HREC Registration Number
REC251015-048

HEALTH RESEARCH ETHICS COMMITTEE

30 September 2025

STANDARD OPERATING PROCEDURES

Life Healthcare

Making life better

Contents

BACKGROUND OF LIFE HEALTHCARE HEALTH RESEARCH ETHICS COMMITTEE

Life Healthcare is committed to leading in the advancement of quality research involving human participants and recognises its role in generating cutting edge health knowledge aligned to the health imperatives. Moreover, Life Healthcare acknowledges that research is multidisciplinary in respect of the research contexts used and the research methodological approaches and practices implemented. The need for excellence in research and scholarship is underpinned by the importance of conducting research with the utmost integrity, as such this policy outlines the standards and practices of responsible research conduct as it relates to various aspects of research scientific integrity and research ethics inherent in research involving humans.

The Life Healthcare Health Research Ethics Committee functions under the ambit of the College as per the Higher Education requisite and is registered with the National Health Research Ethics Council (NHREC) as of 2015. The registration number of the Life Healthcare Health Research Ethics Committee (hereafter referred to HREC) is REC-251015-048. As such the Life Healthcare HREC is duly mandated to fulfil its functions in accordance with the National Health Act No 61 of 2003 as outlined in the National Department of Health (2024) Ethics in Health Research Guidelines: Principles, Processes and Structures, through annual reporting to the National Research Ethics Council (NHREC) and authorised to conducting rigorous ethics reviews, prospectively of all health or health related research proposals to ensure that the welfare and other interests of participants and researchers are correctly protected and that the proposed research complies with ethical norms and standards outlined in the national ethics guidelines.

PURPOSE OF THE STANDARD OPERATING PROCEDURE

The purpose of this Standard Operating Procedure (SOP) is to provide a transparent framework outlining the operations of the Life Healthcare Health Research Ethics Committee (hereafter referred to as Life Healthcare HREC) that functions under the auspices of the Nursing College of the Life Healthcare Group (Pty) Ltd Private Higher Education Institution (hereafter referred to as the Life Healthcare Nursing College). This SOP is aligned to the Life Healthcare Research Ethics Policy (LCL-POL-REC-002) and underpinned by the following legal statutes and standards:

- Constitution of the Republic of South Africa, 1996
- South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd Edition (2024). National Department of Health.
- South African Health Professions Act No. 56 of 1974
- South African National Health Act No 61 of 2003
- South African Protection of Personal Information Act (Act No. 4 of 2013)

This document will present the existing SOPs that guide the function of the HREC. Through these SOPs, it is intended that the standardised processes inherent in the roles and functions of the Life Healthcare HREC will facilitate efficiency, uniformity, and accountability within the HREC. Moreover, this structured approach aims to enhance the quality and fairness of ethical assessments, thereby contributing to ethical research conduct and regulatory compliance.

SOP 1: MANAGEMENT OF STANDARD OPERATING PROCEDURES OF THE HREC

Title	Management of standard operating procedures of the Life Healthcare HREC
SOP Number	SOP 1- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled	L. Roets	14/05/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	31/01/2022	
Reviewed	E.J Ricks	17/01/2023	
Authorised	S. Vasuthevan	28/02/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
14 May 2018	001	Development of the document
14 December 2021	002	Reviewed document
17 January 2023	003	Reviewed document
30 September 2025	004	Revised document

1.1 Purpose of the SOP

This SOP establishes the framework for the creation and management of all HREC SOPs related to the functioning and ethical review of the Life Healthcare Health Research Ethics Committee. The purpose is to ensure that all procedures and processes are documented, therein ensuring standardised and reproducible practices.

1.2 Scope

This document outlines the scope for establishing all new HREC SOPs. It defines the responsibilities and procedures to be followed and specifies the essential elements required in each SOP.

1.3 Responsibilities

All members of the Life Healthcare HREC, the administrator, and relevant Life Healthcare staff are responsible for familiarising themselves with this procedure to ensure a standardised approach to the research ethics SOPs.

1.4 Procedure

A formal, structured procedure is required for the development and management of HREC SOPs to ensure they are consistently reviewed, updated, and aligned with the latest national guidelines and institutional policies.

- **Initiation**: The need for a new or revised HREC SOP may arise from a specific request or from a change in the ethical landscape, such as the publication of revised national or institutional guidelines. In either case, the request or need must be formally submitted to the HREC Chairperson. The Chairperson will review and either authorise or decline the development of the SOP, communicating the decision to the relevant parties via email.
- **Drafting and Formatting:** Upon receiving authorisation, the designated requestor will draft the SOP in accordance with this document and using the provided template. The official Life Healthcare font, Arial, with a font size of 11 and 1.5 line spacing, must be used.
- **Document Identification:** SOPs must be systematically numbered using the following prefix: SOP-Life Healthcare-HREC-version 00x.
- **Review and Approval:** Once the first draft is completed, it must be sent electronically to the HREC Chairperson for review. The SOP will be distributed to all HREC members and other relevant stakeholders for their formal comments and input. Any proposed changes will be tabled for discussion and approval at a formal HREC meeting, ensuring a transparent review process.
- **Finalisation and Dissemination**: After the SOP is finalised, it must be approved and signed by all relevant parties. The approved SOPs will be placed on the Life Healthcare Webpage and the Gateway for easy access, and a notice will be sent to all HREC members and Life Healthcare staff to announce the SOP's effective implementation date.
- **Document Control and Adherence**: The administrator is responsible for maintaining a central and updated database of all SOPs. It is mandatory that all SOPs are consistently adhered to by all relevant parties.
- **Withdrawal**: If an SOP is made redundant or superseded by a revision, it must be officially withdrawn from all platforms, and its withdrawal must be widely communicated to all stakeholders.

1.5. Essential elements

As per the NDOH (2024 v 3) Research Ethics guidelines, all HREC SOPs must contain the following essential elements to ensure proper document control and clarity:

- SOP Identification (Title, SOP Number, Version Number, Approval Date, Revision Date, and Number of Pages)
- Compilation and Authorisation
- Distribution
- Document History
- Purpose of the SOP
- Scope
- Key Concepts, Definitions, Abbreviations
- Responsibilities
- Procedures to be followed
- Reference Documents
- Appendix (e.g., checklists, guides, and forms)
- Any other elements deemed essential to the specific SOP

1.6 Review cycle

SOPs are considered living documents and must be formally reviewed at least every three years. This process ensures they remain current, relevant, and compliant with all legislative and institutional requirements.

1.7. References

- Life Healthcare Group (Pty) Ltd. (2025) *LCL-POL-REC-002: Research Ethics Policy*. Rev 006.
- National Health Research Ethics Council. (2024). *South African Ethics in Health Research Guidelines: Principles, Processes and Structures*. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- North-West University. (2016). *Policy and Rules for Research Ethics*. Available at: https://services.nwu.ac.za/sites/services.nwu.ac.za/files/files/research-

support/documents/9P-9.1.5_Policy%20of%20research%20ethics_eng1.pdf. (Accessed: 13 September 2025).

- Stellenbosch University. (2023). *Health Research Ethics Committee (HREC) Terms of Reference and Standard Operating Procedures*. Version 6. Available at: https://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/HREC%20Terms%20of%20Reference%20and%20Standard%20Operating%20Procedures_Final2023.pdf. (Accessed: 07 July 2025).
- University of KwaZulu-Natal. (2023). *Biomedical Research Ethics Committee (BREC) Standard Operating Procedures*. Available at: https://research.ukzn.ac.za/wp-content/uploads/2025/01/UKZN-BREC-Standard-Operating-Procedures-2023.pdf. (Accessed: 07 July 2025).

SOP 2: HREC MEMBERSHIP: SELECTION, APPOINTMENT AND RESPONSIBILITIES

Title	HREC Membership: Selection, Appointment and Responsibilities
SOP Number	SOP 2- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	20/04/2018	
Revised	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	31/01/2022	
Revised	E.J Ricks	17/01/2023	
Authorised	S. Vasuthevan	28/02/2023	
Revised	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
24 April 2018	001	Development of the document
14 December 2021	002	Revision
17 January 2023	003	Revision
28 November 2023	004	Revision
30 September 2025	005	Revision

2.1 Purpose of the SOP

The Life Healthcare HREC is registered with the National Health Research Ethics Council (NHREC) and operates in accordance with the National Health Act 61 of 2003, its regulations, and the latest NDOH 2024 South African Ethics in Health Research Guidelines. The purpose of this SOP is to provide a comprehensive framework for the selection, appointment, and management of Life Healthcare HREC members, ensuring that the committee's composition, roles, and functions uphold the highest standards of research ethics.

2.2 Scope

This SOP covers the entire lifecycle of HREC membership, from the selection and appointment process to the responsibilities and conduct of members. It applies to all current and prospective HREC members, including the Chairperson, Vice-Chairperson and committee members.

2.3 Responsibilities of the HREC

The HREC members collectively hold the responsibility for ensuring that all research proposals are ethically and scientifically sound. Their primary aim is to protect the welfare, rights, dignity, and safety of human research participants, while also upholding research integrity and promoting high ethical standards. The HREC and all researchers must comply with institutional, national, and international requirements for health and health-related research ethics.

The key objectives of the HREC members are to:

- **Conduct Ethical and Scientific Review**: Rigorously review all research proposals and amendments for ethical and scientific integrity in a timely manner.
- **Monitor and Manage Research:** Oversee ongoing research to ensure strict adherence to approved protocols and legal requirements, and to monitor and manage adverse events and incidents.
- **Provide Guidance and Support**: Act as a source of ethical expertise, ensuring that all research is conducted according to the required ethical norms and standards.

2.4. Procedure: Selection, Appointment, and Responsibilities of Members

2.4.1 Selection and Appointment of HREC Members

The selection of all HREC members, including the Chairperson and Vice-Chairperson, must align with the formal membership requirements of the NDOH 2024 guidelines and the operational needs of the Life Healthcare.

2.4.2 Selection and Appointment of the Chairperson

When a vacancy for the Chairperson becomes available, the Executive Management Committee of Life Healthcare, in consultation with the HREC members, will invite nominations. Shortlisted candidates, selected based on their experience and knowledge of research ethics and the scientific process, will be interviewed by the Chairperson of the Executive Management Committee and the current HREC Chairperson. The final decision is made by the Chief Executive Officer and confirmed by the Executive Management Committee and HREC members. The Chairperson may serve a maximum of two consecutive four-year terms. An Acting Chairperson can be appointed for a period of up to six months.

