HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE AND STANDARD OPERATING PROCEDURES

Prof E.J. Ricks and Dr S. Vasuthevan

26/01/2022

Life Healthcare

Making life better

TABLE OF CONTENTS

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 LHC HREC.
CIOMS	The Council for International Organizations of Medical Sciences
Confidentiality	Confidential information shall mean certain proprietary, personal, clinical or proposal-specific information, which the LHC 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.
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**.**
Fraud	Involves actions such as dishonesty or forgery that manipulate others into providing benefit that would normally not benefit that person.
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, LHC or a community at large**.**
LHC	Life Healthcare
LHC HREC	Life Healthcare Human Research Ethics Committee
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
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 LHC HREC or any member of LHREC) about any alleged research misconduct related or incidental to the execution of research

NB LHC HREC-TOR-ADMIN-002 *Life Healthcare Research Ethics Committee Terms of Reference* replaces LCL-Guide-REC-002 *Research Ethics Committee Constitution* in its entirety.

1. TERMS OF REFERENCE

1.1 Standard

All activities of the Life Healthcare Health Research Ethics Committee (LHC HREC) are carried out in line with international and national legislation, protocols and guidelines, as well as relevant Life Healthcare policies and procedures. All research activities approved by the LHC HREC will function seamlessly with the operations of Life Healthcare Group and should maintain the same levels of quality expected of the group.

1.2 Scope

In line with the National Health Act s73, all health institutions are required to establish Health Research Ethics Committees (HRECs) which will review all health related research, including but not exclusively, clinical trials, academic research, business, training or educational research, administration, management and human resource research activities where human participants are involved.

The Terms of Reference (ToR) of the LHC HREC must be read in conjunction with all Life Healthcare policies and procedures which may pertain to the research activities which may take place in Life Healthcare facilities. These ToR have been put in place to ensure alignment of all LHC HREC activities with, but not solely, the following national legislation and guidelines:

- National Health Act, Act No 61 of 2003
- Department of Health's Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, 2nd edition (2006)
- Protection of Personal Information Act (POPIA), No.4 of 2013
- South African Department of Health: Ethics in Health Research: Principles, Processes and Structures (2015) and international statements, declarations and protocols as below.
- The Australian National Statement on Ethical Conduct in Human Research (2007)
- The Council for International Organizations of Medical Sciences (CIOMS) (2002)
- The Council of Europe Steering Committee on Bioethics: Guide for Research Ethics Committee Members (2011)

- The Nuffield Council on Bioethics: Ethics of Research Related to Healthcare in Developing Countries (1999)
- The World Medical Association: Declaration of Helsinki (2013)
- The World Health Organization Operational Guidelines for Ethics Committees that review Biomedical Research (2000)
- The World Health Organization Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)
- The Montreal Statement (2013)
- The Singapore Statement (2010)
- Cartagena Protocol on Biosafety May 2000
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (2014)

1.3 Authority

The LHC HREC is registered with the National Health Research Ethics Council (NHREC) in compliance with the National Health Care Act 61 of 2003, section 73. The registration number is: REC-251015-048. The LHC HREC is mandated to carry out its activities in line with those outlined in the National Health Act, 61 of 2003. The LHC HREC reports to the National Health Research Ethics Council, and to the Life Healthcare Executive Management through the Nursing and Quality Executive, SA.

1.4 Mandate

The LHC HREC is mandated to review all health-related research proposals, which, as broadly defined by the South African National Health Act 61 of 2003, includes any research which may contribute to the broader body of health knowledge including:

- the biological, clinical, psychological or social processes in human beings, for example, Clinical trials, improving staff health and wellbeing or developing effective ways of communication across the business.
- improved methods for the provision of health services, which can include increased vigilance of patient confidentiality, better trained managers in hospitals, staff retention strategies, fair remuneration and skills improvement plans.
- human pathology and the understanding of human disease. These studies can include experimental pathology, and other means to aid the diagnosis of disease.

- the causes of disease and the progression of pathogens and internal dysfunction. Research into medical conditions that negatively affect humans, and which provide broader understanding of means to both treat and eradicate these disorders.
- the effects of the environment on the human body. These are often complex and may present as variously as a potential reaction of a gene to an environmental stimulus, because of environmental factors, for example poverty and social circumstances.
- the development of new applications of pharmaceuticals, medicines and related substances. New medications and pharmaceutical interventions are continually being trialled to gauge their efficacy in treating disease. Life Healthcare provides a controlled environment where these trials can take place effectively, thus aiding development of new drugs to combat disease.
- the development of new applications of technology which may have a positive impact on health, for example; patient monitoring applications in hospitals, new imaging techniques and equipment for use in oncology, these include, but are not limited to the areas of:
    - Medical and nursing
    - Pharmacy
    - Allied therapy – physiotherapy, occupational therapy, psychology, social work, dietetics, speech therapy
    - Engineering and facilities management
    - Business administration, including human resources, billing and record keeping
    - Environmental matters
    - Quality, patient safety and infection prevention
    - Policy development and governance
    - Management and executive functions
- Any person who could be either an employee of Life Healthcare or not affiliated to Life Healthcare in any way, may approach the LHC HREC for a review of a health-related research proposal. Correspondingly, any person may approach Life Healthcare and request to conduct health related research at a Life Healthcare facility.
- The LHC HREC may decide to review the proposal or may decide to refer the proposal to an alternative HREC, if the LHC HREC does not have the capacity or expertise to evaluate the submission appropriately. There may be a cost levied for ethical clearance review services provided to external applicants or projects.

