HUMAN RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

27 March 2024

Life Healthcare

Making life better

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ABBREVIATIONS AND DEFINITIONS

ABREVIATION	DEFINITION
AE	**Adverse events** Any unfortunate medical or psychological event in the human participant not necessarily related to the research or the risk associated with the research. Any such event that can affect the research, the researchers, or data integrity should be reported to HREC.
Auditor	The concept auditor will refer to persons who possess the necessary knowledge, skills and expertise to provide a professional and independent review on HREC matters.
CIOMS	The Council for International Organizations of Medical Sciences
Confidentiality	Confidential information shall mean certain proprietary, personal, clinical or proposal-specific information, which the HREC member acknowledges to be confidential. Such information includes all proposals relating to research with human participants and associated documentation (University of Stellenbosch, June 2016).
Conflict of interest	Refers to any situation or relationship that compromises, or has the potential to compromise, the conduct or outcome of an ethics review. Conflicts of interest may arise when the reviewer has financial ties to the research or a funder of the research, or is the principal researcher or research supervisor.
Documents	The concept document refers to information stored in any medium, tangible as well as electronic.
Document Management	Document management is a system or process used to capture, track and store electronic documents.
DoH	Department of Health

ED	**Ethical difficulties** Issues that influence the researcher or fieldworker to obtain consent (verbal and written) from potential participants. These issues include: unwillingness to sign consent, participants' suspicion about research, demands for incentives, capacity to give consent as well as determination on providing collective rather than individual consent**.**
External Researcher	An external researcher is an individual that is not employed by the Life Healthcare and plans to undertake a research study that is health or health-related or includes staff and/or students as participants or access to documents and data bases from Life Healthcare.
Gatekeeper	A gatekeeper in health care research is the responsible person who permit or deny access to a selected research site. It is a complex process that researchers should be aware of in gaining the confidence of the various gatekeepers.
Health Research	Research that contribute to biological, clinical, psychological or social welfare matters, including processes as regards humans; causes and effects of and responses to disease; effects of the environment; health care systems; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care (DoH, 2015: 7 1.1.3).
Health Related Research	Refers to any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.
Records	An authentic official copy of documents
Records Management	Records management is a HREC function devoted to the management of information from the time of creation or receipt to its eventual disposition.

Research misconduct	Involves actions such as dishonesty or forgery that manipulate others into providing benefit that would normally not benefit that person.
Internal Audit	The concept internal audit will refer to *an independent, objective assurance and consulting activity designed to add value and improve an HREC's operations*.
Internal Audit Tool	An internal audit tool will be used by auditors to identify weak points, inefficiencies, and non-compliance with regard to HREC operations
HEI	Higher Education Institution
HPCSA	Health Professions Council of South Africa
HR	Human Resources
HREC	Health Research Ethics Committee
IN	**Incident** An unanticipated episode that happens with participants or researchers during the course of the research; with unexpected consequences for the health, privacy and safety of the participants involved in the research, Life Healthcare or a community at large**.**
Misconduct	Involves the intentional deception during research through falsification, fabrication, plagiarism, reviewing research **or** reporting of research results.
NHA	National Health Act
NHREC	National Health Research Ethics Council
PI	Principal Investigator
PMR	Progress and monitoring report
Round Robin	A written method of acquiring a resolution by the circulation of email documentation which is both commented on and either approved or declined. This decision is then returned to the convenor and collated into a final document to form a

	composite resolution which can be ratified at the next available meeting.
SAE	Serious Adverse Event Refers to any situation that arose during data gathering which relates to the research participant and resulted in death, life threatening consequences, required hospitalisation and prolonged hospitalisation or resulted in persistent disability/incapacity of the participant.
SAHPRA	South African Health Products
SOP	Standard Operating Procedure
ToR	Terms of Reference
UP	Unanticipated Problems Refers to unexpected events which the researcher did not anticipate, neither the extent or full details of the expected incidents when applying for ethical clearance.
Whistle-blowing	The act of informing someone in authority (Chairperson of the Executive Resourcing Committee, chairperson of Life Healthcare HREC) about any alleged research misconduct related or incidental to the execution of research

1. SOP FOR WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURES

Life Health Care Human Research Ethics Committee	
Title	SOP for the writing, revision, and managing of SOPS
SOP	SOP 1- Life Healthcare -HREC – 003
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Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
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Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**14.05.2018**	
Reviewed by:	**E.J. Ricks**	**14/12/2021**	
Authorised by:	**S. Vasuthevan**		
Reviewed by:	**E.J Ricks**	**17/01/2023**	
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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

1.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide a framework for the establishment of all SOPs for the HREC relating to research ethics matters. Important procedures and processes should be documented to ensure standard and uniform practices so that activities can be reproduced.

1.2 SCOPE

The scope of this document covers the establishment of all new SOPs for the HREC. It covers the responsibilities and procedure(s) to be followed, the essential elements to be included, as well as a template to be used for the establishment of a SOP.

1.3 RESPONSIBILITIES

All members of the Life Healthcare HREC, the administrator as well as the staff of Life Healthcare should be aware of the procedure to follow for the establishment of a SOP for research ethics within HREC to ensure a standardised approach.

1.4 PROCEDURE

- Should the need arise for the establishment of a new SOP for the HREC a request must be submitted to the chairperson of the HREC.
- The chairperson will review the request and authorise or decline the development of the SOP.
- The decision of approval or disapproval will be communicated to the requestor via email.
- On receipt of approval the requestor will then write the SOP in accordance to SOP 1- Life Healthcare -HREC-003, SOP for the establishment of SOPs and use the provided template.
- The Life Healthcare official font ‘Arial’ is used with a font size of 11, 1.5 line spacing.
- SOPs are numbered using the following prefixes:
    - For SOPs for the Life Healthcare HREC – SOP - Life Healthcare -HREC- version 00x
- When the first draft of the SOP has been written, the draft must be sent electronically to the Chairperson of HREC. The version number of this draft will be indicated as Draft 00x.
- The SOP will be distributed to all members of HREC with a view to inviting comment and input from various stakeholders who are affected by the implementation of the draft SOP.

- Any changes will be sent to the Chairperson and be tabled for discussion and approval at HREC.
- The SOP is finalised, approved and signed by all relevant parties.
- After approval, the SOPs are placed on the Life Healthcare Webpage and the Gateway for easy access and a notice is sent to all HREC members and Life Healthcare staff to raise awareness of the SOP's implementation date.
- A database of all SOPs is kept by the administrator.
- SOPs are revised as indicated on the specific SOP, following the same process that was followed during its development.
- SOPs must be adhered to consistently.
- When a SOP becomes redundant or is revised, it should be withdrawn and its withdrawal widely communicated.

1.5 ESSENTIAL ELEMENTS TO BE INCLUDED

- SOP identification:
    - Title of SOP
    - SOP number
    - Version number
    - Date of approval
    - Revision date
    - Web address
    - Number of pages
- Compilation and authorisation
- Distribution
- Document history
- Purpose of the SOP
- Scope
- Key concepts, definitions, and/or abbreviations
- Responsibilities
- Procedure(s) to be followed
- Reference documents
- Addenda
- Any other elements essential to the specific SOP (e.g., checklists, guides, and so forth)

1.6 REVIEW CYCLE

SOPs must be reviewed every three years.

REFERENCES

- North West University SOP for SOPs

2. SOP FOR SELECTION, APPOINTMENT AND RESPONSIBITIES OF HREC MEMBERS

Life Health Care Human Research Ethics Committee	
Title	SOP for the selection, appointment and responsibilities of Life Healthcare HREC members
SOP	SOP 2- Life Healthcare -HREC – 003
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2.1 PURPOSE OF THE SOP

The Life Healthcare HREC is registered with the National Health Research Ethics Council (NHREC) and functions according to the requirements stipulated by the National Health Act 61 of 2003, the supporting regulations (relating to Research with Human Participants 19 September 2014, as well as the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015). The registration number is: REC-251015-048. The purpose of the SOP is to provide a framework for the selection, appointment and responsibilities of members of the Life Healthcare HREC.

2.2 SCOPE

The scope of this document covers the selection, appointment and the functioning of the members of the Life Healthcare HREC as well as the responsibilities as outlined below.

2.3 RESPONSIBILITIES

The responsibility of Life Healthcare HREC members is to ensure that researchers conduct research ethically, and of a high scientific standard.

2.4 AIM

The aim of the Life Healthcare HREC members is to ensure that:

- The welfare, rights, dignity and safety of the human research participants are protected as well as ensuring that research integrity and high ethical standards are upheld.
- Life Healthcare HREC as well as researchers comply with the institutional, national and international requirements for research ethics in health and health related research.
- Research where humans are involved is scientifically grounded and ethically sound.

2.5 OBJECTIVES

The objectives of the Life Healthcare HREC members are to:

- Review all research proposal applications and amendments for ethical and scientific rigor (See SOP 4- Life Healthcare -HREC-003).
- Monitor and manage all adverse events and incidents related to the research being conducted.
- Monitor ongoing research to ensure adherence to approved proposals and legal requirements.

- Conduct rigorous ethics reviews of all health and health-related research proposals to ensure the welfare, interests and protection of participants and researchers involved in the research, and to ensure that the research is conducted according to the required ethical norms and standards.

2.6 PROCEDURE

2.6.1 Selection and appointment of members

The selection of members needs to align with the formal membership requirements of section 4.1 of the DoH (2015) guidelines and the operational needs of the Life Healthcare environment.

2.6.1.1 Selection, appointment and responsibilities of the Chairperson

When a vacancy such as the chairperson becomes evident, the Executive Management Committee of Life Healthcare in consultation with the Life Healthcare HREC members, invites nominations for possible candidates, based on their experience as HREC members as well as knowledge of the scientific research process and research ethics. The chairperson of the Executive Management Committee of Life Healthcare and the current chairperson of the Life Healthcare HREC will have preliminary discussions with the prospective candidates who were shortlisted by the Life Healthcare HREC members, regarding the roles and responsibilities of the chairperson. A final decision is made by the Chief Executive Officer and confirmed by Executive Management Committee and Life Healthcare HREC members. The Chairperson may serve a maximum of two consecutive terms of four years. A formal appointment letter is sent by the Life Healthcare HREC setting out the (1) term of office, (2) information for new Chairpersons (3) indemnification from personal liability against claims that may arise due to the ordinary business of the Life Healthcare HREC. An acting chairperson can be appointed to act for a limited period of six months.

The chairperson of the Life Healthcare HREC performs a leadership, oversight and advisory role in the conceptualisation, management and conduct of health research ethics initiatives at Life Healthcare. To be and do such, the Chairperson needs to be a respected member of the medical and healthcare community, knowledgeable and experienced in operationalising research ethics, research in medicine/medical sciences, health, legal frameworks and enabling sound committee leadership practices.

2.6.1.2 Term of Membership

Members are appointed for a term of 4 years, renewable once. The member will then step down and can be appointed after one year and may be reappointed for a next term should they make themselves available for re-appointment.

2.6.1.3 Responsibilities of the chairperson include but not limited to:

- **Play a health research ethics leadership role in** Life Healthcare**:**
    - Providing courageous and respected leadership in research ethics.
    - Be a champion for the importance of ethics-in-context.
    - Cooperate and liaise with research ethics committees nationally, towards developing and promoting best practices in research ethics oversight and improving participant welfare and safety, particularly in multicentre trials.
    - Advise and consult, as agreed, with researchers and HREC members on research ethics issues.
    - Identify and support the enactment of research integrity where deemed necessary and the right thing to do.
    - Participate in non-compliance investigations.
    - Play a leadership role in the development and implementation of HREC policies and procedures.
    - Possess a comprehensive knowledge of national and international research ethics guidelines and regulations, institutional policies and relevant legislation.
    - Represent the HREC in the Executive Committee (EXCO) of the HRECs.
    - Represent the HREC at the annual National Health Research Council (NHREC) meetings and other meetings at national level.
    - Promote a culture of respect within the research community for the Health Research Ethics Committee process and for research ethics more broadly.
    - Have an in-depth understanding of the ethical issues, HREC research policies and the NHREC/Department of Health guidelines that are applicable to studies that are reviewed by the HREC. The HREC Chair is not expected to be the only, or ultimate authority on compliance issues – the manager of the Research Office or Secretariat also take responsibility for compliance verification, but the HREC Chair is expected to be an active and knowledgeable partner in this aspect of the HREC system.

- Represent the HREC in discussing HREC decisions and requirements with researchers and other stakeholders, and have the courage and confidence to uphold decisions that may not be popular with investigators, the research community, University officials and/or external stakeholders.
- With the assistance of the research manager, prepare an annual report for the National Health Research Ethics Council (NHREC) on the nature and volume of the HREC's activities.
- Make inputs to ensure or support adequate resources (financial, human, knowledge development) to conduct health research ethics duties in line with national and international benchmarks.
- Contribute to the development, review, enactment and monitoring of HREC policies, guidelines and SOPs.
- Perform administrative duties such as the review and signing of letters, electronic communication, appointments and the preparation of directive documents.
- Delegate their duties to HREC Vice Chairpersons on a case-by-case basis, where necessary.
- Under exceptional circumstances, jointly with the research manager, conduct specific reviews and or review and provide input to specific research ethics issues.

- **Conduct and direct proceedings of monthly HREC meetings**
  - Chairpersons are expected to attend a minimum of 70% of the HREC meetings scheduled for the year. 100% attendance is however preferable;
  - With the assistance of the research manager, decide on review categorization, for example expedited review, meeting assigned or excluded from review;
  - With the assistance of the research manager, select reviewers with necessary expertise to perform initial and ongoing reviews;
  - With the assistance of the research manager, prepare the agenda before meetings, and review the minutes after meetings;
  - Have respect for committee members from diverse backgrounds, perspectives and sources of expertise;
  - Facilitate sound ethical discourse, teamwork-with-integrity and the reaching of consensus at meetings;
  - Be a gatekeeper for the welfare and safety of the participant, their communities and vulnerable populations - carefully managing risk and benefit;

- Where necessary, enact review decisions in line with national guidelines and with careful consideration of participant(s), researcher(s) and important scientific endeavours;
- Conduct selected expedited and full committee reviews, as agreed, or delegate this task to suitably qualified individuals;
- Preview all protocols presented to the full-committee and when necessary communicate with reviewers so that important HREC issues are identified ahead of the full-committee sitting;
- Vote on protocols at the full committee meeting together with other HREC members;
- Review and sign letters to researchers conveying HREC decisions and requirements relating to their protocols;
- Manage complaints and concerns as communicated and support timeous solutions;
- Delegate their duties to HREC Vice Chairpersons on a case-by-case basis, where necessary.

2.6.2 Vice-Chairpersons: Appointment and Responsibilities

One Vice-Chairperson is nominated and selected by members of the Life Healthcare Health Research Ethics Committee for a four-year renewable term. The Vice-Chairperson's terms should preferably overlap with the Chairperson for the purpose of continuity.