The Chairperson's responsibilities include, but are not limited to:

- Providing courageous and respected leadership in health research ethics at Life Healthcare.
- Liaising with national and international research ethics committees to promote best practices.
- Advising and consulting with researchers and HREC members on ethical issues.
- Playing a leading role in the development and implementation of HREC policies and procedures.
- Representing the HREC at national and institutional meetings and promoting a culture of respect for the ethics review process.
- Overseeing the HREC's administrative duties and delegating tasks to the Vice-Chairpersons as needed.
- Chairing HREC meetings, ensuring a sound ethical discourse, and reaching consensus on decisions.
- Ensuring the welfare and safety of participants is carefully managed.

2.4.3 Vice-Chairpersons: Appointment and Responsibilities

One Vice-Chairperson is nominated and selected by the HREC members for a four-year renewable term. The Vice-Chairperson's term should preferably overlap with the Chairperson's for continuity.

The Vice-Chairperson's responsibilities are to:

- Perform duties delegated by the Chairperson
- Act as Chairperson in the Chairperson's absence
- Provide active in-meeting support to the Chairperson and members
- Advise and consult on research ethics issues
- Participate in non-compliance investigations
- Contribute to the development and implementation of HREC policies and procedures

2.4.4 Term of Membership

All HREC members are appointed for a term of four years, which is renewable once. After serving two consecutive terms, a member must step down and may be considered for re-appointment after one year.

2.4.5 Co-opted Members, Observers, and Visitors

The HREC may co-opt members as needed to provide expert input on specific matters. Observers and visitors are allowed only in exceptional cases and for specific, approved purposes. Researchers may be invited to meetings to provide clarity on their applications. Co-opted members, observers, and visitors do not have voting rights.

2.5 HREC Composition

The composition of the Life Healthcare HREC must meet the minimum standards and requirements stipulated in the NDOH 2024 guidelines and the South African Good Clinical Practice (GCP) guidelines. The committee must comprise at least nine members and should be representative of a diverse range of disciplines, including both clinical and non-clinical disciplines.

The committee must include representation from the following categories as per the NDOH 2024 guidelines:

- At least one person who is not affiliated with the institution and is not a health professional
- At least one person with knowledge of and current experience in the professional care, counselling or health-related treatment of people
- A mix of genders
- At least one member with professional training and experience in quantitative research methodologies
- At least one member with professional training and experience in qualitative research methodologies
- At least one member with professional training and experience in research ethics
- At least one person who is a biostatistician or has professional training and experience in biostatistics
- At least one person with a qualification in law
- The committee must be diverse and representative of the community it serves

2.6 Quorum and Voting

- The HREC meets monthly, except in December and January.
- A quorum is a simple majority of 50% plus one of all registered members.
- The HREC can only review studies at a full committee meeting when a quorum is present.
- The outcome for each application is determined by consensus. If a vote is required, a simple majority is sufficient for a decision to be made.
- Co-opted members, observers, and visitors are not allowed to vote.
- Any member with a conflict of interest related to a specific study must declare the conflict, recuse themselves from the discussion, and may not vote on the protocol.

2.7 Resignations and Training

Resignations:

HREC members must provide written notice of resignation to the Chairperson, at least one month in advance.

Training:

- All new members must undergo an assessed training such as the TRREE training program.
- Complete the HREC induction which is facilitated through the Life Healthcare Research Office or Research Manager and includes a comprehensive review of HREC guidelines and SOPs
- Attend at least one full HREC meeting as an observer
- Members are required to participate in ongoing professional development, use opportunities of the monthly HREC hosted research webinars and refresh their ethics training at least once during their term of office to stay agile to the evolving national and international health research ethics guidelines.

2.8 Code of Conduct and Confidentiality

All HREC members must adhere to the Life Healthcare Code of Conduct and are expected to act with integrity and professionalism at all times. This includes:

- Familiarising themselves with all relevant institutional and national guidelines.
- Attending at least 70% of HREC meetings annually.
- Performing all delegated responsibilities in compliance with ethical and regulatory requirements.
- Conflict of Interest: All conflicts of interest must be declared at the beginning of each HREC meeting. A member with a conflict of interest may not review, deliberate on, or vote on the related application.
- Confidentiality: On appointment, all HREC members sign a confidentiality and non-disclosure agreement. All information regarding research proposals, reviews, and decisions must be kept strictly confidential.

2.9 References

- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- South Africa. Department of Health. (2020). Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Pretoria: National Department of Health of the Republic of South Africa.
- South Africa. Department of Health. (2020). Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Pretoria: National Department of Health of the Republic of South Africa.

- University of Pretoria Health Sciences Research Ethics Committee. Standard Operating Procedures.
- University of South Africa Health Research Ethics Committee. Standard Operating Procedures.

SOP 3: HREC MEETINGS PREPARATION AND PROCEDURE

Title	HREC Meetings Preparation and Procedures
SOP Number	SOP 3- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L. Roets	14/05/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	31/01/2022	
Reviewed	E.J Ricks	17/01/2023	
Authorised	S. Vasuthevan	28/02/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
14 May 2018	001	Development of the document
14 December 2021	002	Reviewed document
17 January 2023	003	Reviewed document
30 September 2025	004	Revised document

3.1 Purpose

The purpose of this SOP is to establish a clear and formal framework for the preparation, conduct, and documentation of Life Healthcare HREC meetings. This includes providing clear guidelines on the pronouncement of a quorum to ensure that all decisions and approvals are legally binding. This SOP is in accordance with the National Health Act 61 of 2003, the NDOH 2024 South African Ethics in Health Research Guidelines, the Life Healthcare Research Ethics Policy, and the HREC Terms of Reference.

3.2 Scope

This SOP applies to all HREC members, including the chairperson, vice-chairpersons, and the administrator; and covers all aspects of HREC meetings, from the pre-meeting preparation of documentation to the finalisation of meeting minutes. It also covers the responsibilities and procedures for establishing a quorum at all HREC meetings.

3.3 Responsibilities

The HREC office bearers, including the Chairperson, Vice Chairperson, Research Manager, and Administrator, are responsible for the effective and efficient conduct of all meetings to ensure that the set outcomes are achieved in accordance with established ethical and procedural standards. The Research Manager works in close collaboration with the Chairperson to oversee meeting preparations, reviewer allocation, and the overall management of the meeting process. The Chairperson, Vice Chairperson, and Administrator are specifically responsible for ensuring the correct procedure for the pronouncement of a quorum is followed.

3.4 Procedures

3.4.1 Preparation for Meetings

- *Meeting Schedule*: A meeting schedule and submission deadlines for the upcoming year will be communicated to all members by the end of November of the preceding year.
- *Documentation:* At least 10 working days prior to a scheduled meeting, the Research Manager, in consultation with the Chairperson, will finalise the agenda and assign reviewers. The Administrator will then distribute the agenda and all relevant application documentation to each committee member via email.
- *Agenda Content*: The agenda will be systematically organised to facilitate a productive meeting. It will include:
    - Attendance list and apologies
    - Correspondence and announcements
    - Ratification of minutes from the previous meeting
    - Matters arising from the previous minutes
    - Ratification of conditional approvals
    - Amendments to research proposals
    - New research proposals for approval, including:
        - Name(s) of the researchers
        - Names of assigned reviewers
        - Project title
        - A list of all relevant documents
    - Expedited research projects
    - Progress reports
    - Adverse events and serious adverse events (SAEs) for committee notification and deliberation.
    - Any other general ethics related matters

3.4.2 Meeting Procedures

Frequency:

- The HREC meets monthly, except for January and December, as stipulated in the Terms of Reference.

Quorum:

- A quorum is required to ensure that any decision or approval is resolved and binding. A quorum is a simple majority (50% plus 1) of the appointed members. In the event that the number of committee members is more than 15, the quorum can be pronounced at 33% of the total number of appointed committee members. Non-appointed members will not be considered part of the quorum.
- If a quorum does not exist at the start of the meeting, the meeting will be postponed.
- Should any member leave during the meeting and the number of remaining members falls below the quorum, the meeting must be adjourned. The remaining agenda items will be handled via a round-robin process if possible or be discussed at the next meeting, as determined by the Chairperson.

Meeting Attendance:

- Given that the HREC committee are spread geographically across all of Life Healthcare regions and that members are also outside of Life Healthcare employ, the HREC meetings are held virtually using a shared platform such as MS Teams.
- Attendance will be recorded via an attendance list generated by the virtual meeting platform (e.g., MS Teams).
- Meeting Protocol:
- The Chairperson will call the meeting to order and welcome all attendees.
- The minutes from the previous meeting will be reviewed for accuracy, approved, and seconded by two members who were present at that meeting.
- The lead reviewer for each new research proposal will present a summary and their feedback to the committee. All committee members will have the opportunity to ask questions and provide comments.
- Deliberation will be based on the principles of research ethics and scientific integrity.
- Decisions will be made by consensus. If a consensus cannot be reached, a vote will be held, with a simple majority required for approval.
- Any member with a declared conflict of interest must recuse themselves from the discussion and voting on the relevant proposal.

3.4.3. Documentation and Communication:

- The Administrator will record detailed notes of the meeting, including all decisions and action items.
- The Research Manager will ensure that all decisions are clearly communicated to the researchers via email as soon as possible after the meeting.
  The draft minutes and attendance list will be finalised by the Administrator, approved by the Chairperson, and distributed to all members within 10 working days of the meeting.

3.5 References

- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- South Africa. Department of Health. (2020). Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Pretoria: National Department of Health of the Republic of South Africa.
- University of Pretoria Health Sciences Research Ethics Committee. Standard Operating Procedures.
- University of South Africa Health Research Ethics Committee. Standard Operating Procedures.

SOP 4: REVIEW AND APPROVAL OF RESEARCH PROPOSALS

Title	Review and approval of research proposals
SOP Number	SOP 3- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	28/04/2018	
Reviewed	G. Ure	10/01/2021	
Reviewed	E.J. Ricks	09/09/2021	
Authorised	S. Vasuthevan	31/01/2022	
Reviewed	E.J. Ricks	17/01/ 2023	
Authorised	S. Vasuthevan	17/01/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
28 April 2018	001	Development of the document
January 2021	002	Revision of the document
09 September 2021	003	Revision of document
26 January 2023	004	Revision of document
27 March 2024	005	Revision of document
30 September	006	Revision of document

4.1. Introduction

This SOP outlines the formal process for the review of all research proposals submitted to the Life Healthcare Health Research Ethics Committee (HREC), ensuring that the process is robust, transparent, and aligned with national and international ethical standards.