1.5 Documentation

The LHC HREC will develop documents and standard operating procedures which will guide the activities of the LHC HREC to ensure that all processes are standardised and in line with required legislation. This is to enable the LHC HREC to operate in a non-discriminatory and fair manner, and to ensure that all proposals reviews and research activities take place uniformly. This includes an online application process, and forms, templates for reviews, round robins, clinical trial ratifications and any other documentation which may be required. All documents are to be document controlled and must comply with Life Healthcare's quality standards. These will be updated and reviewed every three years, or when necessary, to ensure that researchers are provided with the latest information and guidance.

1.6 Standard operating procedures (SOPs)

These have been developed to inform researchers and the business of research processes, obligations, operational requirements and reporting requirements. These SOPs are reviewed every two years, or sooner if necessary. These SOPs are designed to assist both researchers and the LHC HREC to comply with necessary national and international guidelines, as well as various relevant protocols and mandates. Information is to be made available on the Gateway, and internet and is to be communicated to the business via marketing and communication streams.

1.7 Operational scope

The function of the LHC HREC is to vigorously defend the rights, welfare and dignity of all human participants engaged in research related activities in Life Healthcare facilities. To do this, the LHC HREC must carry out the following:

1.7.1 Conduct prospective reviews of all potential research projects, including clinical trials and academic pursuits which occur at Life healthcare. No retrospective reviews are permitted. These reviews must be rigorous and must ensure that the rights, welfare, and all interests of both researchers and participants are protected. The research must also be in line with both national and international norms and standards.

1.7.2 Comply with generally accepted scientific and ethical norms and standards. The LHC HREC must approve, request modification or revision of, or reject any proposals which do not comply with recognised scientific and/ or ethical norms and standards.

1.7.3 All research carried out at Life Healthcare must be operationally feasible and may not undermine the daily activities of the unit in which the research occurs. It may not

incur unfair or unexpected costs for patients, healthcare funders or the business, and may not utilise any staff or resources which are paid for by Life Healthcare Group, without formal undertakings by both the researcher and the hospital manager/ function manager prior to the research approval process taking place.

1.7.4 The LHC HREC is required to provide an oversight function to both the NHREC and Life Healthcare Group management by ensuring that regular reporting is done. This must be done to ensure that there is ongoing monitoring of wellbeing and welfare of all participants.

1.8 Monitoring and adverse event management

1.8.1 All research must be conducted in line with accepted scientific and ethical principles. The LHC HREC must provide a monitoring function to ensure that research is conducted according to these norms.

1.8.2 Manage adverse events in line with processes required by the NHREC, relevant national and international legislation, policies and guidelines and quality reporting mechanisms managed by Life Healthcare.

1.9 Audits

Audits, or third-party audits will be carried out annually to verify that compliance is in line with norms and legislation, and with Life Healthcare policies and procedures.

1.10 Suspensions and terminations

Research which is not conducted in line with regulatory requirements, or which fail to meet ethical and scientific principles, or where there is harm to participants will be terminated immediately by the LHC HREC. If it is necessary, these projects will be referred to SAHPRA, the HPCSA or any other oversight bodies for further sanction.

1.11 Measurement and monitoring

Evaluation or Measurement method	Frequency	Area/Equipment	Indicator Methodology
Tools e.g. ▪ ***Audits***	▪ ***Annually***	▪ ***Research Specialist office***	▪ ***Researcher correspondence*** ▪ ***Meeting minutes***

1.12 Recordkeeping requirements

Record Number	Record Name	Retention Location	Retention Period	Disposal authority
LCL-Guide-REC-002	Research Ethics Committee Constitution	***Head of college office***	***2 years***	***LCLHREC Chairperson***
LHC HREC-TOR-ADMIN-002	Life Healthcare Research Ethics Committee Terms of Reference	***Research specialist office***	***2 years***	***LHC HREC Chairperson***

1.13 Document history

Revision	Date	Revision description	Compiled by / Revised	Approved by
0	***October 2017***	***New Document***	***P Naicker***	***S Vasuthevan***
1	***January 2021***	***Replacement Document***	***G Ure***	***S. Vasuthevan***

REFERENCES

- National Health Act, Act No 61 of 2003
- Australian Government NHMRC. (2018). *National Statement on Ethical Conduct in Human Research.* Retrieved 10 11, 2019, from https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
- Council for International Organisations of Medical Sciences. (2019). *International Ethical Guidelines for Health Related Research Involving Humans.* COIMS. Retrieved from https://cioms.ch/
- Department of Health, South Africa. (2015). Ethics in Health Research: Principles, Processes and Structures. Pretoria: South African Government.
- HPCSA. (2016). Guidelines for Good Practice in the Healthcare Professions. Booklet 11: Guidelines on overservicing, perverse incentives and related matters. Pretoria: Health Professions Council of South Africa.

2. WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURES

Life Health Care Human Research Ethics Committee (LHC HREC)	
Title	SOP for the establishment of SOPS
SOP	SOP 1-LHC-HREC - 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
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**14.05.2018**	**l. Roets**
Reviewed by:	**E.J. 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 December 2021	002	Reviewed document

2.1 PURPOSE OF THE SOP

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

2.2 SCOPE

The scope of this document covers the establishment of all new SOPs for the LHC 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.

2.3 RESPONSIBILITIES

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

2.4 PROCEDURE

- Should the need arise for the establishment of a new SOP for the LHC HREC a request must be submitted to the chairperson of the LHC HREC.
- The chairperson will review the request and authorise/decline the establishment of the SOP.
- The decision of approval/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-LHC-HREC-002, SOP for the establishment of SOPs and use the provided template.
- The LHC 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 LHC HREC – SOP x-LHC-HREC- version 00x
- When the first draft of the SOP has been written, the draft must be sent electronically to the Chairperson of LHC HREC. The version number of this draft will be indicated as Draft 00x.
- The SOP will be distributed to all members of LHC HREC.
- Any changes will be sent to the Chairperson to implement with the requestor.
- The SOP is finalised, approved and signed by all parties.
- After approval, the SOPs are placed on the LHC Webpage for easy access and a notice is sent to all LHC HREC members and LHC staff.
- 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 stringently.
- When a SOP becomes redundant it should be withdrawn and its withdrawal widely communicated.

2.5 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
- Abbreviations and/or definitions
- Responsibilities
- Procedure(s) to be followed
- Reference documents
- Addenda
- Any other elements essential to the specific SOP

REFERENCES

- North West University SOP for SOPs

3. SELECTION, APPOINTMENT AND FUNCTIONING OF LHC HREC MEMBERS

Life Health Care Human Research Ethics Committee (LHC HREC)	
Title	SOP for the selection, appointment and functioning of LHC HREC members
SOP	SOP 2-LHC-HREC - 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
Pages	5

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**20.04.2018**	**I. Roets**
Revised by:	**E.J.Ricks**	**14 December 2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
24 April 2018	001	Development of the document
14 December 2021	002	Revision

3.1 PURPOSE OF THE SOP

The LHC 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 purpose of the SOP is to provide a framework for the selection, appointment and functioning of members of the LHC HREC.

3.2 SCOPE

The LHC HREC is responsible for the review and approval of all research ethics applications, amendments to research proposals, applications requesting permission to conduct research in LHC facilities and the monitoring of research in the Life Healthcare Group. Research studies cannot be conducted in Life Healthcare facilities before an Ethics certificate is issued or permission granted by LHC HREC. Studies may not continue without the successful completion of the required monitoring report (six-monthly for medium and high-risk studies and annually for minimal risk studies).

The LHC HREC is notified in the event of any adverse event or any incident occurring during the research process that impacted the safety or wellbeing of participants.

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

3.3 RESPONSIBILITIES

LHC HREC is responsible for ensuring that researchers conduct research ethically, and of a high scientific standard.

3.4 PROCEDURE

3.4.1 Aim

The aim of the LHC 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.
- LHC 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.

3.4.2 Objectives

The objectives of the LHC HREC members are to:

- Review all research proposal applications and amendments for ethical and scientific rigor (See SOP 4-LHC-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.

3.4.3 Selection and appointment of members

The selection of the members is according to the composition requirements of the research ethics guidelines, section 4.1 (South Africa, Department of Health, 2004:15). 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.

CVs of all the LHC HREC members must be on file in the administrator's office.

3.4.3.1 Selection and appointment of the chairperson

When a vacancy such as the chairperson becomes evident, the Executive Management Committee of LHC in consultation with the LHC HREC members, suggests possible candidates, based on their experience as HREC members as well as knowledge of the scientific research process and research ethics. A qualification in research ethics is a requirement, or the intention that training will be completed within three calendar months after appointment as the chairperson. The chairperson of the Executive Management Committee of LHC and the current chairperson of the LHC HREC will have preliminary discussions with the prospective candidates regarding the roles and responsibilities of the chairperson. A final decision is made by the Chief Executive Officer and confirmed by Executive Management Committee. A formal appointment letter is sent by the LHC 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 LHC HREC. An acting chairperson can be appointed to act for a limited period of six months.