The Vice-Chairpersons' responsibilities are to:

- Attend a minimum of 70% of the HREC meetings scheduled for the year. 100% attendance is however preferable;
- Perform duties delegated by the Chairperson;
- Act as Chairperson in the absence of the Chairperson;
- Provide active in-meeting support, for example meeting management, timekeeping, and conceptual and psycho-social support to the Chairperson and members;
- Vote on protocols at the full committee meeting together with other HREC members;
- Act as a member of the HREC EXCO;
- Advise and consult, as agreed, with researchers, HREC members and members of the HREC offices on research ethics issues;
- Participate in non-compliance investigations;

- Contribute to the development and implementation of HREC policies and procedures;
- Represent the HREC in the Executive Committee (EXCO) of the HRECs;
- Represent the HREC at the annual National Health Research Council (NHREC) meetings and other meetings at national level;
- General responsibilities which accompany committee membership.

2.6.3 Selection and appointment of committee members

As soon as the Life Healthcare HREC becomes aware of a vacancy in a specific position, they make it known to the Chairperson in consultation with the Executive Management of Life Healthcare who will invite appropriate nominations either from within or external to Life Healthcare. The candidates are informed in writing that they have been nominated to serve on the Life Healthcare HREC and are requested to respond in writing whether they accept the nomination. The Chairperson of the Life Healthcare HREC will have preliminary discussions with the candidates who have accepted the nomination regarding the roles and responsibilities of the specific position. A final decision will be taken at a Life Healthcare HREC meeting and confirmed by the EXCO. A formal appointment letter is sent by the Life Healthcare HREC setting out the (1) term of office, (2) information for new members (3) indemnification from personal liability against claims that may arise due to the ordinary business of the Life Healthcare HREC. The appointment letter must reflect the task agreement, of the Life Healthcare HREC member. HREC members may serve two consecutive terms of four years and must attend 70% of HREC meetings scheduled for the year. 100% attendance of HREC meetings is preferable. Life Healthcare obtains liability insurance to cover members when carrying out any professional duties related to HREC matters. The NHREC is notified of changes in membership.

Committee members' responsibilities are:

- To perform review timeously and meet review deadlines communicated by the research manager.
- Provide timeous written notice if unable to take on a particular review (within 3 working days of receiving review allocations) to the HREC Chairperson and research manager;
- Attend meetings on a regular basis and not leave until meetings are adjourned;
- Provide timeous written apologies for meeting attendance to the Chairperson and research manager within three working days of receiving review allocations. It is crucial for the primary reviewer to be present at the meeting to present their review to the committee. If this will not be possible, the reviewer should make arrangements with the Chairperson to take over these review duties in order not to delay the review process;

- Maintain strict confidentiality regarding protocol information, reviews and decisions, and all other matters discussed at committee meetings (see *Section 3.5.4 Confidentiality* for more detail);
- Disclose potential conflicts of interest to the Chairperson and research manager, and where a conflict does exist, not review the protocol and leave the room during discussion of and voting on the protocol (see *Section 3.8 Conflict of Interest* for more detail);
- Remain impartial and objective when reviewing protocols;
- Respect each other's views and the deliberative process;
- Serve as a primary reviewer for research in their area of expertise;
- Serve as a general reviewer of all research discussed at full committee meetings;
- Decide independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare, and comply with relevant ethics guidance and regulations;
- Decide by vote whether to approve, require revisions, defer or reject studies following deliberation at full committee meetings;
- Perform expedited reviews of minimal risk research;
- Keep up to date with national and international research ethics guidelines and regulations;
- Take part in research ethics and good clinical practice (GCP) Continuous professional development and submit documented proof of such to the HREC office.

2.6.4 Co-opted members, observers and visitors

- The Life Healthcare HREC may co-opt members as the need arises for the purpose of providing input and or guidance on specific matters as agreed to by the HREC.
- Observers and visitors will only be allowed in exceptional cases and for specific purposes. Researchers can be invited for discussions of their applications if clarity is needed.

2.7 **HREC COMPOSITION**

The composition and function of the Life Healthcare HREC must meet the minimum standards and requirements as set out in:

- Ethics in Health Research: Principles, processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015.
- Guidelines for Good Clinical Practice in the Conduct of Clinical trials with Human Participants in South Africa. Department of Health, Republic of South Africa, 2020.

- Members should be representative of active research disciplines including both clinical and non-clinical fields.
- The term of membership is four years, which is renewable for a second consecutive cycle.
- The Life Healthcare HREC must comprise of at least nine members. Additional members may be co-opted as deemed necessary. New members may be appointed as required.
- Each of the following categories should be represented in the membership of the committee and include those specified by the Department of Health in 'Ethics in Health Research: Principles, Processes and Structures, 2nd Edition, Department of Health, Republic of South Africa, 2015:
    - At least one lay person who is a non-expert in the health sciences disciplines.
    - At least one member with knowledge of, and current experience in the professional care, counselling or health related treatment of people. Such a member may be a medical practitioner, psychologist, social worker or nurse.
    - At least one member with professional training and experience in qualitative research methodologies.
    - At least one member with professional training and experience in quantitative research methodologies.
    - At least one member with expertise in bio-statistics.
    - At least one member with expertise in research ethics.
    - At least one person who has a qualification in law.
    - Ethnically and diverse members and appropriate mix of males and females.
    - At least one member from the Research Scientific Committee.

2.8 FREQUENCY OF MEETINGS, QUORUM AND VOTING REQUIREMENTS

- HREC meets monthly, except in the months of December and January.
- Meetings will take place on the dates as circulated and the agenda for these meetings close on the dates indicated, usually 10 working days prior to a scheduled meeting.
- The quorum is determined according to the stipulated guidelines of the Department of Health and the NHREC (2015), with a simple majority of 50% plus 1.
- The HREC must review relevant new and continuing studies at a full committee meeting only when a quorum is present;
- The Chair and Vice-Chairs count towards the quorum;
- Co-opted members, observers and visitors are not allowed to vote.

- A quorum must be maintained for each vote. If the quorum fails, further studies cannot be reviewed and must be held over until the next convened meeting;
- The outcome for each application is based on consensus;
- Any member with a conflict of interest with respect to a specific study must leave the room during deliberations and decision-making and may not vote on the study.

2.9 RESIGNATIONS

HREC members may resign from the committee in writing, addressed to the Chairperson of HREC, after giving one months' notice.

2.10 TRAINING

- All new HREC members must attend a formalised orientation presentation and must have documented proof of research ethics training.
- The orientation presentation will include:
  - Orientation to HREC's ToR and SOPs guidelines and processed as coordinated by and offered by the Research office.
  - Receive a full set of the HREC guidelines and SOPs as well as relevant National Guidelines and core reading material.
  - Attendance of at least one full HREC meeting as an observer.
  - Successful completion of an online research ethics programme such as TTREE.
  - GCP training for members who review clinical trials (if no evidence of a valid and current certification exists)
- Training and refresher courses should be available and members are expected to refresh their training at least once in their term of office.

2.11 CODE OF CONDUCT

All HREC members will adhere to the Life Healthcare Code of Conduct (2017) (See Addendum 1). Added to this code of conduct it will be expected of HREC members to:

- Familiarise themselves with the institutional documentation as well as the national and international research ethics guidelines.
- Always act with integrity.
- Attend at least 70% of HREC meeting annually.
- Perform all responsibilities delegated to them.

- Maintain all responsibilities in compliance with national and international ethical and regulatory requirements.
- Declare any prior interest and/or involvement in any matter being discussed at the HREC meetings to avoid potential conflict of interest.
- Keep all matters coming to their attention during HREC meetings confidential.
- To review independently, impartially and objectively whether the proposed design and conduct of research are likely to protect participants' safety, rights and welfare.
- To contribute to ethics related continuing education.
- To serve as a main reviewer where possible in the area of expertise.

2.12 CONFLICT OF INTEREST

All conflicts of interest should be declared by committee members at the beginning of each HREC meeting. Committee members should not be allowed to review an application if any possibility of a conflict of interest is present.

2.13 CONFIDENTIALITY

On appointment, HREC members sign a confidentiality and non-disclosure agreement. The entire review process will be treated confidentially. No information regarding research proposals will be distributed or shared with a third party, unless legally required.

REFERENCES

- The National Health Act, No 61 of 2003
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- Format adopted from (1) North West University (2) Unisa, Department of Health Studies and (3) Stellenbosch University.

3. SOP FOR PREPARATION FOR MEETINGS AND MEETING PROCEDURES

Life Health Care Human Research Ethics Committee	
Title	SOP for the preparation for meetings and procedures
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Reviewed by:	**E.J Ricks**	**17/01/2023**	
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28 April 2018	001	Development of the document
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3.1 PURPOSE OF THE SOP

The purpose of this SOP is to set out the formal preparation and procedures for the Life Healthcare HREC meetings.

3.2 SCOPE

The scope of this SOP relates to the preparation and procedures of the Life Healthcare HREC meetings.

3.3 RESPONSIBILITIES

The Life Healthcare HREC office bearers, namely the chairperson, deputy chairperson and the administrator are responsible for ensuring a productive and orderly meeting to achieve the set outcomes of the meetings.

3.4 PROCEDURE

3.4.1 Preparation for meetings

At least 10 working days prior to the scheduled meeting, the administrator will provide each committee member with the agenda, and all application documentation embedded, via e-mail. Notice of ad hoc meetings must reach all members at least two days before the meeting.

Complete sets of documents handed in for notification, discussion, evaluation or approval are included in the agenda and sorted under the respective sections:

- Attendees and apologies
- Correspondence and announcements
- Ratification of the minutes of the previous meeting
- Matters arising
- Ratification of conditional approvals
- Amendments to research proposals
- New research proposals for approval: the following information will appear on the agenda
    - Name of the researcher/s
    - Name of the research supervisor if applicable
    - Names of reviewers
    - Project title
    - All relevant documents
- Expedited research projects
- Progress/Final reports
- Adverse events/SAEs for committee notification/deliberation
- Extension of the agenda

3.4.2 Meeting procedures:

- The Life Healthcare HREC meets monthly except in January and December as stipulated.
- The meeting dates as well as the submission deadlines are communicated via e-mail in November of the preceding year.
- Ad hoc meetings, in exceptional cases may be convened, but communicated with two (2) days' notice prior to the meeting. Quorum requirements are applicable.
- A quorum consists of a simple majority (50% plus 1).
- The attendee list is signed at the meeting or an attendance list generated by MS Teams.
- The meeting procedure is recorded and written notes taken by the administrator.
- The chairperson welcomes all attendees and continues with the meeting.
- The minutes of the previous meeting are then submitted for approval and seconded by two (2) committee members who were present at the meeting.
- Amendments to previously approved research proposals (already reviewed by the chairperson or deputy chairperson) are merely noted. If any queries arise during the meeting, the researcher will be informed in writing and requested to react.
- During the discussion of new projects, the lead reviewer who conducted the review, will present the proposal to the committee and both reviewers will present their feedback. Any member of the Committee has the opportunity to ask question or make comments.
- After all questions are addressed, a consensus decision is made.
- All matters mentioned by members for the extension of the agenda are announced, but discussed at the end of the meeting.
- Decisions are taken down by the administrator and communicated with the researcher, via e-mail.
- The chairperson informs the members about the date and time of the next meeting and thanks them for attending the meeting.
- The minutes of the meeting as well as the attendance list are finalised by the administrator and sent to the chairperson for approval and distributed to all members within 10 days after the meeting.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017

- Format adopted from (1) North West University and (2) Unisa, Department of Health Studies.

4. SOP FOR REVIEW OF RESEARCH PROPOSALS

Life Health Care Human Research Ethics Committee	
Title	SOP for the review of research proposals
SOP	SOP 4- Life Healthcare -HREC-004
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Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
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Pages	14 pages

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**28.04.2018**	
Reviewed by:	**G. Ure**	**01.2021**	
Reviewed by:	**E.J. Ricks**	**09.2021**	
Authorised by:	**S. Vasuthevan**		
Reviewed by:	**E.J.Ricks**	**17/01/ 2023**	
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DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
28 April 2018	001	Development of the document
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09 September 2021	003	Revision of document
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4.1 INTRODUCTION

All research which involves human subjects must have HREC clearance. The proposal review process is not intended to impede scientific progress or innovative research. It must be remembered that a HREC process is a formal collaboration between research ethics committees and researchers to ensure that both the participants in research and the researchers are protected from both risk and harm which can arise from the research process. A research proposal review is primarily concerned with the present research but also with the potential for future developments and the potentially beneficial effects for the community at large.

NB No retrospective approvals will be considered.

In compliance with the requirements of the Department of Health (DOH) Ethics in Health Research: Principles, Processes and Structures (2015) and the South African Good Clinical Practice Guidelines (2020) all research proposals involving human participants must be subjected to an independent ethics review by members of the Life Healthcare HREC, which is accredited by the National Health Research Ethics Council, before any research may take place in a Life Healthcare facility.

A review takes place to ensure that the proposed research will promote health, contribute to the prevention or the cure of disease and disability. The Life Healthcare HREC process ensures that research proposals submitted uphold high levels of scientific rigour and ethical standards which are acceptable to the Life Healthcare Group. This standard is determined by the acceptable norms and standards set out in the South African Good Clinical Practice Guidelines: Third Edition 2020 and DOH 2015.

All reviews must be objective and independent and must carefully assess the potential for benefit, risks and harms to both the potential participants and the daily functioning and operations of the site or environment where the research will occur. Research must comply with the benchmarks and guidelines set out in the relevant legislation and guidelines.

4.2 PURPOSE

All requests for approval to conduct research for academic purposes or research for non-degree purposes in Life Healthcare facilities are conducted in a standardised manner, which is non-discriminatory, fair and which does not place undue time or financial pressure on the researcher.

4.3 SCOPE

The scope of this procedure is to ensure Life Healthcare compliance with, and to ensure that Life Healthcare carries out the mandate of the National Health Act (NHA), 16 of 2003, Section 8. 73. (1) below:

> *Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.*
>
> *A health research ethics committee must –*
>
> *(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases and*
>
> *(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.*

In line with section 4.1.5.2 of the Good Clinical Practice Guidelines, the Life Healthcare HREC should also play a role in increasing the skills of potential researchers by providing sufficient information for the researcher to amend their proposal. Reasons should be given to the researcher if amendment is required, or the proposal is to be rejected. In line with the role of the HREC:

> *"vi. Outright rejection should be avoided if a researcher can be advised to improve the proposal.*
>
> *vii. The educative role of HRECs should be fostered, which means that, where possible, researchers should be encouraged to engage with the concerns and seek to improve their protocols.*
>
> *viii. Feedback should be instructive to assist the researchers to improve the application if appropriate"* (GCP, 2016).