All research involving human participants must undergo independent ethics review and receive HREC clearance before commencing. The review process is a collaborative effort between the HREC and researchers to ensure the protection of participants from potential risks and harm, as well as to safeguard the integrity of the research itself. The review process

must consider not only the immediate research but also its potential for future developments and broader societal benefits. Retrospective approvals will not be considered.

In compliance with the National Health Act 61 of 2003, the NDOH 2024 South African Ethics in Health Research Guidelines, and the South African Good Clinical Practice (GCP) Guidelines, all research proposals must be subjected to an independent ethics review by the Life Healthcare HREC, which is registered with the National Health Research Ethics Council (NHREC), before any research can be conducted in a Life Healthcare facility. The Life Healthcare HREC is committed to upholding high levels of scientific rigor and ethical standards, as defined by the acceptable norms and standards set out in national guidelines. All reviews must be objective, independent, and carefully assess the potential benefits, risks, and harms to both the participants and the operational environment of the research site.

4.2 Purpose

The purpose of this SOP is to ensure that all applications for research approval, whether for academic or non-degree purposes, are processed in a standardised, non-discriminatory, and fair manner.

4.3 Scope

This SOP ensures Life Healthcare's compliance with the National Health Act 61 of 2003, the NDOH 2024 South African Ethics in Health Research Guidelines, the Life Healthcare Research Ethics Policy, and the HREC Terms of Reference. It mandates that every institution where health research is conducted must have or have access to a registered HREC to review and approve research proposals that meet ethical standards. The HREC also plays a crucial educative role, providing researchers with constructive feedback to improve their proposals and avoid outright rejection.

4.4 Application Process

To ensure an efficient review process, all research applicants must submit a complete application package electronically to the Research Manager via the designated email address: Research@lifehealthcare.co.za. The required documents for all research applications are:

- HREC Application & Risk Assessment form (LCL-Form-REC-002).
- A full research proposal/protocol with all attachments.
- An abridged CV of the researcher and supervisor(s) to provide evidence of their expertise.
- Evidence of valid ethics training, as required by the National Research Ethics Committee (NDOH, 2024).
- Data collection instruments.
- Recruitment and enrollment information (written and/or oral).
- Informed consent forms.
- Non-Disclosure Agreements (if applicable).

Additionally, submissions must include the following documentation depending on the type of application:

- *For permission to conduct research at Life Healthcare (when ethics approval has been obtained elsewhere):*
    - An ethics approval letter from the Higher Education Institution (HEI) or other registered ethics committee where the study is registered.
    - Pharma-Ethics and/or SAHPRA approval letters, if applicable.
- *For both ethics approval and permission to conduct research at Life Healthcare:*
    - Proof of the proposal/protocol having been approved at the HEI where the researcher is registered.
    - A letter from the HEI indicating scientific, academic, and higher degrees approval for the study has been granted.

The Research Manager will ensure all documents are complete before proceeding. Missing, incomplete, or incorrectly completed documentation will result in a delay in the review process. All submitted documents will be uploaded to the Life Healthcare restricted shared folder by the Administrator. Only HREC members will have access to all required documents for a specific meeting.

4.5 Proposal Review Process

- Only complete submissions that include all the required documents from the checklist will be deliberated at an HREC meeting.
- The Research Manager, in consultation with the Chairperson, will select a review team of at least two members for each proposal, drawn from the HREC and a list of content experts. The Research Manager will ensure reviewer allocations are distributed equitably among committee members.
- Reviewer selection will be based on expertise and a rotation system to ensure a fair and equitable workload. The Research Manager will ensure that reviewer allocations are distributed equitably among committee members.
- In cases where a disciplinary expert is co-opted, they will provide their comments directly to the lead reviewer or may be invited to the HREC meeting for a discussion. The Research Manager will facilitate this communication.
- Both reviewers will present their independent reviews, and the discussion will then be opened to the full committee.
- Both HREC reviewers will compile a concise report with their recommendations on the HREC review feedback form and submit it to the Administrator and the Research Manager.

4.6 Review Criteria

The HREC uses the following criteria, in line with the NDOH 2024 Guidelines, to review all research proposals:

- *Social and Scientific Value:* The research must demonstrate clear relevance and value to the community involved or the wider South African community and contribute to the advancement of knowledge in its field.
- *Scientific Validity:* The proposal must be scientifically sound with a clear design, adequate sample size, and a rigorous methodology that adheres to GCP guidelines. Poorly designed research is considered unethical as it exposes participants to risk without the potential for valid outcomes. The research team must be suitably qualified, and adequate resources (staff, facilities, and participant access) must be available.
- *Reasonable Risk-Benefit Ratio:* Potential risks to participants must be minimized and clearly outweighed by the potential benefits to the individual or society. The HREC only considers risks and benefits directly resulting from the research itself, not from standard clinical practice. The committee will also assess the use of placebos and whether post-study access to the product will be made available to participants.
- *Fair Selection of Participants:* The selection of participants must be fair and just, based on the scientific goals of the study. Special consideration is given to research involving vulnerable populations, such as children, pregnant women, or economically disadvantaged persons. The research must include additional safeguards for these groups and provide strong justification for their inclusion. The use of socially constructed categories like race, ethnicity, or gender must also be justified.
- *Informed Consent Process:* The proposal must outline a process that allows for an informed and voluntary decision from each participant or their legal representative. Appropriate written consent and assent forms must be included.
- *Respect for Participants:* The research must demonstrate respect for the dignity of participants, allowing them to withdraw at any time without prejudice. Adequate provisions must be in place to protect the privacy and confidentiality of participant data. The proposal should also outline a plan for monitoring data to ensure participant safety and for communicating research results to them.
- *Respect for Communities:* The research must demonstrate respect for the communities involved, including a plan for appropriate community consultation and a mechanism for feeding back research results to them.

4.7 HREC Decisions

- HREC members will review the feedback from the assigned reviewers and discuss the proposal to reach a consensus decision.
- One of the following decisions must be made:
    - Approved: The proposal is approved in its current form. The approval date is the date the decision is made.
    - Approved with Minor Conditions: The proposal is approved, but minor changes are required. The Research Manager will verify that all minor alterations are made before final approval is granted.

    - Major Corrections and Resubmission Required: The proposal has major ethical or scientific concerns and requires significant changes. The revised application must be resubmitted and will be reviewed at a full committee meeting.
    - Rejected: The proposal is deemed unsuitable and may not be resubmitted.
- All decisions, including discussions and points of controversy, will be recorded in the meeting minutes. The minutes will also document any recusals to ensure a quorum is maintained.
- In the event of a tie, the Chairperson will have the final vote.

4.8 Communication of HREC Decisions

- All HREC decisions are communicated to researchers in writing within seven working days of the HREC meeting. The Research Manager is responsible for ensuring this communication is sent in a timely manner.
- Researchers can direct any queries to the Research Office, which will attempt to resolve problems and liaise with the Chairperson when necessary.
- An official approval letter will be issued only after all requested modifications have been satisfactorily addressed. The Research Manager will confirm that the required documentation has been received and verified by the reviewer.
- The researcher may only begin the project once the final HREC approval letter has been received.
- The research applicant is responsible for complying with all requests and returning the amended documentation within six months. If no feedback is received, the application will be cancelled.
- The initial approval period is for one year from the date of final approval. A progress report and a request for re-approval must be submitted at least eight weeks before the expiry date.
- All correspondence with the researcher will be filed on the Ulwazi shared drive by the Administrator.

4.9 References

- Dhai, A. (2019). *Health Research Ethics: Safeguarding the Interests of Research Participants.* Juta, Cape Town.
- Life Healthcare Group (Pty) Ltd. (2025). *HREC Terms of Reference*. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). *LCL-POL-REC-002: Research Ethics Policy*. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). *South African Ethics in Health Research Guidelines: Principles, Processes and Structures*. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.

- South Africa. Department of Health. (2020). *Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa*. Pretoria: National Department of Health of the Republic of South Africa.
- University of Pretoria Health Sciences Research Ethics Committee. *Standard Operating Procedures*.
- University of South Africa Health Research Ethics Committee. *Standard Operating Procedures*.
- World Health Organization (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*.

SOP 5: HREC RELATED APPEAL PROCESS

Title	HREC related appeal process
SOP Number	SOP 5- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

5.1. Purpose of the SOP

This SOP provides a framework for the establishment of an appeal process for decisions made by the Life Healthcare Health Research Ethics Committee (HREC), promoting integrity, dignity, and accountability.

5.2 Scope

This document establishes a standardised appeal procedure, ensuring Life Healthcare's compliance with the National Health Act, No. 61 of 2003, the NDOH 2024 South African Ethics in Health Research Guidelines, and the Life Healthcare Research Ethics Policy. It outlines the responsibilities and procedures to be followed by all parties involved in an appeal.

5.3 Responsibilities

The Chairperson, Vice Chairperson, Research Manager, and Administrator of the Life Healthcare HREC must be aware of the appeal procedure to ensure a standardised approach. Researchers and Life Healthcare staff must also be informed about the process.

5.4 Procedure

5.4.1 Grounds of Appeal

A researcher may appeal in writing against an HREC decision concerning their application, including:

- Significant amendments or changes required; and
- Rejection of the application.

Note: Dissatisfaction with the decision of the Life Healthcare HREC alone is not a sufficient ground for an appeal.

5.4.2 Appeal Process

Researchers have the right to request and receive written reasons for a decision from the Life Healthcare HREC and should exercise this right before initiating an appeal. An informal discussion with the Chairperson or Deputy Chairperson (in cases of a conflict of interest) should be the first step to attempt to resolve the matter. If a solution cannot be found, a formal appeal process is initiated.

- The researcher must submit a formal appeal memo, stating the grounds for the appeal, in writing to the Research Manager within ten working days of receiving the HREC decision. The appeal must be submitted in writing and must include all relevant documents.
- The Research Manager will acknowledge receipt of the appeal within two working days and will ensure the appeal is escalated to the HREC Chairperson.

- The HREC Chairperson, in consultation with the Research Manager, will convene an ad-hoc appeal panel comprising at least two experts who were not involved in the original review of the proposal. The members of the appeal panel will sign a conflict of interest and confidentiality agreement.
- The appeal panel will review the substance of the original application, the HREC's decision, and any additional information submitted by the researcher.
- After deliberation, the appeal panel will make a final decision to either:
    - Uphold the appeal; or
    - Reject the appeal.
- The Research Manager is responsible for communicating the appeal panel's decision to the researcher in writing.