3.4.3.2 Selection and appointment of committee members

As soon as the LHC HREC becomes aware of a vacancy in a specific position, they make it known to the Executive Management of LHC who will invite nominations. The Chairperson of the LHC HREC will have preliminary discussions with the possible candidates regarding the roles and responsibilities of the specific position. A final decision will be taken at a LHC HREC meeting and confirmed by the Executive Management Committee of LHC. A formal appointment letter is sent

by the LHC 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 LHC HREC. The appointment letter must reflect the task agreement, of the LHC HREC member. The NHREC is notified of the change.

3.4.3.3 Co-opted members, observers and visitors

The LHC HREC may co-opt members as the need arises. 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.

3.4.3.4 Resignations

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

3.4.4 Training

LHC HREC members must have documented proof of research ethics training. Training and refresher courses should be available and members are expected to refresh their training at least once in their term of office.

3.4.5 Code of conduct

All LHC 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 LHC 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 75% of LHC 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 LHC HREC meetings to avoid potential conflict of interest.
- Keep all matters coming to their attention during LHC HREC meetings confidential.

3.5 FUNCTIONING OF THE COMMITTEE

3.5.1 Quorum for meetings

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.

3.5.2 Frequency of meetings

Monthly, except in the months of December and January. These applications will be reviewed and tabled for the meeting in February. 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. At least 5 working days prior to the 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.

3.5.3 Conflict of interest

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

3.5.4 Confidentiality

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 and (2) Unisa, Department of Health Studies.

4. PREPARATION FOR MEETINGS AND MEETING PROCEDURES

Life Health Care Human Research Ethics Committee (LHC HREC)	
Title	SOP for the preparation for meetings and procedures
SOP	SOP 3- LHC-HREC-002
Date of approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision date	September 2021
Pages	3 pages

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**28.04.2018**	**L. Roets**
Reviewed by:	**E.J. Ricks**	**09/09/2021**	
Authorised by:	**S. Vasuthevan**	**09/09/2021**	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
28 April 2018	001	Development of the document
09 September 2021	02	Revision of document

4.1 PURPOSE OF THE SOP

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

4.2 SCOPE

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

4.3 RESPONSIBILITIES

The LHC 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.

4.4 PROCEDURE

4.4.1 Preparation of meetings

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
    - Abstract in lay terms
    - All relevant documents
- Expedited research projects
- Progress reports
- Extension of the agenda

4.4.2 Meeting procedures:

- The LHC HREC meets monthly except in December and January 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.
- 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.

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.

5. REVIEW OF RESEARCH PROPOSALS

Life Health Care Human Research Ethics Committee (LHC HREC)	
Title	SOP for the review of research proposals
SOP	SOP 4-LHC-HREC-003
Date of approval	December 2018
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision date	September 2021
Pages	8 pages

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**28.04.2018**	**L. Roets**
Reviewed by:	**G. Ure**	**01.2021**	**G.Ure**
Reviewed by:	**E.J. Ricks**	**09/09/2021**	
Authorised by:	**S. Vasuthevan**	**09/09/2021**	

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
28 April 2018	001	Development of the document
January 2021	02	Revision of the document
09 September 2021	03	Revision of document

5.1 INTRODUCTION

The proposal review process is not intended to impede scientific progress or innovative research. It must be remembered that a HREC process is an informal 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. All research which involves human subjects must have HREC clearance.

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: Second Edition, 2006, all research proposals must be subjected to an independent ethics review by members of the LHC 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 LHC HREC process ensures that research proposals submitted uphold high levels of scientific rigor 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: Second Edition 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.

5.2 PURPOSE

All requests for approval to conduct academic research 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.

5.3 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 the Good Clinical Practice Guidelines 4.1.5.2, the LHC 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 RECs 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)

5.4 PROCESS

5.4.1 All applications for ethics approval must be submitted to the Research Specialist as PDF files via email to Research@lifehealthcare.co.za

5.4.2 A fully completed Application for approval to conduct research at Life Healthcare LCL-Form-REC-001 form must be submitted, signed and dated.

5.4.3 A copy of a higher education institution (HEI) ethics clearance certificate should accompany the application if ethics approval was obtained from another research ethics committee. If this clearance certificate is not present, the submission may be conditionally approved while the researcher awaits their university HREC approval. The HEI clearance certificate must be provided to the Life Healthcare HREC within three months of the conditional approval being received by the researcher, and an approval letter sent to the researcher before research begins. No research may take place until all conditions have been met.

5.4.4 A full research proposal must accompany the application.

5.4.5 A LHC APA 6th Edition toolkit is provided by Life Healthcare for this purpose. The proposal must include an abstract of not more than 300 words. All sections of the proposal must be completed.

5.4.6 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.