4.4 APPLICATION PROCESS

4.4.1 All applications for ethics approval and/or permission must be submitted to the Research manager as PDF files via email to Research@lifehealthcare.co.za

4.4.2 A fully completed Application for approval to conduct research at Life Healthcare LCL-Form-REC-002 form must be submitted, signed and dated.

4.4.3 A copy of a registered NHREC research ethics committee clearance certificate should accompany the application if ethics approval was obtained from another research ethics committee.

4.4.4 A full research proposal with all its attachments must accompany the application.

4.4.5 The proposal must include an abstract of not more than 300 words. All sections of the proposal must be completed.

4.4.6 If the student is engaged in doing a portion of a larger project, the larger project proposal must accompany the application, as well as all the requested HREC and approval documents.

4.4.7 Informed consent letters for participants, legal guardianship consent letters where applicable and assent letters for minors must accompany the submission.

4.4.8 Information letters must be available for each research participant. These should be translated into the language of the participants if possible.

4.4.9 Missing, incomplete or wrongly completed documentation will result in a decision being delayed.

4.4.10 All documents will be uploaded onto the Life Healthcare restricted shared folder, Ulwazi, by the administrator.

4.4.11 Only HREC members will have access to all the documents required for a specific meeting.

4.5 PROPOSAL REVIEW PROCESS

4.5.1 Only full document submissions will be deliberated at a HREC meeting.

4.5.2 Submissions are introduced by the Chairperson.

4.5.3 A two person reviewing team for each proposal will be selected by the Research manager in consultation with the Chairperson, chosen from the combined list of both HREC members and content experts depending on the nature of the research, to review each proposal.

4.5.4 Selection will be based on expertise and rotation to ensure that the review load of both the HREC and expert panel members remains equitable and all proposals receive a full, fair review utilising the reviewers' rubric

4.5.5 In the event of a content/disciplinary expert being co-opted, the content/disciplinary expert reads through the documents and addresses their comments directly to the HREC lead reviewer on the team via a MS Teams meeting or could be invited to attend the HREC meeting.

4.5.6 Reviewers review the allocated research proposal and documentation according to the attached rubric, along with the other members of the review team.

4.5.7 When two HREC members are on the team, the first listed HREC member is the team leader.

4.5.8 The HREC team leader member will provide an overview of the proposal and feedback to the HREC meeting (including the feedback received from the content expert in some cases) as to the final decision together with the second reviewer.

4.5.9 The second reviewer adds comments. Discussion is then opened to the full committee.

4.5.10 Both HREC Reviewers compile a short report on the HREC review feedback form with recommendations, sign them off and submit to the Administrator and Research Manager.

4.6 REVIEW CRITERIA

Please see Life Healthcare *HREC Review Guide* for the detailed HREC review framework. HREC uses the following criteria for review:

4.6.1 Social and scientific value: The proposed research must demonstrate relevance to:

5.6.1.1 The community involved and/or the greater South African community; **and**

5.6.1.2 The advancement of knowledge/the scientific field in the proposed area of study and/or related areas of study.

4.6.2 Scientific validity: The proposed research must be:

4.6.2.1 scientifically valid; **and**

4.6.2.2 Research must be well designed and conducted (e.g. clear aims, rigorous design, adequate sample, adherence to GCP, sound data analysis). Even a valuable

research question can be poorly researched, resulting in unreliable data. Poorly designed research that is not scientifically sound is unethical because it wastes resources and exposes participants to risks and inconvenience for no purpose if the research yields inaccurate conclusions/ misleading answers;

4.6.2.3 To meet ethical requirements, research ought not expose patients and staff to inconvenience or risk of harm without possible benefit to society or where the research will not generate the intended knowledge;

4.6.2.4 The proposed investigators/researchers/study coordinators must be:

4.6.2.4.1 *Suitably qualified to undertake the research*. Studies that have a substantial clinical component, where the principal Investigator is not a clinician, s/he should appoint a practicing clinician as a co-Investigator to the study.

4.6.2.5 The proposed research has the following resources:

4.6.2,5.1 Adequate number of qualified staff;

4.6.2.5.2 Adequate facilities;

4.6.2.5.3 Access to a population that will allow recruitment of the necessary number of participants;

4.6.2.5.4 Availability of medical or psychosocial resources that participants might need as a consequence of the research.

4.6.3 Reasonable risk-benefit ratio

4.6.3.1 The potential risks to individual subjects in the proposed research must be outweighed by the benefits to the individual or society; Risks to participants are reasonable in relation to:

4.6.3.1.1 The *anticipated benefits* to participants and/or the broader community; **and**

4.6.3.1.2 The *importance of the knowledge* that may reasonably be expected to result.

4.6.3.2 ALL the following requirements must be satisfied:

4.6.3.2.1 The potential risks to individual participants are identified and minimized;

4.6.3.2.2 The proposed research involves procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk;

4.6.3.2.3 Risk minimization measures are undertaken and stated in the protocol;

4.6.3.2.4 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants; and

4.6.3.2.5 Whenever appropriate, by using procedures already being `performed on the participants for diagnostic or treatment purposes.

4.6.3.3 The potential benefits of the research to participants and/or the wider community are identified and maximized. **NOTE:** Compensation for time and inconvenience, and reimbursement for expenses such as travel are <u>not</u> considered research benefits;

4.6.3.4 In evaluating risks and benefits, HREC shall consider only those risks and benefits that may result from the research itself (as distinguished from risks and benefits of therapies participants would receive as standard clinical practice, even if not participating in the research). HREC shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks and benefits that fall within the purview of its responsibility;

4.6.3.5 As per SA-GCP 2.2:

4.6.3.5.1 the HREC risk-benefit analysis takes full cognizance of benefits and harms beyond the life of the study itself, particularly in relation to chronic life-threatening conditions;

4.6.3.5.2 If placebos are to be used, whether their use is justified;

4.6.3.5.3 Making specific recommendations regarding the continuation of treatments beyond the life of the study, or mechanisms to ensure that participants are fairly protected;

4.6.3.5.4 Whether the product will be made available to participants after the study ends, and if so whether there is any cost to participant to continue treatment.

4.6.4 Fair selection of participants

4.6.4.1 The selection of research participants for the proposed research must be fair and just;

4.6.4.2 In making this assessment HREC shall take into account the purpose of the research and the setting in which the research will be conducted and shall be particularly cognisant of the special challenges of research involving vulnerable populations, such as children, prisoners, pregnant women, intellectually impaired persons, or economically or educationally disadvantaged persons;

4.6.4.3 Participants must be selected:

4.6.4.3.1 *According to the scientific goals of the study* (not for non-scientific reasons e.g. convenient, vulnerable, less able to protect their rights); and

4.6.4.3.2 *To minimize risks* (some participants may be eligible for scientific reasons, but at substantially higher risk of harm, e.g. impoverished and vulnerable to undue inducements);

4.6.4.3.3 To *fairly distribute benefits and burdens.* Research can provide direct and indirect **benefits.** Participants should be selected so that these benefits are fairly distributed;

4.6.4.4 Participants and/or communities **should not be excluded without sound justification.** Unfair exclusion from research may deny these participants and/or communities relevant knowledge/ health interventions;

4.6.4.5 Individuals and groups who bear the burdens of the research should share its benefits (new knowledge or products). Those who stand to benefit from research must contribute to its risks and discomforts. No group of persons should be asked to bear more than their fair share of the burdens of research; no group (e.g. impoverished) should be asked to bear research risks in order that others (e.g. the wealthy) enjoy benefits (new knowledge or products);

4.6.4.6 The research should avoid vulnerable participants when less vulnerable persons could be involved;

4.6.4.7 When some or all of the participants are likely to be vulnerable, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the applicant has:

4.6.4.7.1 Justified why vulnerable individuals/communities are included;

4.6.4.7.2 Included, and clearly articulated, additional safeguards in the proposed research to minimize risks for, and protect the rights and welfare of, these participants;

4.6.4.8 The use of socially constructed categories, such as race, ethnicity and gender

4.6.4.8.1 HREC recognises that human categories such as race, ethnicity and gender are social constructs;

4.6.4.8.2 The use of socially constructed categories, such as race, ethnicity and gender in research must be adequately justified;

4.6.4.8.3 The onus is on the research applicant to adequately justify to the HREC the value and meaning of the use of such categories, inclusive of how it will be documented and reported on for the purposes of the study;

4.6.4.8.4 The researcher(s) must have the necessary expertise/ background to carefully navigate the contours of these complex constructs, and evidence of such expertise and/or support must be provided to HREC;

4.6.4.8.5 Participants must retain the right to self-identification and preference not to answer;

4.6.4.8.6 Research proposing the use of socially constructed categories will warrant review by two reviewers and if deemed necessary be discussed at a full HREC meeting. The discussion will be documented in HREC meeting minutes;

4.6.4.8.7 When reviewing research protocols where human categories are included in the fabric of the study (e.g. in the aim, methodology, research instrument(s), or recruitment strategies) HREC reviewers must carefully consider the rationale, justification and evidence of the

careful unpacking of intricacies as provided by the researcher(s) for the inclusion of such variables(s) for data collection, analysis or reporting;

4.6.4.8.8 HREC follows a structured and disciplined process as outlined by the SA Constitution, international and national guidelines, for example the NDoH guidelines (2015) that explicitly states that:

4.6.4.8.8.1 It must be necessary to collect this data: “Information about a person’s race or ethnic origin must be necessary (s29(a)) or for affirmative action purposes (s29(b))”; and that

4.6.4.8.8.2. Nobody may be excluded based on race, gender, etc.: “Persons should not be excluded unreasonably or unfairly on the basis of any of the prohibited grounds for discrimination: race, age, sex, sexual orientation, disability, education, religious belief, pregnancy, marital status, ethnic or social origin, conscience, belief or language (s 8 of the Constitution); or

4.6.4.8.8.3 Nobody may be unfairly targeted based on race, gender, etc.: “Similarly, persons should not be unfairly targeted for research merely on the basis of one or other of these grounds.”

4.6.5 Informed consent process

The informed consent process for the proposed research allows for:

4.6.5.1 An informed and voluntary decision from each prospective participant, or the participant's legally authorized representative, in accordance with, and as required in SOP 15; and

4.6.5.2 Appropriately documented written informed consent, in accordance with, and as required by SOP 15 of this document;

4.6.5.3 Informed consent and assent templates, including templates for child research, genetic research, case reports, and online research, can be found on the HREC website.

4.6.6 Respect for participants.

When reviewing the protocol, HREC ensures that:

4.6.6.1 The proposed research demonstrates respect for the dignity of participants throughout the course of the research;

4.6.6.2 Participants may withdraw from the study at any time without prejudice;

4.6.6.3 There are adequate provisions to protect the privacy of participants and to maintain the confidentiality and security of participant data;

4.6.6.4 Maintaining privacy and confidentiality respects participants' rights to choose to whom, and what personal information, is disclosed. Participants must consent to the ways in which confidentiality will be maintained (using codes instead of identifiers, restricted access to data), as well as to how the results will be published, and to any limits to confidentiality where these apply;

4.6.6.5 There are adequate measures in place to monitor participant welfare throughout;

4.6.6.6 The research plan makes adequate provisions for monitoring data to ensure the safety of participants. HREC will consider the following provisions:

4.6.6.6.1 What safety information will be collected, including serious adverse events;

4.6.6.6.2 How the safety information will be collected (e.g. at study visits);

4.6.6.6.3 The frequency of data collection, including when safety data collection starts;

4.6.6.7 Participants are informed of research results

4.6.7 Respect for communities

4.6.7.1 The proposed research demonstrates respect for communities by appropriate community interaction and feedback of results;

4.6.7.2 There are adequate provisions to respect the autonomy of communities and to maintain the confidentiality and security of community data;

4.6.7.3 There is appropriate community consultation via community representatives during the planning phase of the research, before the commencement of the research, i.e. the community should be part of the research process; and

4.6.7.4 Communities are informed of research results.

4.7 HREC DECISIONS

4.7.1 HREC members consider the proposal reviews presented by the reviewers of each proposal.

4.7.2 HREC members reach consensus and make an informed decision on outcome of the application.

4.7.3 For each of the reviews conducted by Life Healthcare HREC, one of the following decisions must be made:

4.7.3.1 **Approved:** The proposed research is approved in its current form, with no changes required. The date of approval is considered the date that all conditions were determined to be met;

4.7.3.2 **Approved with conditions:** The proposed research is approved with minor alterations required. The corrected documents are returned to the Research manager who ensures that all the minor alterations were effected prior to the start of any research related activities;

4.7.3.3 **Major corrections and re-submission required:** The proposed research has major ethical and/or scientific concerns and a number of clarifications or methodological changes are required. The research applicant must resubmit the revised research application. The revised research application will be reconsidered at a convened (full) committee meeting;

4.7.3.4 **Rejected:** The proposed research may not be resubmitted;

4.7.4 Once a decision is made, an HREC official notification will be sent to the investigator;

4.7.5. The secretary records all decisions, and the method by which they were made, in the minutes. All discussion points, issues of controversy and reasons for decisions are documented in the minutes. The secretary also documents any member leaving or entering the room during the meeting, in order to record recusals and ensure that a quorum is always present;

4.7.6 In the event that a clear decision cannot be established by the committee, the HREC the Chairperson (or acting Chairperson) will have the final deciding vote.

4.8 PROCEDURE FOR THE COMMUNICATION OF HREC DECISIONS

4.8.1 All decisions taken at an HREC meeting are communicated in writing to researchers within seven working days of the outcome of the HREC meeting.

4.8.2 Researchers can address any queries to the Research office, which will attempt to resolve problems and liaise with the Chairperson when necessary

4.8.3 Research applicants should follow up with the Research office if they have not received an HREC letter within the time frames specified above;

4.8.4 HREC letters are issued electronically via email.

4.8.5 It is not unusual for the committee to request some changes to the project, information and consent form, or clarification of certain issues. Only once these requirements are satisfactorily fulfilled will a formal letter of approval be issued;

4.8.6 **The research applicant may start the project only once an Life Healthcare HREC approval letter has been received.** If modifications are required, then all requested changes must be made before a final letter of approval is issued;

4.8.7 It is the responsibility of the research applicant to comply with all requests and return the requested documentation with a covering letter responding to the points raised, to the HREC as soon as possible but not later than 6 months from the date of issue. **The application will be cancelled if no feedback is received from the research applicant within 6 months;**

4.8.8 All requested protocol and informed consent form changes must be clearly marked in red.

4.8.9 The lead Life Healthcare reviewer (or another HREC member, if requested to do so by the primary reviewer or Chairperson) will carefully check all amended documentation, including patient information and consent forms.