In the event that a researcher remains dissatisfied with the appeal panel's decision, they have the right to appeal to the National Health Research Ethics Council (NHREC) as mandated by the National Health Act No. 61 of 2003.

5.5. References

- Life Healthcare Group (Pty) Ltd. (2025). *HREC Terms of Reference*. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). *LCL-POL-REC-002: Research Ethics Policy*. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). *South African Ethics in Health Research Guidelines: Principles, Processes and Structures*. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- University of North- West. (2021). SOP no 2.24_SOP_NWU-HREC_2.2 Version 1.
- University of South Africa, Department of Health Studies. *Standard Operating Procedures*.

SOP 6: PROTECTION OF VULNERABLE POPULATIONS IN RESEARCH

Title	Protection of Vulnerable Populations in Research
SOP Number	SOP 6- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

6.1. Purpose

The purpose of this SOP is to provide comprehensive guidance for the Life Healthcare HREC regarding the protection of the well-being and rights of vulnerable research participants, including children and adolescents. This SOP ensures the protection of all vulnerable persons by outlining the ethical, regulatory, and legal requirements for conducting such research, in alignment with the NDOH 2024 South African Ethics in Health Research Guidelines, the Life Healthcare Research Ethics Policy, and the HREC Terms of Reference.

6.2. Scope

This document covers the ethical considerations and procedures to be followed when conducting research with all vulnerable populations, including minors. It outlines the responsibilities and safeguards necessary for providing ethics clearance for such research.

6.4 Procedures

The following procedures provide the minimum conditions for research involving vulnerable persons or populations. The Life Healthcare HREC may require additional safeguards to protect participants, as determined by the specific context and nature of the research.

6.4.1 Research involving minors

The legal status of "minor" protects individuals under 18 years of age due to their potential for emotional, cognitive, and physical immaturity. Research with minors should only be approved if the research, including observational research, is not contrary to the best interest of the minor.

- Justification: Children should participate in research only when their participation is scientifically indispensable and the research investigates a problem of relevance to children. If the research can be conducted with adults, strong justification must be provided for including minors.
- Consent and Assent: All research involving minors requires documented permission from a parent or legal guardian. This is a legal requirement under the National Health Act and POPIA.
    - Assent: The HREC will review the assent process and the proposed assent form to ensure it is brief, in simple, age-appropriate language, and includes an explicit affirmation of agreement to participate. The HREC will not construe a minor's failure to object as assent.
    - Dissent: A minor's refusal to participate, as indicated by words or behaviour, takes precedence over the permission of a parent or guardian. This is known as dissent.
- Expert Consultation: The HREC will ensure that the researcher has planned with expert organisations, such as Childline, to consult on issues of safety, protection, and assent.
- Child Abuse and Neglect: Researchers have a legal obligation to report child abuse and neglect as required by the Children's Act 38 of 2005 (as amended by Act 41 of 2007).
- Clinical Trials: All clinical trials involving minors must be carefully reviewed, and precautions or protective conditions may be required by the HREC.

6.4.2 Research involving adults with impaired capacity

Adults who, either temporarily or permanently, have an impaired capacity to provide informed consent should participate in research only where it is essential to the research and the specific group, and where the desired outcomes cannot be delivered without their participation. The research must not be contrary to the individual's best interest.

Research involving persons with impaired capacity should only be approved if:

- The research, including observational research, does not expose the individual to more than minimal risk. The risk must be justified by the potential for direct benefit to the participant or significant societal benefit.
- The legally appropriate person (as stipulated in the National Health Act or relevant legislation) gives permission for the person to participate.
- Where appropriate, the proxy will provide assent, but the incapacitated person's dissent or refusal, as indicated by words or behavior, takes precedence over permission from a proxy.
- The National Health Act specifies the sequence of legally appropriate proxies as spouse or partner, parent, grandparent, adult child, and brother or sister.

6.4.3 Persons in dependent relationships

These individuals are in hierarchically structured groups, such as patients and healthcare workers, students and teachers, or employees and employers. In such cases, the HREC will pay specific attention to ensuring that:

- Participants are adequately informed and can voluntarily indicate whether they want to participate without fear of reprisal.
- Issues related to potential coercion and undue influence are adequately addressed in the protocol.
- A mechanism for dealing with dissension from participants is clearly outlined.

6.4.4 Persons with physical disabilities

- Recruitment strategies for research participation should be sensitive to the possibility that individuals with a physical disability may wish to volunteer.
- No unintended barriers should inhibit participation.
- Research involving participants with physical disabilities should anticipate possible barriers and include measures to minimise them, such as ensuring physical accessibility to research sites.

6.4.5 Offenders

The recruitment strategy must pay special attention to how coercion and undue influence will be avoided amongst such a "captive audience." The researchers must be aware of the environmental factors that may influence the participants. The Life Healthcare HREC should include, on an ad-hoc basis when such a research proposal is reviewed, a member with experience and knowledge of working with offenders.

Research involving offenders should only be conducted if:

- Their participation is crucial to the research and cannot be conducted with non-offenders.
- The research concerns a problem relevant to offenders.
- Sound informed consent processes can be ensured.
- Engagement with relevant role players/advisory structures has occurred.

6.4.6 Collectives

Collectives are groups distinguished by shared beliefs, values, and social structures. Research involving collectives should include the following measures:

- Formal consultation and respectful negotiation with the collective's leaders or appropriate advisory structures to obtain community permission to conduct the research.
- Clear protocols for managing potential disputes between the researcher and the collective.
- The fair distribution of any benefits resulting from the research.
- An agreement about the ownership of data and a plan for feeding back findings to the collective.
- While permission from the collective is required, informed consent from individual members of the collective is also mandatory.

6.5 References

- National Health Act, Act No. 61 of 2003
- Children's Act 38 of 2005 (as amended by Act 41 of 2007)
- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Bracken-Roche, D., Bell, E., MacDonald, M & Racine, E. (2017). The concept of vulnerability in research ethics: an in-depth analysis of policies and guidelines. Health Research Policy and Systems, 15:8.
- Dhai, A. (2019). Health Research Ethics: Safeguarding the Interests of Research Participants. Juta, Cape Town.
- North West University. (2021). SOP no 2.24_SOP_NWU-HREC_2.2 Version 1.
- University of South Africa, Department of Health Studies. Standard Operating Procedures.
- World Health Organization (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.

SOP 7: CONTINUING REVIEW AND MONITORING OF RESEARCH

Title	Continuing Review and Monitoring of Research
SOP Number	SOP 7- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

7.1 Purpose

The purpose of this SOP is to provide guidelines for the continuing review and monitoring of all research approved by the Life Healthcare HREC. This SOP ensures the ongoing protection of research participants and the integrity of the research from the time of initial approval until completion. It is aligned with the NDOH 2024 South African Ethics in Health Research Guidelines, the Life Healthcare Research Ethics Policy, and the HREC Terms of Reference.

7.2 Scope

This document covers the establishment of the procedures for both passive (report-based) and active (on-site) continuing review and monitoring. It requires the Life Healthcare HREC to request and review regular reports from all Principal Investigators whose proposals have been approved to maintain ethics approval and ensure compliance with all approved protocols.

7.3 Responsibilities

All members of the Life Healthcare HREC, the Research Manager, and the Administrator must be aware of the procedures for continuing review and monitoring. The Principal Investigator is responsible for the timely submission of all required reports to the HREC. The Research Manager, in collaboration with the Administrator, is responsible for ensuring that all reports are received, logged, and included on the agenda for HREC review. The HREC members are responsible for reviewing all submitted reports and deciding on the continuation of ethics approval.

7.4 Procedures

Ethics approval is valid for a period of one year from the date of initial approval. To maintain ethics approval, the Principal Investigator must submit a continuing review report at a minimum of an annual basis.

7.4.1 Continuing Ethics Approval

- All approved research by the Life Healthcare HREC is subjected to a continuing review to assess the status of the research within one year after ethics approval was granted. This process is mandatory for the re-certification of the ethics approval certificate.
- More frequent reports (e.g., six-monthly) may be required by the Life Healthcare HREC, particularly for medium and high-risk studies.
- The HREC reserves the right to suspend or terminate a study if the Principal Investigator fails to submit a continuing review report by the designated deadline.

7.4.2 Content of Continuing Review Report

- The Principal Investigator must submit the Life Healthcare HREC Progress Report form, which will contain the following information:
- Progress of the study to date, including recruitment numbers versus target enrollment.
- An account of any challenges encountered during the study, including recruitment difficulties or unforeseen events.
- A summary of all new or ongoing adverse events and serious adverse events (SAEs) that have occurred since the last report, as well as a description of any new risks or benefits identified.
- A list of all protocol amendments or changes to the research team since the last report, with approval letters from the HREC and/or other relevant authorities (e.g., SAHPRA).
- Details of any complaints or concerns from participants, their families, or the community.
- An update on the security and maintenance of research records and data.
- An explanation of any non-compliance with the approved protocol or conditions of approval.
- The status of the study (e.g., ongoing, complete, suspended, terminated).
- A summary of any published findings or presentations.

7.4.3 Monitoring Process

- The Principal Investigator will submit the completed Continuing Review Report form to the Administrator via email.
- The Administrator will log the report and place it on the agenda for the next scheduled HREC meeting for consideration and review by the committee.
- The HREC will review the report and based on the findings, will make a decision to:
    - Grant re-certification for a specified period (typically one year).
    - Request modifications or further information.
    - Suspend or terminate the ethics approval for the study.
- For medium and high-risk studies, the HREC may require additional active monitoring. This may include a request for reports from the Data and Safety Monitoring Board (DSMB) or other trial monitors. The HREC has the authority to conduct random or unannounced on-site monitoring visits to verify adherence to the approved protocol.
- The HREC has the authority to impose restrictions or suspend or terminate any research where the researcher has failed to comply with the stipulations as per the ethics certificate issued or has caused harm to participants, communities, or Life Healthcare**.**

7.5 References

- Life Healthcare Group (Pty) Ltd. (2025). *HREC Terms of Reference*. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). *LCL-POL-REC-002: Research Ethics Policy*. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). *South African Ethics in Health Research Guidelines: Principles, Processes and Structures*. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- South Africa. Department of Health. (2020). *Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa*. Pretoria: National Department of Health of the Republic of South Africa.
- University of Pretoria Health Sciences Research Ethics Committee. *Standard Operating Procedures*.