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

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

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

5.5 PROPOSAL REVIEW PROCESS

5.5.1 Only full document submissions will be reviewed. The only exception is if a HREC clearance is awaiting Life Healthcare approval and the student is therefore unable to provide this document. A conditional approval may then be given.

5.5.2 A two person reviewing team for each proposal will be selected by the administrator. Selection will be based on expertise and rotation to ensure that the review load of both the HREC and expert panel members remains fair and all proposals receive a full, fair review utilising the reviewers' rubric (See Addendum 2).

5.5.3 All documents will be uploaded onto the Gateway and the agenda will be set for the HREC meeting.

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

5.6 HREC MEMBERS

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

5.6.2 When 2 HREC members are on the team, the first listed HREC member is the team lead.

5.6.3 The HREC team leader member will be the de facto leader of the process although all members of the review team provide input into the final decision, which is then taken to the HREC.

5.6.4 The HREC team leader member will provide an overview of the proposal and feedback to the HREC meeting as to the final decision together with the second reader.

5.7 REVIEWERS

5.7.1 Two (2) reviewers are chosen from the combined list of both HREC members and content experts if necessary, to review each proposal.

5.7.2 The content expert reads through the documents and addresses their comments directly to the HREC lead member on the team via a short telecom.

5.7.3 The HREC reviewers compile a short report on the HREC Ethics Feedback Form with recommendations.

5.7.4 Both reviewers present their reports at the LHC HREC, sign them off and submit to the Administrator.

5.8 THE CHAIRPERSON/DEPUTY CHAIRPERSON

5.8.1 Ensures that the previous minutes are signed off.

5.8.2 Ensures that each research team's feedback forms are signed off by the team leader and added to the minutes for compliance and recording purposes.

5.9 THE MEMBERS

5.9.1 Consider the proposal reviews presented by the team leaders of each proposal.

5.9.2 Reach consensus and make an informed decision on outcome of the application.

5.10 **OUTCOMES**

5.10.1 The LHC HREC can decline an application or apply conditions in the form of revisions and/or amendments before ethics approval is re-considered

5.10.2 All decisions are communicated to researchers in writing within seven (7) days of the outcome of the HREC meeting or meeting substitution—for example a round robin or expedited process.

5.10.3 Proof of actions taken by the researcher to address the conditions as specified need to be submitted to the administrator before approval will be granted.

5.10.4 In cases where there is a complex amendment requiring the researcher's original HEI HREC approval to be changed, a full resubmission is required.

5.10.5 In cases where applications are approved during a round robin or expedited process, the results will be ratified at a subsequent meeting of the HREC.

5.10.6 Researcher responses to requests for further information or conditional requirements will be approved provided that they meet administrator requirements for straightforward completion, i.e., provision of a HREC clearance certificate or inclusion of POPI requirements for retention or destruction or information. This approval will be ratified at a subsequent meeting of the HREC.

5.10.7 If the requirements of the HREC were complex or required substantial review, once the researcher has resubmitted the application documents with corrections, the submission in its entirety will be reviewed in full.

5.10.8 If no response is received from the researcher after 60 days (2 months) the submission will be deemed “not known”, and will become dormant.

5.10.9 All correspondence with researchers will be filed under the researcher’s name on the Life Ulwazi shared drive.

5.10.9 All communication with researchers will be done in writing.

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.
- University of New South Wales. Negligible Risk Research. https://research.unsw.edu.au/negligible-risk-research. [Accessed 11 October 2019]
- 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].

- South African Department of Health, 2015. *Ethics in Health Research: Principles, Processes and Structures.* [Online] Available at: https://www.csir.co.za/sites/default/files/Documents/NHREC%20Guidlines%202015.pdf [Accessed 10 11 2019].
- 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].

6. THE APPEAL PROCESS

Life Healthcare Research and Ethics Committee	
Title	SOP for the appeal process
SOP	SOP 5- LHC-HREC-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
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**27.04.2018**	**L. Roets**
Reviewed by:	**E.J. Ricks**	**14/12/2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
27 April 2018	001	Development of the document
14 December 2021	002	Revision

6.1 PURPOSE OF THE SOP

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

6.2 SCOPE

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

6.3 RESPONSIBILITIES

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

6.4 PROCEDURE

6.4.1 Grounds of appeal

A researcher may appeal in writing against a decision concerning his/her application including

- Significant amendments or changes required
- Rejection of the application

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

6.4.2 Appeal process

Researchers have the right to receive written reasons for a decision taken by the LHC 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 LHC HREC. The appeal is directed to the chairperson of the LHC HREC who will escalate the appeal.

- Receipt of the appeal is acknowledged by the administrator within two days after receiving the appeal.
- The basis of the appeal as well as all relevant documents must be submitted in writing to the chairperson of the LHC HREC.
- The chairperson appoints one or two experts 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.
- After deliberation of all the documentation provided to the panel, the panel must either:
    - Uphold the appeal
    - Reject the appeal or

The decision of the panel is final. However, researchers, where applicable, have the right to 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.