4.8.10 If correct, the said documentation will be forwarded to the Chairperson for final approval;

4.8.11 If not correct, a second letter will be sent to the investigator clarifying what aspects of the project still need to be addressed or changed. If the committee requested major alterations to be done, it must be resubmitted to a convened HREC meeting i.e. a full sitting of the committee;

4.8.12 **The initial period of approval is one year from the date of final approval.** A progress report and request for re-approval should be submitted at least 8 weeks before expiry of approval;

4.8.13 Please note the final HREC approval date will be recorded as the research start date and approval will expire in 1 year from this date.

4.8.14 If no response is received from the researcher after 6 months the submission will be deemed “not known”, and will become dormant.

4.8.15 All correspondence with researcher’s will be filed under the researcher’s name on the Ulwazi shared drive

REFERENCES

Legal and other references

- Department of Health. 2019 South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition 9in revision).
- World Health Organization. 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.
- Dhai. A. 2016. Practical Ethics and Regulatory Guide for Researchers and Research Ethics Committee Members. In collaboration with the WMA & UNESCO. Wits University. Johannesburg.
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- Australian Government NHMRC, 2018. *National Statement on Ethical Conduct in Human Research.* [Online] Available at: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 [Accessed 11 10 2019].
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- University of Queensland, 2019. *Integrity and Compliance.* [Online] Available at: http://www.uq.edu.au/research/integrity-compliance/low-and-negligible-risk-reviews [Accessed 11 October 2019].
- Stellenbosch University

5. SOP FOR APPEAL PROCESS

Life Healthcare Research and Ethics Committee	
Title	SOP for the appeal process
SOP	SOP 5- Life Healthcare -HREC-003
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Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	May 2023
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Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**27.04.2018**	
Reviewed by:	**E.J. Ricks**	**14/12/2021**	
Authorised by:	**S. Vasuthevan**	**14/12/2021**	
Reviewed by:	**E.J Ricks**	**02 May 2023**	
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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

5.1 PURPOSE OF THE SOP

The purpose of the SOP is to provide a framework for the establishment of an appeal process in order to promote standard and uniform appeal practices based on integrity, dignity and accountability.

5.2 SCOPE

The scope of this document covers the establishment of a standardised appeal procedure. It covers the responsibilities and procedures to be followed.

5.3 RESPONSIBILITIES

The chairperson, deputy chairperson, Research Manager and administrator of the Life Healthcare HREC must be aware of the appeal procedure to ensure a standardised approach. Researchers and staff must equally be informed about the process.

5.4 PROCEDURE

5.4.1 Grounds of appeal

A researcher may appeal in writing against a decision concerning his/her 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 ground for an appeal.

5.4.2 Appeal process

Researchers have the right to receive written reasons for a decision taken by the Life Healthcare HREC and should first exercise this right before an appeal is launched. An informal discussion with the chairperson or deputy chairperson in cases of conflict of interest should be the first step before an appeal is launched. If a solution could not be found, a formal appeal process is initiated. The researcher writes a memo stating the grounds of the appeal within one week (5 working days) of receiving a decision from the Life Healthcare HREC. The appeal is directed to the chairperson of the Life Healthcare HREC who will escalate the appeal to the committee.

- The basis of the appeal as well as all relevant documents must be submitted in writing to the chairperson of the Life Healthcare HREC.
- Receipt of the appeal is acknowledged by the administrator within two working days after receiving the appeal.
- The chairperson appoints one or two experts from the Life Healthcare Scientific Research Panel to review the substance of the application together with any additional information put forward by the researcher.
- The members of the panel sign a conflict of interest and a confidentiality agreement on acceptance to be part of the appeal panel.
- The chairperson will draw up the timelines for the delivery of the panel's decision.
- The Chairperson will convene a meeting with the panel.
- After deliberation of all the documentation provided to the panel, the panel must either:
    - Uphold the appeal or
    - Reject the appeal.

The decision of the panel is final. However, researchers, where applicable, have the right to appeal to the Head of the Governance and Ethics at Life Healthcare who would conduct further investigation and provide an outcome. In the event of the researcher still being dissatisfied with the outcome could appeal to the NHREC as mandated by the National Health Act No 61. 2003.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- National Health Act, No 61. 2003
- Format adopted from (1) North West University and (2) Unisa, Department of Health Studies.

6. SOP FOR PRONOUNCEMENT OF A QUORUM

Life Healthcare Research and Ethics Committee	
Title	SOP for the Pronouncement of a quorum
SOP	SOP 6- Life Healthcare -HREC-002
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24 April 2018	001	Development of the document
14 December 2021	002	Revised

6.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines on the pronouncement of a quorum for a meeting of the Life Healthcare HREC.

6.2 SCOPE

The scope of this document covers the establishment of a quorum for Life Healthcare HREC meetings and the responsibilities and procedures to be followed.

6.3 RESPONSIBILITIES

The chairperson, deputy chairperson and the administrator must be aware of the procedure to follow for the pronouncement of a quorum at a Life Healthcare HREC meeting to ensure a standardised and consistent approach.

6.4 PROCEDURE

According to the Ethics in Health Research, Principles, Processes and Structures (2015), section 4.4.1.2.a, a HREC should include at least nine members of a specialist list of required members of which a quorum should be a simple majority (50% plus 1). 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 committee members.

A quorum is needed to ensure that any decision or approval is resolved and binding, and is achieved through a majority vote that will not require ratification at any other meeting of the Life Healthcare Life Healthcare HREC.

Should a quorum not exist at the start of the meeting, the meeting will be postponed. Should any member apologise and leave while the meeting is in progress and the number of remaining members becomes unreasonably low, the meeting must be adjourned and the remaining items on the agenda to be sent via round robin if possible or it will be discussed at the next meeting. This will be determined by the chairperson.

Non- appointed members will not be considered part of the quorum.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- Human Research Ethics Committee: (medical) (With independent ethics Committee) SOP-IEC)

- Format adopted from (1) North West University and (2) Unisa, Department of Health Studies.

7. SOP FOR INVOLVEMENT OF VULNERABLE POPULATIONS

Life Healthcare Research and Ethics Committee	
Title	SOP for involvement of vulnerable populations
SOP	SOP 7- Life Healthcare -HREC-002
Date of Approval	December 2018
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29 April 2018	001	Development of the document
14 December 2021	002	Reviewed the document

7.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidance for the Life Healthcare HREC regarding the protection of the well-being of vulnerable participants such as:

- women
- adults with incapacity to provide informed consent
- persons in dependent relationships

- persons highly dependent on medical care
- persons with physical disabilities
- offenders
- collectivises

Research involving children (or minors) are dealt with separately in SOP 9- Life Healthcare - REC-002 for research involving minors.

7.2 SCOPE

The scope of this document covers ethical aspects to be considered when conducting research with vulnerable adult populations. It covers the responsibilities and procedures to be followed in providing ethics clearance.

7.3 RESPONSIBILITIES

The Life Healthcare HREC is responsible for determining and ensuring that the risks to vulnerable populations are adequately addressed. Research studies that plan to involve any vulnerable person or population must have adequate procedures in place for assessing and ensuring each participant's capacity, understanding of consent and assent, and for managing such circumstances when it is necessary to include these communities or collectives in research which would benefit them.

7.4 PROCEDURE

The procedures provide for the minimum conditions for research involving vulnerable persons or populations. The Life Healthcare HREC may require additional safeguards to protect potentially vulnerable persons or populations.

7.4.1 Research involving adults with diminished capacity

Adults who either temporarily or permanently whose capacity to provide informed consent should participate in research only where it is essential to the research and the specific group, and where, without their participation, the desired outcomes cannot be delivered. If capable adults can be included, but the proposal is to use incapacitated adults, strong motivation for their inclusion must be provided, and substantiated with relevant evidence.

When recruiting participants, the crucial element to consider is whether the person retains the capacity to decide whether to participate and if he/she can communicate this decision. The proposed participant must understand the information that is communicated and must be able to communicate verbally or non-verbally the wish to participate or not.

Research involving incapacitated adults should only be approved if:

- The research, including observational research, is not contrary to the best interest of the individual. The individual will not be under more than minimal risk; thus, not more than the everyday standard risk. The risk must be justified by the potential benefit. The risk should be justified by the knowledge-risk ratio.
- Greater than minimal risk must represent no more than a minor increase over minimal risk. The legally appropriate person (treatment proxies as stipulated in the NHA or section 27(1) (a) of the Mental Health Care Act 17 of 2001) gives permission for the person to participate. Where appropriate the proxy will provide assent, but the incapacitated person's refusal as indicated by words or behaviour takes precedence over permission by a proxy.
- The National Health Act specifies the sequence of legally appropriate treatment proxies as spouse or partner, parent, grandparent, adult child and brother or sister.

7.4.2 Persons in dependent relationships

These classes of individuals include persons in subordinate positions in hierarchically structured groups. This may include relationships between (1) older persons and their caregivers; (2) persons with chronic conditions or disabilities and their caregivers, (3) those with health or life-threatening illnesses, (4) patients and health care workers, (5) wards of state and guardians, (6) students and teachers, (7) employees and employers, (8) members of the uniformed services, (9) hospital staff and their respective employers. In the such cases specific attention should be given to ensuring that participants are adequately informed and can voluntarily indicate whether they want to participate or not. Issues related to potential coercion should be adequately addressed. The protocol should also address the mechanism for dealing with dissension.

7.4.3 Patients highly dependent on medical care

Patients who are dependent on medical care deserve special attention. The quality of informed consent may be compromised by the effect the medication has on their decision making and communication abilities. In some instances, the HREC may approve delayed or deferred consent, not meaning that consent is waived. The HREC should ensure full justification for delayed consent

is provided by the applicant. The HREC may approve delay in obtaining informed consent for patients highly dependent on medical care if;

- The research is based on valid scientific hypotheses that support a reasonable possibility of greater benefit than that offered by the standard care.
- Participation is not contrary to the medical interest of the patient.
- The interventions pose no more risk of harm than that inherent in the patients' condition or treatment.

7.4.4 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 to participate. No unintended barriers should inhibit participation; such as the absence of a ramp or lift for wheelchair bound potential participants. Research involving participants with physical disabilities should anticipate possible barriers and include measures to minimise them.

7.4.5 Offenders

The recruitment strategy must pay attention to how coercion and undue influence will be avoided amongst such a "captive audience". The researchers or fieldworkers administering questionnaires or conducting interviews must be aware of the environmental factors that may influence the participants.

The Life Healthcare HREC should include, ad hoc, when such a research proposal needs to be reviewed, a member with experience and knowledge of working with offenders. The researchers must comply with the requirements of the Department of Correctional Services as listed at http://www.dcs.gov.za/services/Research.aspx.

Research involving prisoners should only be conducted if:

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

In case of minors, the restrictions on independent consent are crucial; however, it is unlikely that the Life Healthcare HREC will approve independent consent by minors in conflict with the law.

7.4.6 Collectivises

Collectivises is a concept used to distinguish distinct groups from informal communities, commercial or social groups. Collectives are groups distinguished by

- Beliefs, values and social structures that identify them
- Customary collective decision-making according to tradition and beliefs
- The custom that leaders express a collective view
- The members are aware of common activities and interests

Research involving collectives should include the following measures:

- Resolutions for dispute for anticipated disagreements between the researcher and the collectively
- Respectful negotiations
- Permission from the collectively to approach individuals
- Informed consent from individuals
- Fair distribution of benefits
- Agreement about the ownership of data
- Agreement regarding feedback about the findings

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The National Health Act, No 61 of 2003
- Bracken-Roche, D., Bell, E., MacDonald, M & Racine, E. 2017. The concept of `vulnerability` in research ethics: and in-depth analysis of policies and guidelines. Health Research Policy and Systems, 15:8. https://doi.org/10.1168/s12961-016-0164-6
- Format adopted from Unisa, Department of Health Studies.

8. SOP FOR ANNUAL PROGRESS AND MONITORING REPORTS

Life Healthcare Research and Ethics Committee	
Title	SOP for annual progress and monitoring reports
SOP	SOP 8- Life Healthcare -HREC-003
Date of Approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
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Pages	3

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Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**27.04.2018**	
Checked by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**	**14.12.2021**	
Reviewed by:	**E. Ricks**	**28 March 2023**	
Authorised by:	**S Vasuthevan**	**28 March 2023**	

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27 April 2018	001	Development of the document
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8.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines on the annual progress and monitoring reports.

8.2 SCOPE

The scope of this document covers the establishment of the procedures to follow for both passive and on site/active progress and monitoring as it is required from the Life Healthcare HREC to request at least annual reports from all principal investigators whose proposals were approved; as stipulated in the Ethics in Health Research, Principles, Processes, and structures of 2015.

8.3 RESPONSIBILITIES

All members of the Life Healthcare HREC, the administrator as well as the staff of Life Healthcare must be aware of the procedure to follow for annual PMRs.

8.4 PROCEDURE

Ethics approval is valid for a period of one year. An annual report is required for review and monitoring purposes by the Life Healthcare HREC. Bi-annual report is required from researchers who are conducting medium and high risk studies.

8.4.1 Completion of annual progress and monitoring report

8.4.1.1 All approved research by the Life Healthcare HREC is subjected to assessment of the status of the research within one year after ethics approval and/or permission was granted. More frequent reports may be requested by the Life Healthcare HREC depending on the risk level of the specific research conducted.

8.4.1.2. The Life Healthcare HREC progress and monitoring report must be used for the purpose of re-approval.

8.4.1.3 The report must contain enough information for a meaningful review of the research regarding the progress made to date, the challenges experienced or any adverse events. The report should include the following:

- Progress to date in terms of data collection and analysis
- Outcome in the case of completed research
- Number of participants used for data collection or total number if research project has been finalised
- Whether feedback has commenced or participant follow up is needed
- Information regarding the maintenance and security of records
- Evidence of compliance with the approved research proposal
- Evidence of compliance with any conditions of approval
- Negative reports from monitors

- List of adverse events in the past 12 months
- List all amendments to the originally approved research proposal in the past 12 months

8.4.2 Process for annual reporting

- The principal investigator obtains the PMR from the administrator and completes the form electronically.
- Submit the completed form to the administrator of the Life Healthcare HREC at Research@lifehealthcare.co.za.
- The PMR is then placed on the agenda of the Life Healthcare HREC for consideration and review by the committee.
- The chairperson is responsible for compilation of a short summary report and presents the summary report to the committee for consideration.
- The decisions are reflected in the minutes by the administrator.
- The Life Healthcare 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 ethics certificate issued or has caused harm to participants, communities, or Life Health Care.

8.4.3 Process for active monitoring

Life Healthcare HREC will implement a system of six monthly reporting of medium and high risk studies so that monitoring is conducted more frequent. Researchers must submit the active monitoring reports received from their data safety monitoring boards (DSMBs), trial monitor and SAHPRA. The original reviewers of the application will be requested to review the monitoring reports and table the reports at HREC.