SOP 8: PROTOCOL AMENDMENTS

Title	Protocol amendments
SOP Number	SOP 8- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

8.1 Purpose

The purpose of this SOP is to provide guidelines on the process for submitting and reviewing protocol amendments and changes to research projects already approved by the Life Healthcare HREC. This ensures that all modifications maintain the ethical and scientific integrity of the study and comply with the NDOH 2024 South African Ethics in Health Research Guidelines.

8.2 Scope

This document covers the responsibilities and procedures for submitting, reviewing, and approving all amendments to an approved research protocol, including changes to the study's design, methodology, personnel, or documentation.

8.3 Responsibilities

The Principal Investigator is responsible for submitting all proposed amendments to the HREC for review and approval prior to their implementation. The Research Manager and Administrator are responsible for processing the amendment requests and presenting them to the HREC. All Life Healthcare HREC members are responsible for reviewing and approving the proposed amendments.

8.4 Procedures

Any change to an ethically approved research protocol, no matter how minor, requires HREC review and approval before implementation. The HREC has the authority to suspend or terminate a study if changes are made without prior approval.

8.4.1 Submission of Amendment Request

The Principal Investigator must submit the official 'LIFE HEALTHCARE HREC AMENDMENT OF STUDY APPLICATION FORM' to the HREC administrator via email. The completed form must be accompanied by all relevant revised and updated documents. The amendment form requires the researcher to describe the nature of the change and provide a clear justification for why it is necessary.

8.4.2 Classification of Amendments

Amendments are classified by the HREC into two categories based on their impact on the study and its participants.

- Minor Amendments: These are administrative or minor procedural changes that do not alter the risk-benefit profile or the scientific design of the study. They include:
    - Changes in study personnel, such as adding or removing co-investigators.
    - Administrative changes, such as an extension of the data collection period.
    - Minor changes to recruitment material or data collection instruments.
    - Adding or removing study sites.
    - Changes to a study's title.
- Major Amendments: These are significant changes to the methodology or procedures that may affect the risk-benefit profile, participant safety, or the scientific validity of the study. They include:
    - Changes to the study's aims, objectives, design, or overall methodology.
    - Changes to the sample size or sampling method.
    - Changes to the informed consent or assent process or the documents themselves
    - Changes to the risk profile of participants or the addition of new procedures

8.4.3 Review and Approval Process

- Upon receipt, the administrator will verify the submission and place the amendment request on the agenda for the next scheduled HREC meeting.
- The original reviewers of the protocol, or another designated HREC member, will review the amendment and present it to the committee for discussion.
- Based on the review, the HREC will either:
    - Approve the amendment

    - Request additional information or clarification
    - Decline the amendment
- The decision is documented in the meeting minutes.
- Following a decision, the HREC administrator will issue a new decision letter, which will clearly state the nature of the approved amendments. The updated approval letter must be attached to the original ethics approval certificate.
- The HREC's decision is final. However, a researcher may appeal to the National Health Research Ethics Council (NHREC) as per the National Health Act No. 61 of 2003.

8.5 References

- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- Life Healthcare HREC (2025). Life Healthcare HREC Amendment of Study Application Form.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- University of South Africa, Department of Health Studies. Standard Operating Procedures.

SOP 9: ADVERSE EVENTS, SERIOUS ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Title	Adverse events, serious adverse events and unanticipated problems
SOP Number	SOP 9- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

9.1 Purpose

The purpose of this SOP is to provide clear and unambiguous guidelines for the timely reporting and management of adverse events (AEs), serious adverse events (SAEs), and unanticipated problems (UPs) that may arise during a research study. This SOP is designed to ensure the immediate protection of research participants and the ongoing ethical integrity of the study, as required by the NDOH 2024 South African Ethics in Health Research Guidelines.

9.2 Scope

This document covers the procedures to be followed by all researchers for the reporting of AEs, SAEs, and UPs to the Life Healthcare HREC. It outlines the responsibilities of both researchers and the HREC when such events occur.

9.2.1 Definitions

- **Adverse Event (AE):** Any untoward medical or psychological occurrence in a human participant, which does not necessarily have a causal relationship with the research intervention.
- **Serious Adverse Event (SAE):** Any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, or results in persistent or significant disability or incapacity.
- **Unanticipated Problem (UP):** Any unexpected event that, in the opinion of the researcher, presents a greater risk of harm to participants or others than was previously known or anticipated, or that suggests that the research may need to be modified or halted. This can include events that are not medical related but are nonetheless serious, such as a breach of confidentiality.

9.3 Responsibilities

All researchers to whom ethics certificates have been issued are responsible for the timely and accurate reporting of all adverse events, serious adverse events, and unanticipated problems to the Life Healthcare HREC**.** The Life Healthcare HREC and its Administrator are responsible for the appropriate review of all submitted reports and for taking necessary actions to ensure participant safety.

9.4 Procedures

All AEs, SAEs, and UPs must be reported to the Life Healthcare HREC in accordance with a risk-based approach.

9.4.1 Reporting Requirements

The researcher must use the official HREC reporting form (Annexure A), or an equivalent template, to report the event to the HREC Administrator via email. The report must be submitted within a specified timeframe based on the severity of the event:

- For SAEs, particularly those that are life-threatening or result in death, a preliminary report must be submitted within 24 hours of the researcher becoming aware of the event. A detailed follow-up report must be submitted within seven calendar days.
- For all other SAEs and Unanticipated Problems, a full report must be submitted within seven calendar days.
- For all other AEs and other non-serious events, a summary of all events may be submitted in the annual progress report. The HREC reserves the right to request immediate reporting of these events if deemed necessary.

9.4.2 Content of the Report

The report must contain all the information required on the official reporting form and should include, but not be limited to:

- The nature and severity of the event.
- The date, time, and location of the event.
- A clear description of the circumstances in which the event occurred.
- The researcher's assessment of the causality or relationship of the event to the research.
- The immediate actions taken by the researcher to mitigate the harm.
- The outcome of the event.
- The signature of the researcher(s) and the date of submission.

9.4.3 HREC Review and Action

- The Administrator must inform the Chairperson of any SAE or UP report immediately upon receipt.
- The HREC Chairperson, in consultation with the Research Manager and relevant committee members, will decide on the urgency of the review and may call for an emergency meeting if necessary.
- The HREC will review the report in its entirety and may request additional information from the researcher. The HREC's primary focus is on ensuring participant protection and determining if the research should continue without modification, be modified, or be suspended or terminated.
- The committee may take remedial actions, including but not limited to:
    - Requiring a change in the study's protocol, particularly the informed consent process, to inform current and future participants of the new risks.
    - Advising on a suspension of enrolment or recruitment of new participants.
    - Suspending or terminating the research if the risk to participants is deemed unacceptable.
- All AEs, SAEs, and UPs must be reported to the NHREC annually by the HREC.

9.5 References

- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- University of South Africa, Department of Health Studies. Standard Operating Procedures.

SOP 10: WHISTLEBLOWING PROCESS

Title	Whistleblowing Process
SOP Number	SOP 10- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

10.1 Purpose

The purpose of this SOP is to establish a standardized procedure for the Life Healthcare HREC to follow upon receiving a reportable event. This SOP is aligned with the Life Healthcare Group's commitment to ethical conduct and transparency.

- The Life Healthcare Group is committed to the highest standards of ethical, moral, and legal business conduct. Ethical business behaviour is the responsibility of every person in the company and is reflected not only in our relationships with each other but also with our customers, suppliers, clients, contractors, shareholders, and other stakeholders. In line with this commitment, we expect employees and other stakeholders (contractors, suppliers, healthcare professionals, patients, clients or customers) who have serious concerns about any aspect of the Group's work to come forward and communicate these concerns through the appropriate channels provided by the company, without any concerns or fear of victimization. This obligation extends to the activities of the Life Healthcare HREC.

- Any member of the Life Healthcare HREC, Life Healthcare employee, research student, research participant, or any other interested party may raise concerns when they have reasonable grounds for suspecting:
    - Research misconduct.
    - Maladministration.
    - Non-adherence to approved research procedures, guidelines, or policies by a researcher (in one way or another related to Life Healthcare) in respect of research.
    - Any other misconduct that would have an effect on any research being conducted through the Life Healthcare HREC (hereinafter collectively referred to as “reportable events”).
- All members of the Life Healthcare HREC, Life Healthcare staff members and students as well as research participants enjoy full protection afforded by the Protected Disclosures Act No. 26 of 2000 (PDA) and can blow the whistle on any of the four aspects mentioned without fear of disclosure.
- It is recognized that wherever practical, and subject to any legal constraints, matters reported will proceed on a confidential basis. This SOP aims to ensure the confidentiality of all members of the Life Healthcare HREC, Life Healthcare staff and students as well as research participants and any other interested party, and ensures protection for all parties who disclose any reportable event, in good faith in order to assist the Life Healthcare HREC to meet its obligations in terms of upholding the guiding principles of research integrity, and the regulations as set out in the documents referred to in the references section.
- This SOP should be read in conjunction with the SOP for Complaints Procedure.

10.2 Scope

The scope of this document pertains to alleged actions by researchers within the ambit of research with human participants or the impact on the environment. The SOP primarily deals with aspects of research misconduct, maladministration, or non-adherence to approved research procedures, guidelines, or policies only to the extent that they may relate to the principles and regulations set out in the various documents mentioned.

10.3 Responsibilities

- The Life Healthcare HREC is responsible for ensuring that all research activities are carried out in an open and transparent manner, and in accordance with the relevant code of conduct for researchers in Life Healthcare.
- Every Life Healthcare HREC member, staff member of Life Healthcare, student, researcher, or participant in research who has a reasonable belief that a reportable event has occurred is obligated to report such behaviour in terms of this SOP.

10.4 Procedure

- Any party who reasonably and in good faith believes that a reportable event has occurred must submit a report in writing to the Chairperson of the Life Healthcare HREC. The complaint should be made on the applicable template included as

Annexure A hereto, or any other template that may be issued by the Life Healthcare HREC from time to time.