7. PRONOUNCEMENT OF A QUORUM

Life Healthcare Research and Ethics Committee	
Title	SOP for the Pronouncement of a quorum
SOP	SOP 6-LHC-HREC-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
Pages	2

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**20.04.2018**	**L. Roets**
Reviewed by:	**E.J Ricks**	**14/12/2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
24 April 2018	001	Development of the document
14 December 2021	002	Revised

7.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines on the pronouncement of a quorum which is based on a simple majority (50% plus 1).

7.2 SCOPE

The scope of this document covers the establishment of a quorum for the LHC HREC meeting and the responsibilities and procedures to be followed.

7.3 RESPONSIBILITIES

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

7.4 PROCEDURE

According to the Ethics in Health Research, Principles, Processes and Structures of 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 LHC 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 postponed. 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-))# (version 10).
- Format adopted from (1) North West University and (2) Unisa, Department of Health Studies.

8. INVOLVEMENT OF VULNERABLE POPULATIONS

Life Healthcare Research and Ethics Committee	
Title	SOP for involvement of vulnerable populations
SOP	SOP 7-LHC-HREC-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
Pages	5

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**29.04.2018**	
Checked by:	**E.J. Ricks**	**14/12/2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
29 April 2018	001	Development of the document
14 December 2021	002	Reviewed the document

8.1 PURPOSE OF THE SOP

The purpose of this SOP is to provide an outline for the LHC HREC regarding the protection of the welfare of vulnerable participants such as:

- Adults who lack capacity to provide informed consent
- Persons in dependent positions – for example, the military
- Persons highly dependent on medical care, or who have a compromised health status
- Persons with physical or mental disabilities
- Inmates of Correctional Facilities

- Collectives, communities and societies
- The very old and very young population

Research involving children are dealt with separately in SOP 9-LHC-REC-002 for research involving minors.

8.2 SCOPE

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

8.3 RESPONSIBILITIES

The LHC 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.

8.4 PROCEDURE

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

8.4.1 Research involving incapacitated adults

Adults who are incapable of providing informed consent should participate in research only where it is essential to the research, 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.

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 take 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.

8.4.2 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 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 above mentioned 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 coercion should be adequately addressed.

8.4.3 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 LHC HREC may approve delayed consent, not meaning that consent is waived. The LHC HREC should ensure full justification for delayed consent. The LHC HREC may approved 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 or more 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.

8.4.4 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.

8.4.5 Prisoners

The recruitment strategy must pay attention to how coercion and undue influence will be avoided. The fieldworkers or persons administering the questionnaires or conducting the interviews must be aware of the environmental factors that may influence the participants.

The LHC HREC should include, ad hoc, when such a research proposal needs to be reviewed, a member with experience and knowledge of working with prisoners. 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-prisoners
- Concerns a problem relevant to prisoners
- Sound informed consent processes can be ensured
- Engagement with relevant role players has occurred

In case of minors, the restrictions on independent consent are crucial; however it is unlikely that the LHC HREC will approve independent consent by prison minors.

8.4.6 Collectivities i.e persons participating in research as groups

Collectivity 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 collectivity
- Respectful negotiations
- Permission from the collectivity 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.

9. ANNUAL PROGRESS AND MONITORING REPORTS

Life Healthcare Research and Ethics Committee	
Title	SOP for annual progress and monitoring reports
SOP	SOP 8-LHC-HREC-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
Pages	3

COMPILATION AND AUTHORISATION

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

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
27 April 2018	001	Development of the document
14 December 2021	002	Revised document

9.1 PURPOSE OF THE SOP

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

9.2 SCOPE

The scope of this document covers the establishment of the procedures to follow for the annual progress and monitoring reports as it is required from the LHC 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.

9.3 RESPONSIBILITIES

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

9.4 PROCEDURE

Ethics approval is valid for a period of one year. An annual report is required for review and monitoring purposes by the LHC HREC.

9.4.1 Completion of annual progress and monitoring report

9.4.1.1 All approved research by the LHC HREC is subjected to assessment of the status of the research within one year after ethics approval was granted. More frequent reports may be requested by the LHC HREC depending on the risk level of the specific research conducted.

9.4.1.2. The LHC HREC progress and monitoring report must be used for the purpose of re- approval.

9.4.1.3 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

9.4.2 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 LHC HREC at Reserach@lifehealthcare.co.za.
- The PMR is then placed on the agenda of the LHC 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 minuted by the administrator.
- The LHC 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.

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.

10. RESEARCH INVOLVING MINORS

Life Healthcare Research and Ethics Committee	
Title	SOP for research involving minors
SOP	SOP 9-LHC-HREC-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
Pages	7

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**29.04.2018**	**L. Roets**
Checked by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

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

10.1 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; thus with minors (under the age of 18 years).