REFERENCES

- HREC Standard Operating Procedures and Guidelines, Stellenbosch University, v4.2 May 2015
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Tshwane University of Technology Research Ethics Committee Standard Operating Procedures and Guidelines, June 2012
- Life Healthcare Research Policy, 2017
- Format adopted from (1) Unisa, Department of Health Studies.

9. SOP FOR RESEARCH INVOLVING MINORS

Life Healthcare Research and Ethics Committee	
Title	SOP for research involving minors
SOP	SOP 9- Life Healthcare -HREC-002
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Authorised by:	**S. Vasuthevan**	**14.12.2021**	

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29 April 2018	001	Development of the document
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9.1 PURPOSE OF THE SOP

The purpose of this SOP is to outline general and specific ethical, regulatory and legal requirements for conducting research with children and adolescents; that is, with minors (under the age of 18 years).

9.2 SCOPE

The scope of this document covers the ethical aspects to be considered when conducting research with children and adolescents. It covers the responsibilities and procedures to be followed in providing ethics clearance.

9.3 RESPONSIBILITIES

The Life Healthcare HREC is responsible for determining and ensuring the risks to minors are sufficiently minimised, informed consent and assent are appropriately addressed, and that the privacy and confidentiality protections are adequate.

9.4 PROCEDURE

9.4.1 Definition of terms

- ***Adolescent*** is defined by the WHO (2015) as young people between the ages 10 and 19 years. For the purpose of these guidelines, an adolescent is a child between the ages of 12 and 17 years of age (ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 [http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf]
- ***Caregiver*** is defined as a person who factually cares for a child (s 1 Children's Act, 38 of 2005; a caregiver is obliged (in terms of s 32(1) to safeguard the child's health, well-being and development; and to protect the child from abuse and other harms. Furthermore, a caregiver may exercise the parental right to consent to medical examination or treatment of the child (in terms of s 32(2).
- ***Child*** is a person under the age of 18 years (s 28 Constitution; s 1 Children's Act 38 of 2005).
- ***Guardian*** is defined as a person appointed by the court to look after the financial and welfare interests of a minor, or a person appointed by a parent with sole responsibility for the minor in terms of the parent's will.
- ***Harm*** means physical, emotional, psychological, social or legal harm.
- ***Minor*** is a person (child) under the age of 18 years (s 17 Children's Act 38 of 2005).
- ***Neonate*** is defined as a new-born child, including an infant less than a month old.
- ***Orphan*** means a child who has no surviving parent caring for him or her (s 1 Children's Act 38 of 2005).
- **Parent** includes an adoptive parent (s) Children's Act 38 of 2005).
- **Therapeutic research** means research that includes interventions that may hold out the prospect of direct health-related benefit for the participant (Regulation 135).
- **Non-therapeutic research** implies research that includes interventions that will not hold out the prospect of direct health-related benefit for the participant but may produce results that contribute to generalisable knowledge (Regulation 135).

9.4.2 Minimum conditions for research involving minors

The Life Healthcare HREC, when reviewing research proposals where children and adolescent participants are involved, must include members with appropriate paediatric research and or clinical experience.

The following considerations are critical when the Life Healthcare HREC reviews proposals that involve children and adolescent participants:

1) Children should participate in research when their participation is scientifically indispensable to the research. The research should investigate a problem of relevance to children. The research proposal should provide sufficient information to justify clearly, why children should be included as participants.

2) Children should participate in research only where such research poses acceptable risks of harm; therefore, should only be approved if:

- The research, including observational research, is not contrary to the best interest of the child or adolescent (minor).
- The following are among the criteria which must be considered when determining a child's 'best interests':
    - Age, maturity and stage of development
    - Background
    - The child's intellectual, emotional, social and cultural development
    - Any disability a child may have
    - Any chronic illness from which a child may suffer
- The research, including observational research, places the minor at no more than minimal risk of harm (i.e. the 'everyday risks standard') which means the risk of harm is equal with daily life in a stable society or routine medical, dental, educational or psychological tests or examinations; or
- The research involves greater than minimal risk of harm but provides the prospect of direct benefit for the minor. The degree of risk of harm should be justified by the potential benefit; or
- The research, including observational research, involves greater than minimal risk of harm, with no prospect of direct benefit to the minor, but has a high probability of providing significant generalisable knowledge. The degree of risk of harm should be justified by the risk-knowledge ratio.

- Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.
- Where appropriate, the minor will assent to participation in a manner appropriate to his/her evolving level of capacity.

3) The Life Healthcare HREC will evaluate the degree of risk of harm against the likelihood of benefit to the child-participant as outlined in 2) above.
4) Children should participate in research only where the proper written permissions have been obtained. The consent process for a minor's participation in research requires:
   - Permission in writing from parents or legal guardians for the minor to be approached and invited to participate (in accordance with the Children's Act 38 of 2005);
   - Assent from the minor in writing (i.e. agreement to participate) if he or she chooses to participate.
5) Children's privacy interests should be addressed.
6) The minor's interest in confidentiality, i.e. being identified or identifiable without permission of the minor and his/her parent or guardian must be respected.
7) Research involving children must respect their evolving capacity to give consent.
8) Researchers have a legal obligation to report child abuse and neglect. They should report under the Children's Act 38 of 2005 (as amended by Act 41 of 2007):
   - Physical abuse causing injury
   - Deliberate neglect
   - Sexual abuse that includes sexual offences

The Criminal Law (Sexual Offences and Related Matters) Amendment Act No.32 of 2007

- Rape and sexual assault
- Statutory rape and sexual assault
- Consensual sexual penetration or other sexual activity

9.4.3 Parental permission and substitutes

Permission by parents or guardians for minors to participate in research should be distinguished from their minor child's contribution to the decision by voicing their assent separately. The process should be that the parent or guardian is requested to give permission for the minor to be approached and to be invited to participate in the study with parent provided with adequate information about the study. The parental permission and minor's decision must be consistent with one another. The parents or legal guardian should provide consent in all but exceptional

circumstances where a researcher may, based on existing guidelines, regulations, or benchmarks submit a request for a waiver of parental consent with the necessary justification for such a request. The Life Healthcare HREC could consider appropriate community engagement as a mechanism for informing a decision to balance parental rights with the best interests of minors and their privacy.

Where applicable, parental substitutes should be used in descending order, as listed.

i. The minor chooses whether to participate and thus expresses his/her will AFTER
ii. The parent gives assistance with understanding (so that the minor makes an informed choice)
iii. If there is no parent, then the legal guardian: either court-appointed OR as indicated by the parent in a will (s 27 Children's Act)
iv. If there is no guardian, then the foster parent (per order of Children's Court). (Note that social workers should request that the authority to give permission should be included expressly in the court order authorising foster care).
v. If there is no foster parent (per iv. above), then the caregiver (s 1 Children's Act: defined as '…any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care centre where a child has been placed; e) the person at the head of a shelter; f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and g) the child at the head of a child- headed household')
vi. If a minor is a caregiver in a child-headed household and there is no supervisory adult (s 137 Children's Act), then a trusted adult nominated by the minor, including but not limited to social worker, community worker or teacher.

9.4.4 Minor's independent consent

In certain conditions, such as in a discussion about sexual activities, substance abuse etc., it may be necessary and ethically justified for minors (especially older minors i.e. 16 years and older) to choose independently i.e. without parental assistance, whether to participate in research. Generally, only minimal risk research is suitable for independent consent by minors.

An ethical justification for independent consent by minors may be made in the following manner:

- By prior communication and engagement with participating community role players or parent collectives (e.g., SGBs and so forth), the researcher can request (and justify explicitly) Life Healthcare HREC approval of a waiver of the parental (or substitute) permission requirement. Engagement could include outreach to relevant role players such as canvassing the opinion of a representative body of parents e.g. via schools or appropriate community structures.
- Factual evidence of such engagement must form part of the researcher's justification in the research proposal. Factual evidence may be in the form of a letter from a relevant role player (like a community leader, or school principal) that confirms the view that independent consent is acceptable to the parents.
- If the Life Healthcare HREC finds the ethical justification and the factual evidence of parental support for independent choice by the minor children acceptable, the Life Healthcare HREC may grant a waiver of the requirement of written parental permission and will document the process carefully.

9.4.5 Guidelines for drafting an assent form

Assent is an interactive process between a researcher and child participant involving disclosure of cognitively and emotionally appropriate information regarding, at minimum, why the child is being asked to participate, a description of the procedures and how the child might experience them, and an understanding that participation in the study is voluntary. Children should understand that they can decline participation or withdraw from the study at any time, even where parental consent might have been forthcoming.

Assent requires that the child explicitly affirms his or her agreement to participate in a manner that reflects their age- and developmentally appropriate understanding and that is free of undue influence or coercion. In the absence of an explicit agreement, mere failure of the child to object cannot be construed as assent.

For younger children, the document should be limited to one page if possible. Illustrations or visual media might be helpful, and larger font type makes a form easier for young children to read. Studies involving older children or adolescents could include more information and may use more complex language. Researchers should draft a form that is:

- Brief
- Contains simple language written at the appropriate age level (where a cohort of children of various ages is to be included, separate developmentally appropriate assent forms/materials should be included with a submission)

- Study specific
- Takes into account the typical child's experience
- Treats the child respectfully
- Conveys the essential information about the study

The assent form should:

- Explain why the research is being conducted
- Describe what will happen and for how long or how often
- Indicate that it is up to the child to participate and that it is okay to say no
- Indicate what the child's other choices are
- Describe any good things that might happen
- Indicate whether there is any compensation for participating
- Indicate that questions can be asked by the participant, at any stage of the study.

REFERENCES

- Children's Act 38 of 2005 (as amended by Act 41 of 2007)
- Constitution of the Republic of South Africa, 1996
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 [http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf]
- Sexual Offences and Related Matters Amendment Act No.32 of 2007
- The National Health Act, No 61 of 2003
- Trait, A.R & Geisser, M. E. 2017. Development of a consensus operational definition of child assent for research. BMC Medical Ethics, 18:41. https://doi.org/10.1186/s12910-017-0199-4
- Word Health Organization. 2015. http://www.who.int/topics/adolescent_health/en/
- Format adopted from (1) North West University and (2) Unisa, Department of Health Studies.

10. SOP FOR AMENDMENT PROCEDURES

Life Healthcare Research Ethics Committee	
Title	SOP for proposal amendment procedures
SOP	SOP 10- Life Healthcare -REC-002
Date of Approval	
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Action	**Designated person**	**Date**	**Signature**
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29 April 2018	001	Development of the document
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10.1 PURPOSE OF THE SOP

The purpose of the SOP is to provide guidelines on the amendments to research proposals/protocols that may be needed during the duration of the research.

10.2 SCOPE

The scope of this document covers the establishment of the procedures to follow when amendments to a research proposal/protocol are required. It covers the responsibilities and the procedure/s to follow.

10.3 RESPONSIBILITIES

All Life Healthcare HREC members, the administrator, members of staff of Life Healthcare as well as all external researchers to whom an ethics certificate has been issued, should be aware of the procedure to follow for review and re-certification purposes.

10.4 PROCEDURE

It may become necessary to amend a research proposal in order for a study to proceed for reasons of both ethical and scientific integrity. In such cases the Life Healthcare HREC must review the proposed amendments to any research proposal that has already been approved, before commencement of the activities of the amended proposal.

Amendments can be minor or major in nature.

10.4.1 Minor amendments

Do not change the risk benefit profile of the study and include, amongst others:

- Additional study sites to be added
- Changes to the research team
- Small changes in the informed consent
- Changes in background information
- Extension of the period of study
- Changes that will not affect the study design and the outcomes
- Administrative changes
- Inclusion and exclusion criteria.

10.4.2 Major amendments

A change to the methodology or procedures that may result in changes to the risk benefit profile including:

- Changes in the aims, objectives, design or approved study methods
- Changes in consent and or assent forms
- Additional study procedures
- Easing of inclusion or exclusion criteria

A request to approve amendments must be submitted to Life Healthcare HREC prior to implementing changes to the approved protocol.

The proposed amendments must be electronically submitted to the administrator via e-mail: Research@lifehealthcare.co.za

The submission is placed on the agenda of the Life Healthcare HREC for consideration and review by all the committee members.

The chairperson is responsible for compilation of a short summary report and presents the summary report to the committee for consideration.

The main reviewer who reviewed the original submission presents the amendments to the committee; if no longer on the committee another member will be requested to present.

The decisions are reflected in the minutes

A new decision letter clearly indicating the nature of the approved amendments is issued to the researcher.

The decision of the panel is final. However, researchers where applicable have the right to appeal to the NHREC as stipulated and mandated by the National Health Act No 61. 2003.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- Format adopted from (1) Unisa, Department of Health Studies.

11. SOP FOR PRIVACY AND CONFIDENTIALITY

Life-Health-Care- Research-Ethics- Committee	
Title	SOP for privacy and confidentiality
SOP	SOP 11- Life Healthcare -REC-002
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11.1 PURPOSE OF THE SOP

The purpose of the SOP is to provide guidelines to ensure compliance to the protection of the rights of research participants and the sites in which the research is conducted to privacy and confidentiality.

11.2 SCOPE

The scope of this document covers the establishment of the procedures to follow for the protection of research participants' and research sites' right to privacy and confidentiality. It covers the responsibilities and the procedure(s) to follow to ensure privacy and confidentiality.

11.3 RESPONSIBILITIES

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 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 as well as the right to privacy (as provided for in the POPIA) and confidentiality of the research sites in which the research is conducted.

11.4 PROCEDURE

11.4.1 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 and which may lead to stigmatisation. This includes the location of the research sites.

11.4.2 When deciding on what information should be regarded as private, the perspectives of the participant and the site together with any community advisory structures (community engagement mechanisms) should be respected**.**

11.4.3 Data should ideally be collected anonymously, and if not possible, alternative ways to ensure unidentifiable data must be used.

11.4.4 Personal, identifiable information must only be collected with the participants' explicit permission and should be stored separate from the participants' individual data collected.

11.4.5 Researchers must ensure that personal data collected is stored in a manner that enhances maximum protection of privacy and confidentiality; for example, securely locked in cabinets or password protected on electronic saving devices, or secure cloud platforms/environments.

11.4.6 Researchers must ensure that the participants' rights are protected during data sharing, or when making it public in any way.

11.4.7 If participants' verbatim quotes are used (as is the case in qualitative data collected), these must be presented in a manner that ensures that the name of the participant cannot be linked to the direct quote**.**

11.4.8 When data are gathered in group sessions such as focus or nominal groups, the researcher must emphasise the limits and risks to confidentiality in group settings. Researchers are responsible for urging members of these groups to observe the principles of confidentiality and privacy.

11.4.9 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.

11.4.10 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.