- Should the complaint be against the Life Healthcare HREC Chairperson, the complaint should be lodged in writing to the Deputy Chair of HREC and the Life Healthcare Chief Executive Officer.
- For the purposes of this SOP the HREC Chairperson or the Deputy Chairperson or Life Healthcare Chief Executive (where the complaint relates to the Chairperson) shall be referred to as the "receiving party".
- Upon receipt of the relevant complaint, the receiving party shall acknowledge receipt of the disclosure directly to the whistle-blower within three working days and shall notify the Life Healthcare HREC immediately.
- The receiving party shall, as soon as reasonably practicable after receipt of the compliant, set up an appointment with the whistle-blower and the legal representative of Life Healthcare HREC within 10 working days from the date of acknowledgement. The aim of this appointment is to conduct an initial investigation to establish whether there is a prima facie case to answer. The Life Healthcare HREC chairperson and legal representative may co-opt an independent resource for assistance with the investigation.
- The investigation and all outcomes will be documented accordingly for record purposes.
- Investigations will be dealt with sensitively and in a timely manner. Details of the allegations and the identity of the person(s) who disclosed will remain confidential.
- If the investigating team finds that there is no prima facie case to be answered, no action will be taken against the person in question, and the decision will be communicated to the reporting party.
- If the investigating team finds that there is a prima facie case to be answered, the HREC will be informed accordingly, and the necessary and appropriate action will be taken in line with the prevailing protocols and Life Healthcare internal procedures.
- Once the outcome of the investigation is concluded, it will be communicated to the reporting party and if he/she is not satisfied with the outcome, the concerns should be raised in writing to the receiving party.
- If disciplinary actions are required, the receiving party shall notify the relevant management and/or Group structures of the appropriate actions taken.

10.5 Protection of Whistleblowers

- The Life Healthcare HREC is committed to good practice and high standards and wants to be supportive of Life Healthcare employees or any other party that submits a reportable event in good faith.

- The Life Healthcare HREC recognizes that the decision to report a concern can be a difficult one to make and is therefore committed to ensuring that a reporting party is protected for a disclosure made in good faith.
- Retaliation by any employee, directly or indirectly, against any person who, in good faith, submits a disclosure or provides assistance to those responsible for investigating the allegations will not be tolerated.
- No employee or other legitimate reporting party will suffer harassment, retaliation, or adverse employment consequences because of the submission in good faith of their disclosure.

10.6 References

- Constitution of the Republic of South Africa, 1996. Pretoria: Government Printer
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Protected Disclosure Act, No 26 of 2000
- The National Health Act, No 61 of 2003
- University of South Africa, Department of Health Studies. Standard Operating Procedures.

SOP 11: DATA MANAGEMENT AND STORAGE

Title	Data Management and Storage
SOP Number	SOP 11- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

11.1 Purpose

The purpose of this SOP is to provide comprehensive guidelines on data management and storage, from the design and collection phase to the cleaning, storage, and final destruction of research data. It also establishes and implements control measures that will ensure easy accessibility and circulation of HREC documents. This SOP is based on the National Department of Health (NDoH) 2024 South African Ethics in Health Research Guidelines and current best practices to ensure data integrity, participant confidentiality, and compliance with legal requirements, including the Protection of Personal Information Act (POPIA). The purpose is also to provide guidelines to ensure compliance with the protection of the rights of research participants and the sites in which the research is conducted to privacy and confidentiality.

Key considerations for data management are:

- Scientific and appropriate data collection instruments must be used to provide reliable and relevant data.
- The quality of data must be high.

- Only data appropriate to the research proposal must be collected.
- Recorded data should be durable and accurately referenced by the researcher.
- Data are retained for a minimum of 5 years, or longer as required by specific legislation or research funders.
- Data reported in research reports and publications must be available, but without breaching the confidentiality or anonymity of the participants or institutions.

11.2 Scope

This document covers the procedures for establishing a data management plan throughout the research project, as well as the procedures for data storage, security, destruction, and potential banking for future use. The scope of this SOP is on the management and control of all documents and records related to the functioning of the Life Healthcare HREC, including the forms and templates used by Life Healthcare HREC administrative staff, Life Healthcare HREC members and research applicants, as well as managing the documentation and records received from applicants. These documents include but are not limited to the Life Healthcare HREC Terms of Reference, SOPs, Policies, Procedures, Protocols, Forms, applications, and correspondence with researchers to ensure that the latest copies of these documents are available at the point of use. It also covers the responsibilities and the procedures to follow to ensure privacy and confidentiality throughout the research lifecycle.

11.3 Responsibilities

All members of the Life Healthcare HREC, the administrator, and all researchers are responsible for being aware of and adhering to the procedures outlined in this SOP to ensure continuous ethical compliance and data integrity.

All Life Healthcare HREC members, the administrator, members of staff of Life Healthcare as well as all researchers to whom ethics approvals have been granted, must be aware of and adhere to the procedures to be followed to ensure the protection of the rights to privacy and confidentiality of personal and health-related information of the research participants.

The roles and responsibilities of the Chairperson, Research Manager and the Administrative assistant regarding document and record management and control will be highlighted below:

- HREC Chairperson
    - Ensuring the Research Manager applies this SOP.
    - Facilitate internal documents and records management and control audits annually.
- Research Manager
    - Ensuring that management of documents/records comply with this SOP.
    - Promoting effective and efficient management of Life Healthcare HREC records in compliance with DoH guidelines and this SOP by conducting checks together with the administrative assistant on all research folders on Ulwazi and immediately managing gaps.
    - Ensuring that there is a folder for all standard HREC documents such as:
        - Terms of reference and SOPs
        - Research Policy
        - List of HREC members

        - Signed HREC appointment letters
        - Signed Codes of conduct for HREC members
        - Signed non-disclosure agreements
        - Training records
        - Evidence of training
        - Register
        - Certificates
        - Templates: HREC outcome letters, HREC application form, HREC reviewer's form, Risk assessment forms, Monitoring and evaluation
    - Safe custodies and keeping of records, compliance to this SOP.
    - Ensuring that versions of documents are aligned on various platforms/records management website.
    - Ensuring the Research Governance Structure, SOPs, HREC application form, research submission, meetings and outcome dates are uploaded onto the research website by the Life Healthcare marketing team.
    - Supervising administrative assistant to ensure that documents and records are filed correctly.
- Administrative Assistant
    - Capturing all applications in an excel register as follow:
        - The name of principal investigator
        - Protocol identification number
        - Title of the project
        - Date of approval or rejection
        - Conditions of approval, if applicable
        - Whether approval was expedited
        - Copy of the signed final proposal or protocol approved
        - Whether and how consultation occurred
        - Records of adverse events
        - Records of amendments
        - Reports of adverse and serious adverse events and action taken
        - Other relevant information such as complaints from participants
    - Create a folder for each applicant with sub-files as follow:
        - Documents submitted
        - Documents reviewed
        - Reviewers' reports
        - Corrected documents
        - Outcome letters
        - Monitoring and evaluation
    - A folder comprising all the applicants for each month from February to November for each year be developed and placed on Ulwazi.
    - Minutes and Agenda to be signed by chairperson and placed in each month's folder.
    - Copy of attendance list of HREC meetings.
    - Compliance to records systems, i.e. usage and allocation of correct HREC reference numbers.
    - Upload documents onto the Ulwazi.
    - Control of any incoming and outgoing mail.

- Ensure proper care and custody of documents/records.
- Compliance with this standard operating procedure and other HREC records management policies of Life Healthcare.

11.4 Procedure

Data Management Plan

- A comprehensive data management plan (DMP) must be developed as part of the research protocol and submitted for HREC approval. The DMP should detail the entire lifecycle of the data, from collection to destruction.
- The researcher must clearly identify and describe the data to be gathered, including the type, format (e.g., numeric, narrative, biological), and purpose of its use.
- The lifespan of the data must be clearly defined.
- The scientific validity and appropriateness of all data collection instruments must be demonstrated. All questionnaires or tools should be scientifically sound and, where applicable, approved by a research supervisor or expert.
- The informed consent form must explicitly state what the data will be used for and who will have access to it. Consent for any future data sharing or secondary use must be obtained from participants at the time of initial consent or through a subsequent re-consenting process.
- Necessary permissions to gather data from all relevant gatekeepers or institutions must be secured in writing before data collection begins.

Data Collection and Capture

- A step-by-step method for data collection must be outlined.
- The specific procedures for each data collection instrument must be described, including how data will be captured (e.g., electronic data capture systems, paper forms).

Data Storage and Maintenance

- The infrastructure for data storage must be clearly outlined.
- The administrative assistant will be responsible for maintenance and storage of records pertaining to the membership of the Life Healthcare REC, and the maintenance and storage of the records related to ethics applications received from researchers from first receipt, rebuttal, approval, monitoring, completion and destruction.
- All records that have been received/created must be stored in a safe environment, such as Ulwazi, which is conducive for preservation of records.
- The researcher must have a robust data security plan to protect against unauthorised access, loss, or misuse. This includes protecting participant privacy by de-identifying or pseudonymizing personal information and implementing strong access controls.
- All consent forms, whether electronic or paper, must be stored separately from the de-identified data in a secure, locked cabinet or password-protected database.
- In cases of verbal consent, the recording must be stored securely and separately from the data.

- Maintenance and storage of records related to ToR, SOPs, Research Policy, and Templates will be the responsibility of the research manager.
- The administrative assistant will be responsible for maintenance and storage of records pertaining to the membership of the Life Healthcare REC, and the maintenance and storage of the records related to ethics applications received from researchers.

Data Entry, Validation, and Analysis

- A clear procedure must be established for data entry, including how missing data and inconsistencies will be handled.
- Data cleaning and validation checks must be performed as a quality assurance measure.
- The process for auditing data must be specified to ensure that it was gathered in accordance with the HREC-approved protocol.
- The plan for data analysis, including how missing values will be handled and the use of techniques such as member checking for qualitative data, must be described.

Data Archiving and Destruction

- Data must be retained for a minimum of 5 years after the completion of the research project, as per the Life Healthcare policy and national guidelines. Researchers must specify a longer retention period if required by the research funder or other relevant legal frameworks.
- Archived data must be easily retrievable but remain de-identified and separate from consent forms.
- When the retention period is complete, all data must be securely and completely destroyed.
    - Paper records must be shredded or incinerated.
    - Electronic data must be destroyed by overwriting, reformatting, or using specialised software to ensure irretrievability.
    - Audio-visual data should be degaussed using a magnetic field bulk eraser or physically destroyed.