10.2 SCOPE

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

10.3 RESPONSIBILITIES

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

10.4 PROCEDURE

10.4.1 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 a 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 newborn 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 1 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).

10.4.2 Minimum conditions for research involving minors

The LHC HREC when reviewing research proposals where children and adolescent participants are involved must include members with appropriate paediatric research experience. The following considerations are critical when the LHC 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.

3) The LHC 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 s10 of 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

10.4.3 Parental permission and substitutes

Parents or guardians may not decide whether their minor child should participate in research without the minor's contribution to the decision. 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. 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.

The 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.

10.4.4 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, the researcher can request (and justify explicitly) LHC 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.

- 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 LHC HREC finds the ethical justification and the factual evidence of parental support for independent choice by the minor children acceptable, the LHC HREC may grant a waiver of the requirement of written parental permission and will document the process carefully.

10.4.5 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. Assent requires that the child explicitly affirms his or her agreement to participate in a manner that reflects their age-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[i]"

For younger children, the document should be limited to one page if possible. Illustrations 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 simplistic language written at the appropriate age level
- 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

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.

11. AMENDMENT PROCEDURES

Life Healthcare Research Ethics Committee	
Title	SOP for proposal amendment procedures
SOP	SOP 10- LHC-REC-002
Date of Approval	
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	14/12/2021
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**29.04.2018**	**I. Roets**
Checked by:	**E.Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
29 April 2018	001	Development of the document
12 December 2021	002	Revised document

11.1 PURPOSE OF THE SOP

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

11.2 SCOPE

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

11.3 RESPONSIBILITIES

All LHC HREC members, the administrator, members of staff of LHC as well as all researchers to whom an ethics certificates were issued, should be aware of the procedure to follow for review and re-certification purposes.

11.4 PROCEDURE

11.4.1 It may become necessary to amend a research proposal in order for a study to proceed. In such cases the LHC HREC must review the proposed amendments to any research proposal that has already been approved, before commencement of the amended proposal

11.4.2 Amendments can be minor or major in nature

11.4.2.1 Minor amendments

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

- Additional study sites to be added
- 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

11.4.2.2 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 or design
- Changes in consent forms
- Additional study procedures
- Easing of inclusion or exclusion criteria

11.4.3 A request to approve amendments must be submitted to LHC HREC.

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

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

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

11.4.7 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.

11.4.8 The decisions are minuted by the administrator.

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

11.4.10 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.

12. PRIVACY AND CONFIDENTIALITY

Life-Health-Care- Research-Ethics- Committee	
Title	SOP for privacy and confidentiality
SOP	SOP 11- LHC-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
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**30.04.2018**	**L. Roets**
Checked by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

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

12.1 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.

12.2 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.

12.3 RESPONSIBILITIES

All LHC HREC members, the administrator, members of staff of LHC as well as all researchers to whom ethics certificates were issued, 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 and confidentiality of the research sites in which the research is conducted.

12.4 PROCEDURE

12.4.1 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.

12.4.2 When deciding on what information should be regarded as private, the perspectives of the participant and the site should be respected**.**

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

12.4.4 Personal, identifiable information must only be collected with the participants' permission and should be stored separate from the participant's data collected.

12.4.5 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 pass word protected on electronic saving devices.

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

12.4.7 If participants' verbatim quotes are used, they must be presented in a manner that ensures that the name of the participant cannot be linked to the direct quote**.**

12.4.8 When data are gathered in group sessions such as focus or nominal groups, the researcher must emphasise that he/she can only promise confidentiality from his/her side. Members of these groups must be urged observe the principles of confidentiality and privacy.

12.4.9 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.

12.4.10 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.

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

REFERENCES

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Life Healthcare Research Policy, 2017
- Unisa Policy on Research, 2016
- Format adopted from (1) Unisa, Department of Health Studies.

13. ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Life Healthcare Research Ethics Committee	
Title	SOP for adverse events and unanticipated problems
SOP	SOP 12- LHC-REC-002
Date of Approval	
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	14/12/2021
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**30.04.2018**	**L. Roets**
Checked by:	**E. Ricks**	**14.12.2021**	
Authorized by:	**S. Vasuthevan**		

DOCUMENT HISTORY

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

13.1 PURPOSE OF THE SOP

The purpose of the SOP is to provide guidelines for the timely reporting of adverse events, serious adverse events and unanticipated problems that may place the participant(s) at serious risk.

13.2 SCOPE

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

13.3 RESPONSIBILITIES

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

13.4 PROCEDURE

13.4.1 Any adverse, serious adverse event or unanticipated problem must be reported to the LHC HREC within 7 calendar days of occurrence.

13.4.2 Reporting must be done in writing to the administrator.

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

13.4.4 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

13.4.5 The administrator must inform the chairperson of the LHC 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 LHC HREC meeting subsequent to receipt of the report.