11.4.11 All direct and indirect personal information obtained from files or records that may reveal the identity of a participant must remain confidential**.**

11.4.12 Researchers are responsible for reporting breaches of privacy and confidentiality to the HREC, in writing, within 24 hours of becoming aware of such a breach as well as to the appropriate institutional data compliance officer.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- GOV.ZA, 2022. Protection of Personal Information Act 4 of 2013 | South African Government. [online] Gov.za. Available at: <https://www.gov.za/documents/protection-personal-information-act> [Accessed 26 January 2023]
- Life Healthcare Research Policy, 2017
- Unisa Policy on Research, 2016
- Format adopted from (1) Unisa, Department of Health Studies.

12. SOP FOR ADVERSE EVENTS, SERIOUS ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Life Healthcare Research Ethics Committee	
Title	SOP for adverse events, serious adverse events and unanticipated problems
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12.1 PURPOSE OF THE SOP

The purpose of the SOP is to provide guidelines for the timely reporting of adverse events or serious adverse events or unanticipated problems that may place the participant(s) at serious risk during the course of a study.

12.2 SCOPE

The scope of this document covers the procedures to be followed for the reporting of any adverse event or serious adverse event or unanticipated problems arising during the study. It includes the researcher's responsibilities when such events occur.

Definitions

Adverse event(s): Any unfortunate medical or psychological event in the human participant not necessarily related to the research or the risk associated with the research. Any such event that can affect the research, the researchers, or data integrity should be reported to Life Healthcare HREC.

Serious Adverse Event (s) / SAE: Refers to any situation that arose during data gathering which relates to the research participant and resulted in death, life threatening consequences, required hospitalisation and prolonged hospitalisation or resulted in persistent disability/incapacity of the participant.

Unanticipated Problems/ UP: Refers to unexpected events which the researcher did not anticipate, neither the extent or full details of the expected incidents when applying for ethical clearance.

12.3 RESPONSIBILITIES

All Life Healthcare HREC members, the administrator, members of staff of Life Healthcare as well as all researchers to whom ethics certificates were issued, must be aware of the procedure that must be followed when adverse or serious adverse events or an unanticipated problem occur.

12.4 PROCEDURE

12.4.1 Any adverse or serious adverse event or unanticipated problem must be reported to the Life Healthcare HREC within seven calendar days of occurrence.

12.4.2 Reporting must be done in writing to the administrator.

12.4.3 The report must be submitted to the administrator at Research@lifehealthcare.co.za.

12.4.4 The report must include:

- The nature of the event
- Where and when it happened
- Who was present during the incident
- The context in which the incident occurred
- The action that was taken by the researcher/fieldworker
- The outcome of actions taken
- The signature of the researcher(s) and the date of submission of the report

The report should be made on the applicable reporting template included as Annexure A hereto, or any other template that may be issued by the Life Healthcare HREC from time to time.

12.4.5 The administrator must inform the chairperson of the Life Healthcare HREC of the report that was submitted and discusses the severity of the report. Consideration should be given to including the report on the agenda of the first Life Healthcare HREC meeting after receipt of the report.

12.4.6 Depending on the seriousness of the report a special Life Healthcare HREC meeting may be convened for tabling and discussion of the report.

12.4.7 All Life Healthcare HREC members must receive and study the report as well as the originally submitted documentation that received ethical approval. Any amendments that were approved after the initial ethical approval must also be submitted.

12.4.8 The committee decides on the most appropriate remedial actions to be taken. The researcher may be called to clarify matters if needed. Remedial actions may include but are not limited to:

- Suspension or discontinuation of the research project, depending on the risk to participants
- Suspension of the enrolment/ recruitment of new participants
- Suspension of engagement with research participants

- Modification of the informed consent letters, adding additional information including newly identified risks
- Signature by current participants of an addendum consent letter if applicable (require a copy of the current consent letter)
- Advising the committee on the way forward to minimize continuous risks
- Requests by the committee for more frequent reports
- Research proposal amendments to minimise newly identified risks

12.4.9 All reports must be included in the annual report to the NHREC.

12.4.10 Should the researcher be concerned regarding the impact that an event may have on the study, the researcher should report same to the HREC**.**

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- SOP Department of Health Studies, Unisa 2018

13. SOP FOR WHISTLE-BLOWING

Life Healthcare Research Ethics Committee	
Title	SOP for whistleblowing
SOP	SOP 13- Life Healthcare -REC-003
Date of Approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	December 2025
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COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**12.05.2018**	
Checked by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**	**14.12.2021**	
Checked by:	**E. Ricks & R. Bolasing**	**14.12.2023**	
Authorised by:	**N. Tathiah**	**27.02.2024**	

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Date	**Version no**	**Reason of the document**
12.05.2018	001	Development of the document
14.12.2021	002	Document revised
14.12.2021	003	Document revised

13.1 PURPOSE OF THE SOP

13.1.1 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) that we deal with, 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

13.1.2 The purpose of this SOP is to standardise the procedures to be followed by the Life Healthcare HREC upon receipt of a reportable event as defined below.

13.1.3 Any member of the Life Healthcare HREC, Life Healthcare employee, research student, research participant or any other interested party may raise concerns when he/she has 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, or
- 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").

13.1.4 All members of 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.

13.1.5 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 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 section 8.

13.1.6 This SOP should be read in conjunction with the SOP for Complaints Procedure - SOP 17- Life Healthcare -REC-002.

13.2 SCOPE

13.2.1 The scope of this document pertains to the alleged actions by researchers within the ambit of research in respect of human research participants or 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 the various documents mentioned.

13.3 RESPONSIBILITIES

13.3.1 The Life Healthcare HREC is responsible for ensuring that all research activities will be carried out in an open and transparent manner, and in accordance with the relevant code of conduct for researchers in Life Healthcare.

13.3.2 Every Life Healthcare HREC member, staff member of Life Healthcare, student, researcher or participant in research who has a reasonable belief that any reportable event has occurred is obliged to report any such behaviour in terms of this SOP.

13.4 PROCEDURE

13.4.1 Any party who reasonably and in good faith believes that a reportable event has occurred must submit a report in writing to 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.

13.4.2 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.

13.4.3 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".

13.4.4 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.

13.4.5 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.

13.4.6 The investigation and all outcomes will be documented accordingly for record purposes.

13.4.7 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.

13.4.8 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.

13.4.9 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.

13.4.10 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.

13.4.11 If disciplinary actions are required, the receiving party shall notify the relevant management and/or Group structures of the appropriate actions taken.

13.5 PROTECTION OF WHISTLEBLOWERS

13.5.1 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.

13.5.2 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.

13.5.3 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.

13.5.4 No employee or other legitimate reporting party will suffer harassment, retaliation, or adverse employment consequences as a result of the submission in good faith of their disclosure.

REFERENCES

- Constitution of the Republic of South Africa
- Department of Health Studies, SOP for whistleblowing
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Protected Disclosure Act, No 26 of 2000
- Regulations relating to Research in human participants (Government Gazette no 38000, of 19 September 2014)
- The National Health Act, No 61 of 2003

14. SOP FOR DATA MANAGEMENT AND STORAGE

Life Health Care Research Ethics Committee	
Title	SOP for data management and storage
SOP	SOP 14- Life Healthcare -REC-002
Date of Approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
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COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**12.05.2018**	
Revised by:	**E. Ricks**	**14:12:2021**	
Authorised by:	**S. Vasuthevan**	**14.12.2021**	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
12 May 2018	001	Development of the document
14 December 2021	002	Document revised

14.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines on data management and storage. Data management includes, design, collection, cleaning, and all information or measurements that form part of the research. Key considerations to data management are that:

- Scientific and appropriate for purpose data gathering instruments should be used to provide relevant and reliable data.
- Quality of data must be good.

- Only data appropriate to the research proposal must be collected.
- Recorded data should be durable and appropriately referred to by the researcher.
- The data are retained for 5 years as stipulated in the DoH Guidelines for research (2015) and as required by the Life Healthcare.
- Data reported in research reports and publications are available, but without breaching the confidentiality or anonymity of the participants or institutions (where applicable).

14.2 SCOPE

The scope of this document covers the establishment of the procedures to follow when initiating a data management plan during research projects and the procedures to follow when data are stored, destroyed or banked.

14.3 RESPONSIBILITIES

All members of the Life Healthcare HREC, the administrator as well as the staff of Life Healthcare must be aware of the procedure to be followed during continuous review and re-certification processes.

14.4 PROCEDURE

14.4.1 Identification and description of data

14.4.1.1 Identification of data that the researcher wishes to gather is important and the following must be addressed: (1) what type of data will be collected, (2) why is it needed, and (3) how will it be used?

14.4.1.2 The lifespan of the data must be clear.

14.4.1.3 The types and format (numeric or narrative/textual or biological) of data must be identified:

- All questionnaires must be scientifically formatted according to prescribed guidelines
- All questionnaires must be scientifically sound
- All questionnaires must be approved by a research supervisor, research experts or research committees

- The ability to execute the instrument must be explained to ensure ethical data capturing sessions, without wasting participants' time
- The ability of the participants in terms of the sample to complete the instrument must be considered

14.4.1.4 Consideration must be given to what the data will be used for, in particular who will need access.

- It must be clear in the informed consent form what the data will be used for. The researcher must not go beyond this stipulation without further permission to do so.
- It must be clear who will be working with the data - access must be granted to those persons only.
- There must be adherence to time limitations from a particular source

14.4.1.5 Consideration must be given to the necessary permission to gather data; who owns the data and with whom will data will be shared in future

- Informed consent must be obtained from each participant
- SOP 15 must be followed in terms of informed consent procedures
- The policy on Research Ethics should be followed where gatekeepers (all Managers) or organisational structures are approached for written permission to access or collect data for research

14.4.2 Identifying the mechanism for capturing the data

- The step by step method of data collection must be outlined.
- The procedures for each data collection instrument to be used in the study must be described.

14.4.3 Outline the infrastructure and mechanisms to store the data

- The researcher must be clear on how numeric data will be coded
- Data storage systems such as spreadsheets, text documents (narratives or verbatim transcripts) and computer storage must be specified
- The following questions should be asked:
    - Will storage be centralised or stored on site?
    - Where will the data be stored?
    - What is the timeline for data collection and storage?
    - How much storage is needed?

- How is the system secured?
- In which format will the data be stored?
- Will any software to read, analyse or process the data be used and why?
- Who will be responsible for the data?

14.4.4 Describe data security

- Describe the secure network system in which passwords and documentation to ensure an audit trail to capture changes is clear.
- Protect the participant by de–identifying personal information where necessary.
  - Remove all identifying information from the data to protect anonymity and ensure confidentiality.
  - Use codes or numbers (issued at recruitment) to confirm who the participants were if necessary.
  - Maintain a master file of names to be stored securely, but separate from the data in password protected data base.
- Maintain management programmes to ensure regular backup of data.
- Maintain strong access control with unique IDs for every person who has permission to access the data.
- Formulate criteria for electronic signatures.
- Management procedures for informed consent:
  - Signed consent forms should be kept with the researcher
  - Signed consent forms should be stored separately from the data and secured for five years.
  - In cases of verbal consent, it must be recorded and the records stored as indicated above

14.4.5 Standardising data entry, checking and validation

- Data entry should be very specific pertaining to how missing variables will be coded and inconsistencies dealt with.
- Details must be available on how regularly data will be updated.
- The date that the data was captured should be indicated on top of each questionnaire.
- Cleaning and validation of the data is important and checks should be run as a quality assurance measure.

14.4.6 Strategy for backing up data

- The strategy for backing up data must be clearly indicated.
- It must be indicated if data will be backed up manually or on the systems.
- It must be clear how lost data will be recovered if disaster strikes.

14.4.7 Auditing data

- Audits may be conducted to determine if the data was gathered as was indicated in the research proposal that was approved by Life Healthcare HREC.
- Regularity of audits might be indicated.

14.4.8 Data analysis

- Data cleaning might influence the analysis and should be considered.
- Revision of missing values should be considered in numeric data.
- Member checking should be considered in qualitative data.

14.4.9 Archiving and destruction of data

- Data should be stored for a period of five years as is indicated in Life Healthcare policy guidelines as stipulated in the Archiving of documents.
- Data should be easily retrievable.
- Data should be kept de-identified and separate from consent forms.
- When destroyed, it must be completely destroyed.
- Data on paper format should be shredded.
- Data in electronic format should be destroyed by overwriting or reformatting.
- Audio-visual data should be degaussed through a magnetic field bulk eraser.
- Data that might be permanently kept includes but is not limited to:
    - Controversial or high public interest.
    - Costly or impossible to reproduce.
    - Relates or support the development of an innovative intervention.
    - Support patent application or other services.
    - Has long-term heritage, historical or cultural value.
    - Is of significance to other researchers.

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)

- SOP_4.0.0-121203, Study documentation and data management, Phycology-Oncology cooperative research group, The University of Sydney, Australia
- SOP for Data Management, Collection and Storage, HSREC Department of Health Studies, Unisa, 2017

15. SOP FOR INFORMED CONSENT

Life Health Care Research Ethics Committee	
Title	SOP for informed consent
SOP	SOP 15- Life Healthcare -REC-002
Date of Approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	December 2021
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COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**12.05.2018**	
Revised by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
14 May 2018	001	Development of the document
14/ 12/2021	002	Document revised

15.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines on the processes researchers are required to follow to obtain informed consent from participants taking part in research within the Life Healthcare context. Recorded data should be durable and appropriately referred to by the researcher.

15.2 SCOPE

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

15.3 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.

15.4 PROCEDURE

15.4.1 Principles

- Personal information must be collected in compliance with the Protection of Personal Information Act 4 of 2013.
- The **participation of individuals must be based on voluntary informed consent** and participants must be able to withdraw their participation without providing reasons or the imposition of penalties.
- Participants must give their consent in writing and where possible must be accompanied by their signature.
- If participants are unable to write or prefer not to give written consent, verbal consent can be recorded.
- If the research is done on-line or electronically, informed consent can be obtained electronically.
- Participants or respondents must be provided with verbal and written information containing adequate details of the research including:
    - The purpose of the research
    - The possible risks involved
    - Aspects of privacy and confidentiality
    - Aspects of data sharing
    - Possible harm
    - Possible benefits
    - Freedom to withdraw without penalties
- Consent for participation is freely given and informed if
    - it is given without any direct/indirect coercion or inducement.
    - prospective participants/respondents have been well informed as indicated

- prospective participants/respondents have understood the information and have indicated same by signing the consent letter
- the researcher/fieldworker has answered any question(s) about the research and their participation.
- it is given before research commences.

- If research is conducted in a foreign country, the relevant standards as set out in SOPs will take precedence and must be adhered to.