Privacy and Confidentiality

- Participants have the right to privacy to the extent that is permitted by law. Privacy includes autonomy over personal information, anonymity, and confidentiality, specifically when sensitive or potentially damaging information is obtained. This includes the location of the research sites.
- When deciding on what information should be regarded as private, the perspectives of the participant and the site, together with any community advisory structures, should be respected.
- Data should ideally be collected anonymously, and if not possible, alternative ways to ensure unidentifiable data must be used.
- Personal, identifiable information must only be collected with the participants' explicit permission and should be stored separate from the participants' individual data collected.

- Researchers must ensure that the participants' rights are protected during data sharing, or when making it public in any way.
- If participants' verbatim quotes are used, these must be presented in a manner that ensures that the name of the participant cannot be linked to the direct quote.
- When data are gathered in group sessions, the researcher must emphasise the limits and risks to confidentiality and urge members of these groups to observe the principles of confidentiality and privacy.
- All parties who have access to personal data (fieldworkers, research assistants, administrative officers etc.) should be briefed on the participants' rights to privacy and requested to sign a confidentiality agreement.
- When collecting data through observation; where this information can cause a change in the behaviour of the participant, privacy, confidentiality and anonymity gains additional importance.
- All direct and indirect personal information obtained from files or records that may reveal the identity of a participant must remain confidential.

11.5 References

- Constitution of the Republic of South Africa, 1996. Pretoria: Government Printer.
- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Protection of Personal Information Act 4 of 2013.
- University of South Africa, Department of Health Studies. Standard Operating Procedures.
- Life Health Care. 2018. Control of Documents. Doc. No: QMS-WP-QUA-002

SOP 12: INFORMED CONSENT

Title	Informed Consent
SOP Number	SOP 12- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

12.1 Purpose

The purpose of this SOP is to provide comprehensive guidelines on the processes researchers are required to follow to obtain informed consent from participants taking part in research within the Life Healthcare context. This SOP is aligned with the latest legal and ethical standards to ensure that all participation in research is voluntary, well-informed, and ethically sound.

12.2 Scope

The scope of this document covers the establishment of the procedures and processes to follow to obtain informed consent from participants in research within the Life Healthcare context.

12.3 Responsibilities

All members of the Life Healthcare HREC, the administrator, as well as the staff and students of Life Healthcare must be familiar with the procedure and processes that must be followed when obtaining informed consent.

12.4 Procedure

- Personal information must be collected and managed in full compliance with the Protection of Personal Information Act (POPIA) 4 of 2013 and other relevant privacy regulations.
- The participation of individuals must be based on voluntary informed consent, and participants must be able to withdraw their participation at any time without providing reasons or facing any form of penalty.
- Written consent is the primary standard and must be obtained from all participants. The signed consent form must be accompanied by the date of signature.
- If participants are unable to write or prefer not to give written consent, verbal consent can be obtained in the presence of an impartial witness and must be recorded.
- If the research is conducted online or electronically, electronic informed consent is acceptable provided it uses a secure, auditable method that ensures the participant's identity is verified and the integrity of the consent process is maintained.
- Participants must be provided with both a verbal explanation and a written information letter containing adequate details of the research, including:
    - The purpose and nature of the research.
    - The procedures to be followed and the expected duration of participation.
    - Any foreseeable risks, discomforts, or possible harms involved.
    - Any anticipated benefits, both to the participant and to others.
    - Aspects of privacy, anonymity, and confidentiality, including how personal information will be protected.
    - Clear information on how data will be stored, managed, and a clear statement on whether the data will be shared for future research.
    - A statement confirming the participant's freedom to refuse to participate or to withdraw at any time without penalty.
- Consent for participation is considered freely and fully informed if:
    - It is given without any direct or indirect coercion or undue inducement.
    - Prospective participants have been well-informed and have demonstrated understanding of the information provided.
    - The researcher or fieldworker has answered all questions about the research and their participation.
    - It is given before any research procedures commence.
- If research is conducted in a foreign country, the relevant local ethical and legal standards, in addition to this SOP, must be adhered to.

12.4.2 Process

- The researcher must compile a clear, concise, and easy-to-understand participant information letter and consent form.
- The information letter must include, but is not limited to:
    - Contact details of the researcher(s) and supervisor(s).
    - The purpose of the study.
    - The reason the participant has been selected.

    - A clear explanation of the participant's right to choose and to withdraw.
    - Details of any incentives or remuneration.
    - A description of how privacy, anonymity, and confidentiality will be maintained.
    - Details on data storage and a clear statement on whether the data will be shared for future use.
    - A statement on the publication of results.
    - A description of possible harm or risks.
    - The participant's right to receive the study results.
    - Contact details of the Life Healthcare HREC in case of adverse events or concerns about the research.
    - An invitation for the participant to ask questions.
- A copy of the information letter and consent form must be provided to the participant well in advance of the study commencing to allow for an informed decision.
- The researcher must take specific measures to ensure that consent is truly informed, especially for participants with low literacy, visual impairment, or who speak a different language.
    - An impartial witness, who is fluent in both English and the participant's language (if different), must be present when explaining the documents.
    - The witness must attest to the fact that the information was accurately explained, that the participant appeared to understand, and that consent was freely given.
    - The witness must not be involved in the design, data collection, or reporting of the study.
    - The researcher should take care to verify the participant's understanding and ensure they do not feel pressured.

12.5 References

- Constitution of the Republic of South Africa, 1996. Pretoria: Government Printer.
- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Act, Act No. 61 of 2003.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Protection of Personal Information Act 4 of 2013.
- University of South Africa, Department of Health Studies. Standard Operating Procedures.

SOP 13: CONFLICT OF INTEREST AND CONFIDENTIALITY MANAGEMENT

Title	Conflict of Interest and Confidentiality Management
SOP Number	SOP 13- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

13.1 Purpose

The purpose of this SOP is to provide a framework to establish a procedure that promotes free, unbiased decision-making by Life Healthcare HREC, based on the principles of integrity, dignity, fairness, transparency, and accountability.

13.2 Scope

This SOP covers the responsibilities and procedures to be followed by Life Healthcare HREC members to foster ethical decision-making that is free from inappropriate influence. It also establishes the responsibilities of all HREC members to protect the privacy rights of researchers and research participants by maintaining strict confidentiality.

13.3 Responsibilities

The chairperson, deputy chairperson, administrative officer, and every Life Healthcare HREC member must be aware of and adhere to the conflict-of-interest and confidentiality procedures outlined in this document.

13.4 Procedure
Conflict of Interest

- Members of the Life Healthcare HREC are expected to make decisions and conduct their ethics review responsibilities in an independent manner, free from bias and undue influence. The integrity of the HREC review process can be compromised if such conflicts of interests are not disclosed and, where necessary, avoided or mitigated.
- Only members without a conflict of interest may participate in the review, deliberations, or voting process for a specific protocol.
- Life Healthcare HREC members must disclose any relationship, interest, or other circumstance that could reasonably be perceived as creating a conflict of interest related to their ethics review role, including:
    - **Relationship to the research study**: The HREC member, their spouse, or immediate family member is the principal investigator or a co-investigator of the research under review.
    - **Financial interest**: The HREC member has a financial interest in the research, its sponsor, or any entity that could be affected by the outcome of the research. This includes equity holdings, for-profit consulting arrangements, or intellectual property rights.
    - **Personal relationship**: The HREC member has a personal relationship with the principal investigator, peers, subordinates, or superiors involved in the research under review.
    - **Business relationship**: The HREC member serves as a trustee, director, officer, owner, or partner of a for-profit entity that could be affected by the research protocol under review.
    - **Personal biases**: Members must declare any pre-existing biases, such as those related to a specific subject field, methodology, or personal belief system, that might compromise an objective review.
- The Chairperson of the Life Healthcare HREC must request members to declare any potential conflicts of interest at the start of all meetings.
- When a member identifies a real or perceived conflict of interest, they must immediately declare it to the chairperson. The member must then recuse themselves from the review process, discussion, and voting for that specific research protocol.
- The Chairperson and the committee will determine whether a conflict exists. The determination, along with member recusals, must be recorded in the official meeting minutes.
- If the Chairperson has a potential conflict of interest, they must discuss the matter with the committee or the chairperson of the next level of ethics review. In this event, the chairperson must appoint the deputy chairperson or another member to act as chairperson for the duration of the discussion and decision-making on the item in question.
- A member with a conflict of interest will not be counted toward the quorum for the review of that specific protocol. They must leave the meeting room during the discussion and voting process, unless requested by the chairperson to provide factual

information. The minutes must document the member's absence and the reason for it. The outcome of the decision will not be discussed with the recused member upon their return.

Confidentiality

- All information related to research protocols, including personal and confidential data from researchers and participants, is considered sensitive and must be handled with the utmost discretion.
- HREC members, reviewers, and administrative staff must sign a confidentiality agreement before assuming their duties.
- Confidentiality extends to all aspects of the review process, including meeting discussions, documents, and correspondence.
- Breaches of confidentiality, whether intentional or accidental, must be reported immediately to the chairperson and will be investigated in accordance with the Life Healthcare Group's disciplinary procedures.
- Members must not discuss any protocol, review comments, or decisions with anyone outside of the HREC, including the researcher, unless specifically authorised to do so.
- All electronic and physical documents must be stored securely, and access must be restricted to authorised personnel only.

13.5 References

- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Protection of Personal Information Act 4 of 2013.
- University of Stellenbosch. (2023). HREC Terms of Reference and Standard Operating Procedures, Version 6. Approved by Senate Research Ethics Committee.

SOP 14: COMPLAINTS PROCEDURE

Title	Complaints Procedure
SOP Number	SOP 14- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	004	Revision

14.1 Purpose

The purpose of this SOP is to provide guidelines for the management of two types of complaints:

- Complaints from researchers about a Life Healthcare HREC matter
- Complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher.

14.2 Scope

This SOP covers the responsibilities and procedure(s) to be followed by the Life Healthcare HREC members to follow for the implementation of complaints received. This document also covers the responsibilities and procedure to be followed for the complaints process.

14.3 Responsibilities

The Chairperson, deputy chairperson, administrative officer and every Life Healthcare HREC member must be familiar with the procedure that must be followed during the complaints process.

