accepts the decision, the required corrective actions must be implemented within the timeframe specified by the HREC.

9.4.2. In disagreement – decline- the researcher may submit a written appeal to the HREC Chairperson, stating the grounds for the appeal and providing supporting information.

9.5. Review of appeal

The HREC Chairperson reviews the appeal and supports information.

9.5.1. Where necessary, the appeal may be referred to the HREC or an appropriate Subcommittee for further consideration.

9.5.2. The outcome of the appeal is communicated to the researcher in writing.

9.6. Communicate outcomes to researchers and NHREC

The outcome and any required corrective actions are communicated to the researcher.

9.6.1. The HREC Chairperson reports the outcome to NHREC, where required.

9.6.2. All records relating to the complaint, review, decision and appeal are retained by the HREC Secretariat in accordance with SANBS requirements.

## 10. Limitations / Measurement of Uncertainty

10.1

## 11. Record Documents

| Document Number | Document Title | Initial On Site Retention Period | Off Site Retention Period | Total Retention period |
|-----------------|----------------|----------------------------------|---------------------------|------------------------|
| N/A.            | N/A.           | N/A.                             | N/A.                      | N/A.                   |

## 12. Internal Referenced Documents

| Document Number | SAP DIR Number | Document Title |
|-----------------|----------------|----------------|
| N/A.            | N/A.           | N/A.           |

## 13. External References

- 13.1. Constitution of The Republic of South Africa No. 108 of 1996.
- 13.2. The National Health Act of 61 of 2003 and its regulations.
- 13.3. Protection of Personal Information Act 4 of 2013 and its regulations.
- 13.4. Material Transfer of Human Biological Materials (National Health Act, 2003 - Act No. 61 of 2003).
- 13.5. Health Professions Council of South Africa: General Ethical Guidelines for Health Researchers Booklet 13, 2016.
- 13.6. 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)
- 13.7. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268.
- 13.8. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3rd ed. 2020).
- 13.9. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268.
- 13.10. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2024).
- 13.11. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS.

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- 13.12. Operational Guidelines for Ethics Committees That Review Biomedical Research, WHO Geneva 2000
- 13.13. World Health Organisation Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)
- 13.14. International Conference on Harmonisation Good Clinical Practice Guideline, (10 November 2016).
- 13.15. 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>)
- 13.16. 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.

#### 14. Revision Summary

| Version Number | Revision Details                                               |
|----------------|----------------------------------------------------------------|
| 0              | <ul style="list-style-type: none"> <li>New Document</li> </ul> |