15.4.2 Procedures

- Compile an information letter
- Ensure that the information letter includes, but is not limited to the following:
  - The details of the researcher
  - The purpose of the study
  - The reason why the participant has been selected as a potential participant and the contribution he/she can make to the research
  - Information about the right to choose to participate
  - The right to withdraw without penalty
  - Aspects of incentives or remuneration
  - Privacy, anonymity and confidentiality
  - Data storage and sharing
  - Publication of results
  - Possible harm or risks involved
  - The right to receive the results
  - Contact details of Life Healthcare HREC in case of adverse events or misconduct
  - Invite questions from the respondent or participant regarding the information communicated to them
- Ensure that the consent to participate is attached to the information letter
- Ensure that the participant has received a copy of the participant information sheet as well as the consent to participate section well in advance of the study commencing to allow for enough time for the respondent or participant to study the document and make an informed choice
- If the participant cannot read, the researcher should ensure that

- an impartial witness is present when explaining the content of the documentation to the respondent or participant.
- The witness is required to attest to the fact that the researcher/fieldworker has accurately explained the information and that the participant has apparently understood the information presented to him/her and that consent thereafter was freely given.
- The witness may be a family member or friend or colleague but who is not involved in the design, data gathering or reporting of the study.

- If the participant cannot speak English:
  - An interpreter, fluent in English as well as the language understood by the participant, must explain the information letter.
  - The interpreter may be a family member, friend or colleague but who is not involved in the design, data gathering or reporting of the study.
  - The details of the information letter should be explained to the participant in such a manner that the participant can make an informed decision on what it would be like to participate in the study and to consider if this is what they want to do.
- Provide enough time for the participant to discuss or consider the information given to him/her
- Verify the information provided to the participant by checking whether the participant:
  - Understands the information given by the researcher
  - Does not feel pressured to make a decision to participate or not
  - Understands that there is a voluntary choice to participate
  - Understands that they may withdraw at any time
  - Is able to make and communicate an informed choice

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy

16. SOP FOR MANAGEMENT OF CONFLICT OF INTEREST AND CONFIDENTIALITY

Life Health Care Research Ethics Committee	
Title	SOP for the management of conflict of interest and confidentiality
SOP	SOP 16- Life Healthcare -REC-002
Date of Approval	14 may 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
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COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**14.05.2018**	
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Authorised by:	**S. Vasuthevan**	**14.12.2021**	

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14 May 2018	001	Development of the document
14 December 2021	002	Document revised

16.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide a framework to establish a procedure to promote free, unbiased decision-making of the Life Healthcare HREC based on integrity, dignity (fairness, transparency, care and respect) and accountability.

16.2 SCOPE

This SOP covers the responsibilities and procedure(s) to be followed by the Life Healthcare HREC members to foster ethical decision-making that is free from inappropriate influence. In addition, it covers the responsibilities of Life Healthcare HREC members to respect the privacy rights of researchers regarding confidentiality.

16.3 RESPONSIBILITIES

The chairperson, deputy chairperson, administrative officer and every Life Healthcare HREC member must be aware of the conflict-of-interest procedure.

16.4 PROCEDURE

16.4.1 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 Life Healthcare HREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided or mitigated.
- Only members without conflict of interest may participate in the review, deliberations or voting process.
- Life Healthcare HREC members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest as part of their research ethics review role including the following:
    - Relationship to the research study: The Life Healthcare HREC member (his/her spouse or immediate family member) is the principal researcher or co-researcher of the research under review by the Life Healthcare HREC.
    - Financial interest: The Life Healthcare HREC member has a financial interest related to the research that could be affected by the outcome of the research under review by the Life Healthcare HREC. These might include equity holdings, for-profit consulting arrangements or payment or expectation of payment derived from intellectual property rights (e.g. patent royalties); payments received from for-profit service or associated with the funders of the research project.
    - Personal relationship and/or loyalty to colleagues: The Life Healthcare HREC member has a personal relationship with the principal researcher, peers, subordinates or superiors involved in the research under review by the Life Healthcare HREC.

- Business relationship or affiliation: The Life Healthcare HREC member serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the Life Healthcare HREC.
- Personal biases: Members who share similar subject fields or research niche areas may show more leniency or act overly critical than they might to other areas with which they are less familiar. Both these personal biases are not conducive to the objective review or by the Life Healthcare HREC.

- The chairperson of the Life Healthcare HREC requests members to declare conflicts of interests at the start of all meetings.
- When a member of the Life Healthcare HREC identifies real or perceived conflicts of interests, he/she should declare the conflict of interest upfront to the chairperson when requested to act as a reviewer or during the discussion of the review at a meeting or any formal deliberation relevant to the review. The member concerned should recuse herself/himself from the review process or from the meeting at that time.
- The chairperson and committee shall determine whether a conflict exists. The determination of whether or not a conflict exists shall be reflected in the minutes together member recusals against the relevant items.
- The chairperson may similarly become involved in a situation of potential conflict of interest. In this case he/she should discuss the matter with the Committee, or the chairperson of the next level of Ethics Review Committee, whichever is seen to be most appropriate. In the event that the conflict of interest involves the chairperson, he or she will appoint the vice-chairperson, or another member as acting chairperson (with approval of the committee). The acting chairperson will conduct the meeting, for the remainder of the discussion, of the item in question.
- Life Healthcare HREC members who have a conflict of interest related to any research that the Life Healthcare HREC is about to consider will refrain from participating in any discussion of the protocol or related matters, except to the extent necessary to provide relevant factual information requested by the chair.
- Unless requested by the chairperson to provide such information to the Life Healthcare HREC, the member with a conflict of interest will leave the meeting during the discussion and voting process i.e. will not be counted toward the quorum. The Life Healthcare HREC member's absence will be documented in the minutes with the indication that a conflict of interest was the reason for the absence. The outcome of the committee decision in the

absence of the recused member will not be discussed upon return of the member concerned but may be conveyed after closure of the meeting.

REFERENCES

- Department of Health Studies, SOP for conflict of interest
- South Africa. Department of Health. 2015. Ethics in Health Research: Principles, Processes and Structures
- University of Stellenbosch. 2016. Standard Operating Procedures and Guidelines, V4: Health, Research Ethics Committee 1 & 2.

17. SOP FOR COMPLAINTS PROCEDURE

Life Health Care Research Ethics Committee	
Title	SOP for complaints procedure
SOP	SOP 17- Life Healthcare -REC-002
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Action	**Designated person**	**Date**	**Signature**
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Authorised by:	**S. Vasuthevan**	**14.12.2021**	

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14 May 2018	001	Development of the document
14 December 2021	002	Document revised

17.1 PURPOSE OF THE SOP

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.

17.2 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.

17.3 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.

17.4 PROCEDURE

17.4.1 Procedure for complaints from researchers about a Life Healthcare HREC – issue

17.4.1.1 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.

17.4.1.2 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 Deputy Chair of HREC and then Chief Executive Officer.

17.4.1.3 The written complaint will initiate the following process:

- 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 in an attempt 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 process will be as described below*:
  The Life Healthcare HREC Chairperson shall convene a meeting as soon as possible with the complainant/s and the Chief Executive Officer to discuss the complaint to find an amicable/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 aforementioned 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.

17.4.2 Complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher

17.4.2.1 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.

17.4.2.2 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.

17.4.2.3 The chairperson of the Life Healthcare HREC shall immediately notify the Chief Executive Officer of the complaint, as a professional courtesy. Within a week of receiving the complaint, the chairperson of the Life Healthcare HREC shall call a meeting with the complainant and thereafter with the researcher.

17.4.2.4 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 Chief Executive Officer.

17.4.2.5 Should this not be achievable, a final meeting between all parties mentioned previously, as well as the of the Chief Executive Officer will be called as soon as possible in an attempt to find a solution.

17.4.2.6 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.

17.4.2.7 The HSREC chair shall keep a register of all the complaints and the outcomes of each complaint.

17.4.2.8 If the Executive Management committee 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.

REFERENCES

- Department of Health Studies, SOP for complaints
- North West University Faculty of Health Sciences Ethics Office SOP for complaints management, available at http://health-sciences.nwu.ac.za/sites/health-

sciences.nwu.ac.za/files/files/Health_Ethics/TOR%20&%20SOPs/5%20SOP%20for%20complaints_1.5_AL.p df accessed on [18.05. 2018].

18. SOP FOR CONDUCTING A ROUND ROBIN

Life Health Care Research Ethics Committee	
Title	SOP for conducting a round robin
SOP	SOP 18- Life Healthcare -REC-003
Date of Approval	August 2019
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	27 March 2024
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**G. Ure**	**August 2019**	
Revised by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**	**14.12.2021**	
Revised by	**E. Ricks**	**27 March 2024**	
Authorised by	**N. Tathiah**	**27 March 2024**	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
August 2019	001	Development of the document
14 December 2021	002	Document revised
27 March 2024	003	Document revised

18.1 INTRODUCTION

In the absence of a quorum being available for a Life Healthcare Health Research Ethics Committee, or in the case where there are sufficient grounds to warrant allowing an extenuating circumstance for approval outside of the meeting schedule, a round robin may be conducted.

18.2 Scope

The scope of this procedure is to gain a majority decision on medium and high risk research proposals submitted for approval to the Life Healthcare HREC when a formal meeting of either cannot be convened. A round robin will be conducted to ensure that potential researchers are not put under time pressure by having to wait for the following round of research meetings. This process ensures that a majority consensus on the acceptability of the research can be acquired.

18.3 PROCESS

18.3.1 Indications

A round robin may only be held under the following circumstances:

a) When there is an absence of a quorum for a regular Life Healthcare HREC meeting, or
b) When there are extenuating circumstances which make it necessary to divert from the normal time frames and process. For example, a researcher would like to take advantage of a specific unanticipated event, or not often seen phenomenon which might occur rarely, for example, a natural disaster.

18.3.2 Extenuating circumstances

In the case of a request to accelerate a review and the ethics review process due to time limitation, or an unforeseen circumstance, the researcher must provide a written motivation to the Chairperson validating the request, and demonstrate that there are indeed extenuating circumstances which would require initiating an ad hoc process. If the motivation is not sufficient, the Life Healthcare HREC reserves the right to decline the request, and no correspondence or discussion will be entered into. The application will be added to the next round of reviews for processing.

18.3.3 Process

The full document application pack submitted for approval is made available to Life Healthcare HREC members for their respective meeting via email to all members.

Each committee member is allocated the responsibility of reviewing the submissions for scientific rigour and ethical concerns, legal compliance and the potential for risk and harm to

the participants for the Life Healthcare HREC.

The round robin feedback provides a synopsis of the research, and provides space for the committee member to make comments, request further information and indicate their decision.

The forms are then returned to the research office, who then collates the information into a composite resolution to be ratified at the following meeting of the Life Healthcare HREC.

The decision reached by the round robin will be considered as carrying the same weight as a discussion at a full Life Healthcare HREC meeting.

REFERENCES

Legal and other references

- Department of Health. 2019 South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition
- World Health Organisation. 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

19. SOP FOR CONDUCTING AN EXPEDITED REVIEW

Life Health Care Research Ethics Committee	
Title	SOP for conducting an expedited review
SOP	SOP 19- **Life Healthcare** -REC-002
Date of Approval	August 2019
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	31 January 2022
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Action	**Designated person**	**Date**	**Signature**
Compiled by:	**G. Ure**	**August 2019**	
Checked by:	**E. Ricks**	**22.01.2022**	
Authorised by:	**S. Vasuthevan**	**22.01.2022**	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
August 2019	001	Development of the document
January 2022	002	Revised the document

19.1 INTRODUCTION

Under specific circumstances, low/minimal risk research proposals may be considered for expedited review, in compliance with the relevant national legislation and guidelines.

19.2 SCOPE

The scope of this procedure is to work efficiently in ensuring that proposals that pose no more than minimal risk of harm to both/ either research participants, staff or communities are reviewed thoroughly, while not expending valuable resources and time.

Minor changes to proposals which do not alter the content materially, may allow proposals to be expedited on provision of requested alteration and information. Medium and high risk proposals may not be expedited.

19.3 DEFINTION

Expedited review is a review which occurs involving a representative of the Life Healthcare Scientific Research committee and Life Healthcare HREC, usually in consultation with the Chairperson. The review occurs in the same way as a full review. The process of approval can be accelerated through expedited reviews.

19.4 PROPOSALS FOR EXPEDITED REVIEW

19.4.1 Proposals included for expedited review

- Low risk proposals may include, but are not limited to the below categories:
    - Research which does not involve direct interaction with human participants.
    - Research which does not include vulnerable subjects or special groups.
    - Research which does not involve deception.
    - The research comprises study of normative information available in the public domain. This is research about people in the public arena using only information that is publicly available or accessible without interacting with the individual/s themselves.
    - Research which involves secondary use of data that was been collected separately from the research that the researcher will be doing, and which has already been anonymised so that none of the information can be linked to a specific individual.
    - An expedited review may also take place when there are minor changes to be made to an approved research project during the authorised time period of the approval.

19.4.2 Proposals excluded from expedited review

- An expedited review may not be used in the following instances and does not exclude an attendant low risk of harm:
    - Where there is a risk that identification of subjects and/ or their responses may place them at risk of liability, whether civil or criminal action.
    - Where the participant may be placed at risk of personal damage, whether reputational or financial.

- Any risks related to invasion of privacy, or breach of confidentiality due to this research must be minimal.
- Any research that involves human participants whether it is low risk.

N.B. If there is doubt whether a research proposal can be expedited or not, it must preferably be referred for full review.

19.5 PROCESS

- An HREC member and a member from the Scientific Research Panel will be tasked by the research manager after consultation with the Chairperson to review the proposal for scientific and ethical rigour.
- Once the proposal has been reviewed, an outcome in writing will be provided to the Chairperson.
- The Chairperson will review the outcome, and, in the case of the proposal having been accepted without due concern, will be approved, and ratified at the next formal meeting of the HREC.
- In a case of the Chairperson and the committee member being unsure about a finding, the proposal will be referred to a full Life Healthcare HREC meeting.

REFERENCES

Legal and other references

- Department of Health. 2015. Ethics in Health Research: Principles, Processes and Structures.
- Department of Health. 2019 South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition
- World Health Organisation. 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

20. SOP FOR DOCUMENTS AND RECORDS MANAGEMENT AND CONTROL

Life Health Care Human Research Ethics Committee	
Title	**SOP for Documents and records management and control**
SOP	SOP 20- Life Healthcare -HREC-001
Date of Approval	28 March 2023
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee
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Pages	6 pages

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled by	**E.J. Ricks**	**28 March 2023**	
Authorised by	**S. Vasuthevan**	**28 March 2023**	

DOCUMENT HISTORY

Date	Version number	Reason
28 March 2023	**001**	**New SOP**

20.1 INTRODUCTION

Legal and ethical requirements regarding the protection of human participants in research require that records collected during the research process should be retained in an orderly manner and be easily accessible for future reference and audit purposes. A distinction must be made between data collected during a clinical trial versus other types of research to adhere to additional legal requirements associated with SA GCP guidelines.