14.4. Procedure

- Should a researcher experience a problem with a Life Healthcare HREC member's behaviour regarding the application of management procedures or reviewer report(s), they could lodge a complaint.
- The complaint should be lodged in writing to the Chairperson Life Healthcare HREC. Should the complaint be against the Life Healthcare HREC Chair, the complaint should be lodged in writing to the Vice- Chair of HREC and then Chief Executive Officer.
- The written complaint will initiate the following process:
    - The Life Healthcare HREC will acknowledge receipt of the complaint in writing within 10 working days.
    - The Chairperson shall convene a meeting, within a week of receiving the complaint, with the complainant/s and the Life Healthcare HREC member to discuss the complaint to find a solution. The chairperson will compile a written report of this meeting, and the incident will be reported to the Chief Executive Officer, the Chairperson of the Executive Management Committee and the Life Healthcare HREC. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.
    - If a solution is not reached, The Life Healthcare HREC Chairperson shall convene a meeting as soon as possible with the complainant and the Chairperson of Senate to discuss the complaint to find an acceptable solution.
    - The Chairperson will compile a written report of this meeting to chairperson of Life Healthcare HREC, the Chairperson of the Executive Management Committee and the NHREC. If a mutual agreement regarding a workable solution is reached the matter will be considered resolved.
    - If a resolution is still not reached, the process will proceed to the next phase as described below:
    - The complainant may approach the Chairperson of the Executive Management Committee to lodge the unresolved complaint, providing proof that the mediation process was followed unsuccessfully. The Chairperson of the Executive Management may appoint a sub-committee that will meet with the complainant and try to resolve the matter, or he/she may decide to bring the complaint before the full Executive Management committee to deliberate on the complaint.
- Complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher
    - The Life Healthcare HREC`s requirements for an Informed Consent letter clearly states that in case a research participant has any queries or complaints

against a researcher or a researcher's conduct, he/she may contact the Chairperson of the Life Healthcare HREC.

- The complainant may lodge a complaint with the chairperson of Life Healthcare HREC through a formal written complaint, an email or via the telephone, stating the complaint clearly and substantiated with facts and proof.
- A telephonic lodge should be followed by an email to keep a written record of the complaints.
- The HREC will acknowledge receipt of the complaint within 10 working days of receiving it.
- The chairperson of the Life Healthcare HREC shall notify the Chairperson of Senate of the complaint, as a professional courtesy. Within 7 working days of receiving the complaint, the chairperson of the Life Healthcare HREC shall call a meeting with the complainant and thereafter with the researcher.
- The outcome of the two meetings (one with the complainant and one with the researcher) will inform the necessity of a further meeting as soon as possible where the researcher, the complainant, the chairperson of the Life Healthcare HREC will finalise the complaint. The Chairperson of the Life Healthcare HREC shall keep a written record of the meeting and its outcome and shall communicate it to the Chairperson of Senate
- Should this not be achievable, a final meeting between all parties mentioned previously, as well as the of the Chairperson of Senate will be called as soon as possible in an attempt to find a solution.
- A detailed written report of the aforementioned processes and outcomes will be compiled by the chairperson of the Life Healthcare HREC and circulated for correctness and fairness. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved and confirmed in writing by both parties.
- If a solution is not reached, the process will proceed to the next phase as described below:
- The complainant shall be advised of his/her right to escalate the matter to Executive Management Committee. The Chairperson of the Executive Management may decide to appoint a sub-committee to deal with the complaint or he/she may decide to bring the complaint before the whole Executive Management committee for deliberations.
- The complainant may also be advised of their right to escalate the matter to the National Health Research Ethics Council (NHREC) as the final step in the formal complaints process, in accordance with the 2024 guidelines.

- If a solution is not reached, the process will proceed to the next phase as described below:
- The complainant shall be advised of his/her right to escalate the matter to Executive Management Committee. The Chairperson of the Executive Management may decide

to appoint a sub-committee to deal with the complaint or he/she may decide to bring the complaint before the whole Executive Management committee for deliberations.

- The complainant may also be advised of their right to escalate the matter to the National Health Research Ethics Council (NHREC) as the final step in the formal complaints process, in accordance with the 2024 guidelines.
- If the Chairperson of Senate is unable to find an amicable solution or it becomes apparent that the researcher acted in a deliberate maleficent manner, the matter shall be escalated to the HR Department of Life Healthcare for disciplinary measures.

14.5. References

- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- National Health Research Ethics Council. (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures. 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.
- Protection of Personal Information Act 4 of 2013.
- University of Stellenbosch. (2023). HREC Terms of Reference and Standard Operating Procedures, Version 6. Approved by Senate Research Ethics Committee.

SOP 15: CONDUCTING AN INTERNAL AUDIT

Title	Conducting and internal audit
SOP Number	SOP 15- Life Healthcare- HREC– 003
Date of first approval	December 2018
Location	https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/
Revision date	30 September 2025

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled:	L Roets	27/04/2018	
Reviewed	E.J. Ricks	14/12/2021	
Authorised	S. Vasuthevan	14/12/2021	
Reviewed	E.J Ricks	02/05/2023	
Authorised	S. Vasuthevan	02/05/2023	
Reviewed	J. Naidoo	01/09/2025	
Authorised	N. Tathiah	30/09/2025	

DOCUMENT HISTORY

Date	Version no	Reason of the document
27 April 2018	001	Development of the document
14 December 2021	002	Revision
02 May 2023	003	Revision
30 September 2025	005	Revision

15.1. Purpose

The Life Healthcare HREC is responsible for reviewing proposals and either granting ethics approval and or permission for studies to be conducted at Life Healthcare facilities. To ensure compliance with the National Health Research Ethics Council (NHREC) policies and NDOH 2024 Ethics Guidelines, the Life Healthcare HREC should ensure that there is a process/system in place for conducting internal audits. The purpose of this SOP is to provide a framework that could facilitate the conducting of an internal audit to ensure and demonstrate compliance with the regulatory requirements, protocol, the institution's own SOPs and Good Clinical Practice (GCP) guidelines. An internal audit process will also prepare the Life Healthcare HREC for external audit processes that may be conducted by the NHREC or other regulatory bodies.

15.2. Scope

This SOP defines the internal process to be followed by the appointed auditors for the Life Healthcare HREC internal audit. The scope of the audit extends to all HREC functions, including but not limited to the review of ethical applications, post-approval monitoring, complaints handling, and record management.

15.3. Procedure:

The Life Healthcare HREC will appoint two independent external auditors who have the necessary knowledge, skills and expertise to biennially conduct an internal audit of all documents (as indicated in the Internal Audit Tool) as well as the document and record management process and control. The documents of selected research studies of applicants who requested ethics approval and/or permission to conduct their studies at Life Healthcare facilities will also be audited.

A lead auditor will be appointed from an external HREC.

The lead auditor will be expected to assume the following responsibilities:

- Review documents and records as indicated in the internal audit tool.
- Identify the type of research projects to be audited.
- Review the ethics review process undertaken by the Life Healthcare HREC.
- Check the membership composition, appointment letters, CVs, record of training, signed codes of conduct and confidentiality agreements of the members of the Life Healthcare HREC.
- Compile a report of audit findings identifying areas of non-conformance, good practices and other observations and submit to the Life Healthcare HREC Chairperson
- Escalate critical non-conformances as appropriate to the Chairperson;
- Identify any potential misconduct in research matters and report on that to the Chairperson.
- Ensure that the process and associated documentation is kept confidential, unless concerns are raised relating to misconduct in research.
- Ensure appropriate follow-up in the event of non-compliances being identified.
- Provide a summary to the HREC Chairperson on the main aspects of the audit and any unresolved issues.
- The auditors must operate with independence and objectivity, free from any influence or conflict of interest with the HREC or its members.

The HREC Chairperson and Research Manager

It is the responsibility of the Life Healthcare HREC Chairperson to identify and approach external auditors to conduct the audit and discuss the choice of auditors with the Life Healthcare HREC. The research manager will be responsible for the process of getting documents ready for the audit. Upon completion of the audit, the auditors will discuss the findings with the chairperson and Life Healthcare HREC members on a date and time suitable for the Life Healthcare HREC and the auditors. A written report must also be provided to the chairperson who will share it with the Life Healthcare HREC committee. The responsibility for responding to the report and addressing the findings of the report will rest with the Chairperson and research manager.

Preparation for Audit

On a biennial basis, the HREC Chairperson in collaboration with the Life Healthcare HREC will arrange for an internal audit to be conducted as guided by this SOP.

One month prior to the audit being undertaken the research manager will provide the external auditors with a link to a shared file containing all documents and records required for auditing and a copy of the internal audit tool for their information. A mutually convenient date will be arranged for the internal audit to be conducted and the Research Manager will be advised of any additional documentation required and the files to be audited.
The HREC Chairperson and the research manager must be available to answer any queries that may arise during the audit. In addition, other members of the HREC must also be available to clarify any points.
A suitable space must be made available (online or in person) for discussion and feedback from the auditors.

Audit Processes
The auditors will use a combination of the following in conducting the internal audit:

- Reviewing documentation.
- Assessing and comparing documentation.
- Determining compliance with the HREC SOPs for research governance.
- Assessing adherence to the NHREC-approved scope of work for the HREC.
- Verifying that all ethical reviews were conducted in accordance with the principles outlined in the NDOH 2024 Ethics Guidelines.

Audit Findings
The audit team will compile a report detailing their findings, within two weeks of completing the audit.
The audit report will include:

- A list of identified non-conformities with GCP, and research governance.
- An assessment of how well regulatory requirements have been met.
- Where appropriate, a list of corrective actions to be taken to ensure compliance;
- In the event of critical and/or moderate findings, a date for re-audit.
- The audit report will be submitted to the HREC Chairperson.

Audit Outcome
Where corrective actions are identified these will be discussed with the Chairperson and the research manager and a timeframe agreed within which actions must be addressed and the auditors notified. A follow-up visit may be scheduled to provide assurances that recommendations have been implemented.

Audit Close-out
Once all recommendations have been addressed and assurances gained the auditors will inform the HREC Chairperson in writing. The Chairperson will table the report at a full HREC meeting. The HREC will ensure that the report and its findings are used for continuous quality improvement.

15.4. References

- National Health Research Ethics Council. (2024). *South African Ethics in Health Research Guidelines: Principles, Processes and Structures.* 3rd ed. Pretoria: National Department of Health of the Republic of South Africa.

- Department of Health. 2011. National Core Standards for Health Establishments in South Africa.
- Life Healthcare Group (Pty) Ltd. (2025). LCL-POL-REC-002: Research Ethics Policy. Rev 006.
- Life Healthcare Group (Pty) Ltd. (2025). HREC Terms of Reference. Rev 004.
- ICH-GCP Guidelines