The Documents and Records Management and Control Standard Operating Procedure (DRMC SOP) has been developed for the purpose of ensuring uniform records management and control to standardise administrative procedures and ensure consistency throughout the Life Healthcare Research Office and HREC. It is further aimed at increasing efficiency and effectiveness regarding all document management and record keeping associated with the Life Healthcare

HREC. For the successful implementation of the DRMC SOP it is imperative for the Research Office to have sufficient human and physical resources assigned by the overarching institution.

20.2 PURPOSE OF SOP

The purpose of the documents and records management and control process is to establish and implement control measures that will ensure easy accessibility and circulation of documents. The DRMC SOP also provides guidance on adequately creating, keeping, managing, retrieving, archiving and destroying records including those held electronically.

20.3 SCOPE

The scope of this SOP is to outline the responsibilities and requirements of the Chairperson, research manager, and administrative assistant of the Life Healthcare HREC, in terms of documents and records management as well as the procedure to be followed, from capturing and registration of an application, through to naming, filing, storage and disposal. Responsibilities are set out for each one of the aforementioned individuals. 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.

Consideration is to be given to the National Department of Health (DOH) Core Standards related to record keeping and Life Healthcare's Control of Documents, Doc. No: QMS-WP-QUA-002.

An HREC documentation management system collects, stores and provides data to meet the DOH and NHREC needs. Confidential information is handled in line with data protection policies and legislation such as POPIA. Research applicant's information is accurately and completely recorded according to DoH guidelines for research, legal and ethical requirements. An efficient system must be in place to archive and retrieve HREC records or research applicants' files.

20.4 ROLES AND RESPONSIBILITIES

The roles and responsibilities of the Chairperson, research manager and the administrative assistant regarding document and record management and control will be highlighted below.

20.4.1 HREC Chairperson

20.4.1.1 Mandating the Research Manager to implement the DRMC SOP in the Research Office.

20.4.1.2 Facilitate internal documents and records management and control audits annually

20.4.2 Research Manager

20.4.2.1 Ensuring that management of documents/records comply with the Document Management and Control Standard Operating Procedure.

20.4.2.2 Promoting effective and efficient management of Life Healthcare HREC records in compliance with DoH guidelines and DRMC SOP by conducting checks together with the administrative assistant on all research folders on Ulwazi and immediately managing gaps.

20.4.2.3 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
    - Appointment letters
    - Codes of conduct
    - Non-disclosure
- Signed HREC appointment letters

- Signed Codes of conduct for HREC members
- Signed Non-disclosure agreements

20.4.2.4 Safe custodies and keeping of records, compliance to DRMC SOP

20.4.2.5 Ensuring that versions of documents are aligned on various platforms records management website

20.4.2.6 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

20.4.2.7 Supervising administrative assistant to ensure that documents and records are filed correctly.

20.4.3 **Administrative assistant is responsible for:**

20.4.3.1 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

20.4.3.2 Create a folder for each applicant with sub-files as follow:

- Documents submitted
  - Proposal
  - Ethics clearance
  - Recruitment materials
  - Consent documents
  - Completed Life Healthcare HREC application
  - Letter from SAHPRA for clinical trials

- Documents reviewed
- Reviewers reports
    - Proposal with track changes (if reviewer used track changes)
- Corrected documents
    - Corrected documents returned by researcher
- Outcome letters
- Monitoring and evaluation

20.4.3.3 A folder comprising all the applicants for each month from February to November for each year be developed and placed on Ulwazi.

20.4.3.4 Minutes and Agenda to be signed by chairperson and placed in each month's folder

20.4.3.5 Copy of attendance list of HREC meetings

20.4.3,6 Compliance to records systems, i.e. usage and allocation of correct HREC reference numbers;

20.4.3.7 Upload documents onto the Ulwazi

20.4.3.7 Control of any incoming and outgoing mail;

20.4.3.8 Ensure proper care and custody of documents/records.

20.4.3.9 Compliance with the DMC standard operating procedure and other HREC records management policies of Life Healthcare.

20.5 RECORDS STORAGE AND MAINTENANCE

20.5.1 Maintenance and storage of records related to ToR, SOPs, Research Policy, and Templates will be the responsibility of the research manager. The research manager will also be responsible for arranging with the Marketing Department to share the documents on the research website.

20.5.2 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.

a) All records that have been received/created must be stored in a safe environment, such as Ulwazi, which is conducive for preservation of records.

REFERENCES

- Department of Health. 2011. National Core Standards for Health Establishments in South Africa (Abridged version). The Republic of South Africa, 2011 Department of Health Private Bag X828 Tshwane 0001 Tel +27 (0) 12 395 8000. http://www.doh.gov.za
- Department of Health. 2015. Ethics in Health Research. Principles, Processes and Structures. Department of Health: South Africa
- Life Health Care. 2018. Control of Documents. Doc. No: QMS-WP-QUA-002.

21. SOP FOR CONDUCTING AN INTERNAL AUDIT

Life Health Care Human Research Ethics Committee	
Title	**SOP for conducting an internal audit**
SOP	SOP 21 -Life Healthcare-HREC-002
Date of Approval	28 March 2023
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee
Revision date	March 2024
Pages	4 pages

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled by	**E.J. Ricks**	**23 March 2023**	
Authorised by	**S. Vasuthevan**	**23 March 2023**	
Reviewed by	**E. Ricks**	**27 March 2024**	
Authorised by	**N. Tathiah**	**27 March 2024**	

DOCUMENT HISTORY

Date	Version number	Reason
28 March 2023	**001**	**New SOP**
27 March 2024	**002**	**Revised**

21.1 INTRODUCTION

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 NHREC policies and DoH Guidelines, the Life Healthcare HREC should ensure that there is a process/system in place for conducting internal audits.

21.2 PURPOSE OF SOP

The purpose of this SOP is to provide a framework that could facilitate the conducting of an internal audit to ensure compliance with the regulatory requirements, protocol, SOPs and GCP guidelines. An internal audit process will also prepare the Life Healthcare HREC for external audit processes.

21.3 SCOPE

This SOP defines the internal process to be followed by the appointed auditors for the Life Healthcare HREC internal audit.

21.4 ROLES AND RESPONSIBILITIES

The Life Healthcare HREC will appoint two 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.

21.4.1 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.

21.5 PROCEDURE

21.5.1 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 the Life Healthcare SOP for Conducting an Internal audit.

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.

21.5.2 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.

21.5.3 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.

21.5.4 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.

21.5.5 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.

REFERENCES

Department of Health. 2015. DoH Ethics in Health Research: Principles, Processes and Structures.

22. SOP FOR EXTERNAL RESEARCHERS WHO HAVE RECEIVED PRIOR ETHICAL APPROVAL FROM A NHREC REGISTERED HREC REQUESTING TO CONDUCT HEALTH OR HEALTH-RELATED RESEARCH AT LIFE HEALTHCARE FACILITIES

Life Health Care Human Research Ethics Committee	
Title	SOP for external researchers who have received prior ethical approval from a NHREC registered HREC requesting to conduct health or health-related research at Life Healthcare facilities
SOP	SOP 22- Life Healthcare -HREC-001
Date of Approval	28 March 2023
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee
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COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by	**E.J. Ricks**	**23 March 2023**	
Authorised by	**S. Vasuthevan**	**28 March 2023**	

DOCUMENT HISTORY

Date	**Version number**	**Reason**
23 March 2023	**001**	**New SOP**

22.1 INTRODUCTION

The Life Healthcare HREC receive many application requests from researchers who have received prior ethics approval from a registered NHREC HREC to conduct health or health-related research at Life Healthcare facilities. Many of the applicants are registered with various universities in South Africa for their undergraduate research component or post-graduate research degrees such as Honours, Masters or PhDs. Some of the applicants are medical doctors affiliated to various sponsors and external organizations. Applications for permission to conduct research at Life Healthcare facilities will only be considered if the applicants submit their full final proposals, ethics clearance from a registered NHREC HREC and all other the necessary addendums, e.g. an approval letter from SAHPRA for clinical trial applications.

22.2 PURPOSE OF SOP

This SOP guides external researchers planning to conduct their research studies at Life Healthcare facilities on how to apply for permission via an expedited review process by the Life Healthcare HREC and Scientific committees to ensure that the scientific and ethical aspects of the research within this specific context have been addressed. It will guide the aforementioned external researchers in the process of obtaining permission needed from the Life Healthcare HREC. If staff or patients of Life Healthcare are to be included in the research, the external researchers will have to obtain further gatekeeper permission from the Hospital, Nurse and Unit Managers of the respective hospitals.

22.3 SCOPE

This SOP is to be used by external researchers that have already obtained research ethics approval from another registered NHREC HREC that plan to undertake health or health related research at Life Healthcare facilities and would like to use Life Healthcare data bases, documents, staff and/or patients as their research participants. This SOP describes the process that should be followed to obtain permission and ethics approval from Life Healthcare HREC. In cases of wanting to include staff and/or patients, gatekeeper permission will also have to be obtained from the Hospital, Nurse and Unit Managers as well. It guides Life Healthcare HREC in the expedited review process that should be followed to ensure that the context of the research is applicable to Life Healthcare.

22.4 ROLES AND RESPONSIBILITIES

There are numerous stakeholders involved in this process:

- The external researcher should follow the application process as outlined in this SOP to ensure the timely approval of their request to conduct health or health-related research or access the staff and/or patients or documents or databases of Life Healthcare. The researchers must ensure that the context of Life Healthcare is well understood and correctly applied during the conduct of their research.
- It is the responsibility of Life Healthcare HREC to ensure that the external request is reviewed in an expedited manner, the context correctly described and applied and that any feedback is sent timeously to the external researcher.
- The administrative staff of Life Healthcare HREC are responsible for ensuring the

effective processing of the external request, communicate effectively with the researcher, as well as timeously communicating the outcome of the review by the HREC to the researcher directly.

- The Life Healthcare HREC is responsible for ensuring that both staff and patients of Life Healthcare and their data are dealt with in a legally appropriate manner, when being included in research.

22.5 PROCEDURE

22.5.1 The external researcher provides the following documentation together with the application request:

22.5.1.1 A clear and systematic cover letter addressed to the chairperson of Life Healthcare HREC indicating:

22.5.1.1.1 the title of the study

22.5.1.1.2 the names of the researchers involved

22.5.1.1.3 that it is a request with prior NHREC registered REC approval for an expedited review process

22. 5.1.1.4 that the request is for health or health-related research or to include staff and/or patients or documents or databases of Life Healthcare

22.5.1.1.5 listing the documents that are attached to the application

22.5.1.1.6 any further explanation needed to clarify the submission

22.5.1.2 A copy of the ethically approved research proposal

22.5.1.3 A copy of the ethics approval certificate obtained from the external NHREC registered REC

22.5.1.4 A copy of the informed consent form that will be used in the study

22.5.1.5 A copy of the questionnaire(s) or interview schedule(s) or spreadsheets

22.5.1.6 Copies of any other documentation that will be used in the recruitment process e.g. advertisements, recruitment flyers

22.5.1.8 Checklist for the submitted documentation.

22.5.2 The application request, addressed to the chairperson of the Life Healthcare HREC, should be sent to Research@lifehealthcare.co.za with the email subject line indicating "Research ethics application for the expedited review of a prior approved study". Each of the aforementioned documents should be attached as separate documents to the e-mail.

22.5.3 The application will be handled via the expedited review process.

22.5.4 The administrative staff of the Life Healthcare HREC, within three working days, sends the application request to the chairperson of the Life Healthcare HREC.

22.5.5 The chairperson of the Life Healthcare HREC, within three working days, assigns at least two reviewers (one from HREC and one from the Scientific Committee) and returns it to the administrative staff.

22.5.6 The administrative staff, within two working days, distributes the application accordingly to the assigned reviewers.

22.5.7 The reviewers have three working days to complete the review and send their feedback back to the administrative staff of Life Healthcare HREC.

22.5.8 The administrative staff within three working days consolidates the feedback into a formal response and forwards it to the Life Healthcare HREC chairperson for approval and returns it to the administrative staff of the Life Healthcare HREC.

22.5.9 The administrative staff of the Life Healthcare HREC within three working days sends the formal response to the external applicant researcher.

22.5.10 If corrections are requested, the external researcher should make the suggested changes and as soon as possible send the amended documentation to Research@lifehealthcare.co.za

22.5.11 A letter should be attached to the amended documentation by the researcher indicating:

- what changes have been made,
- how the queries have been addressed, and
- where the changes were made in the documentation.

22.5.13 Furthermore the changes should be highlighted in all the amended documents as well.

22.5.14 The Life Healthcare HREC administrative staff will re-distribute the amended application to the same reviewers that were previously assigned, who will be given three working days to complete the review of the corrections.

22.5.15 The reviewers will again send their feedback to the administrative staff of the Life Healthcare HREC who will, in turn consolidate the feedback, send it to the Life Healthcare HREC chairperson.

22.5.16 The Life Healthcare HREC chairperson will send a formal response to the administrative staff of Life Healthcare HREC.

22.5.17 The administrative staff of the Life Healthcare HREC, within three days, sends the formal response to the external researcher.

22.5.18 If the application is for health or health-related research, a letter will be sent to the researcher indicating approval of the study to be conducted at Life Healthcare Facilities.

22.5.19 If the application has been approved for research that includes staff or patients of Life Healthcare, the researcher must also obtain approval from the relevant gatekeepers. The external researcher will be furnished with a letter from Life Healthcare HREC indicating that the study has been approved and permission granted for the study to be conducted at Life Healthcare facilities. The approval letter obtained from the Life Healthcare HREC must be attached to the application for obtaining permission from the gatekeepers.

22.5.20. Once permission is obtained from the respective gatekeepers, the researcher can then continue to recruit participants as per the approved proposal.

Checklist for the application documentation

Attached Documents	**Attached (Indicate yes, no or NA)**
A clear and systematic cover letter	
A copy of the ethically approved proposal of the research study	
A copy of the initial completed ethics application form that was submitted to the Primary HREC	
A copy of the ethics approval certificate obtained from the external NHREC registered REC	
A copy of the informed consent form that will be used in the study	
A copy of the questionnaire(s) or interview schedule(s) or spreadsheet	
Copies of any other documentation that will be used in the recruitment process e.g. advertisements, recruitment flyers. Please mention:	
A copy of SAHPRA letter for clinical trial applications	
Checklist for the submitted documentation	

REFERENCE DOCUMENTS

- Department of Health. 2015. Ethics in Health Research. Principles, Processes and Structures. Department of Health: South Africa
- University of North West. 2021. SOP for the ethics application process for external researchers with prior ethical approval by a NHREC registered REC wanting to conduct health or health-related research at the NWU or wanting to include staff or students from the Faculty of Health Sciences of the North West University. SOP no 2.24_SOP_NWU-HREC_2.2 Version 1