13.4.6 Depending on the seriousness of the report a special LHC HREC meeting may be convened for tabling and discussion of the report.

13.4.7 All LHC 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.

13.4.8 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
- 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

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

13.4.10 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
- Format adopted from (1) Unisa, Department of Health Studies.

14. WHISTLE-BLOWING

Life Healthcare Research Ethics Committee	
Title	SOP for whistleblowing
SOP	SOP 13-LHC-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
Pages	3

COMPILATION AND AUTHORISATION

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

DOCUMENT HISTORY

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

14.1 PURPOSE OF THE SOP

The purpose of this SOP is to standardise the procedures to be followed by the LHC HREC when a member of LHC HREC, staff member of LHC, research student or research participant wishes to raise concerns when he/she has reasonable grounds for suspecting misconduct, fraud, maladministration or non-adherence to approved research procedures, guidelines or policies by a researcher (in one way or another related to LHC) in respect of research.

All members of LHC HREC, LHC staff members and students as well as research participants enjoy full protection afforded by the Public Disclosure Act No. 26 of 2000 (PDA) and can blow the whistle on any of the four aspects mentioned without fear of disclosure.

This SOP ensures confidentiality of all members of LHC HREC, LHC staff and students as well as research participants and ensures that there will be no exposure for disclosing, in good faith information that would assist the LHC HREC to meet their obligations in terms of the guiding principles and regulations as set out in the documents referred to in section 8.

14.2 SCOPE

The scope of this document only covers 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 misconduct, fraud, 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 in section 8.

14.3 RESPONSIBILITIES

The LHC HREC is responsible for ensuring that all research activities will be carried out in an open and transparent manner, and in accordance with the code of conduct for researchers in LHC. Every LHC HREC member, staff member of LHC, student, researcher or participant in research who has a reasonable belief that any act of misconduct, fraud, maladministration or non-adherence to approved research proposals has been committed, is obliged to report any such behaviour according to the procedure described in section 7.

14.4 PROCEDURE

14.4.1 A reasonable and honest disclosure should be submitted in writing to the Chairperson of LHC HREC

14.4.2 The chairperson who was notified needs to; within 3 working days acknowledge receipt of the disclosure directly to the whistle-blower and notify the LHC HREC.

14.4.3 The chairperson of LHC HREC will immediately, upon the disclosure set up an appointment with the whistle-blower and the legal representative of LHC 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 LHC HREC

chairperson and legal representative may co-opt an independent person for assistance with the case.

14.4.4 If the investigating team finds that there is no prima facie case to be answered, no action will be taken and the decision will be explained to the whistle-blower.

14.4.5 If the investigating team finds that there is a prima facie case to be answered, the way forward is explained to the whistle-blower to the satisfaction of all implicated.

14.4.6 If the whistle-blower is not satisfied with the outcome, the concerns should be raised in writing to the Chairperson of HREC.

14.4.7 If disciplinary actions are required, the chairperson of the HREC will notify the CEO and the appropriate actions taken.

14.4.8 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.

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)
- Public 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

15. DATA MANAGEMENT AND STORAGE

Life Health Care Research Ethics Committee	
Title	SOP for data management and storage
SOP	SOP 14-LHC-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
Pages	6

COMPILATION AND AUTHORISATION

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

DOCUMENT HISTORY

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

15.1 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 required by LHC.

- Data reported in research reports and publications are available, but without breaching the confidentiality or anonymity of the participants or institutions (where applicable).

15.2 SCOPE

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

15.3 RESPONSIBILITIES

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

15.4 PROCEDURE

15.4.1 Identification and description of data

15.4.1.1 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?

15.4.1.3 The lifespan of the data must be clear.

15.4.1.3 The types and format (numeric or narratives) 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

15.4.1.4 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

15.4.1.5 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 14 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
- All information remains the intellectual property of LHC

15.4.2 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.
- The sequence of the data collection and the execution of the completion of the instrument in each phase of a study should be clear.

15.4.3 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?

15.4.4 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 5 years.
    - In cases of verbal consent, it must be recorded and the records stored as indicated above

15.4.5 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.

15.4.6 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.

15.4.7 Auditing data

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

15.4.8 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.

15.4.9 Archiving and destruction of data

- Data should be stored for a period of 5 years as is indicated in LHC 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

16. INFORMED CONSENT

Life Health Care Research Ethics Committee	
Title	SOP for informed consent
SOP	SOP 15-LHC-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
Pages	4

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**12.05.2018**	**L. Roets**
Checked 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

16.1 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 respondents or participants taking part in research within the LHC context. Recorded data should be durable and appropriately referred to by the researcher.

16.2 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 LHC context.

16.3 RESPONSIBILITIES

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

16.4 PROCEDURE

16.4.1 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 a participant is illiterate, consent should be obtained in the presence of a literate witness who must verify and sign a document stating that informed consent had been given.
- 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.

16.4.2 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 LHC 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 respondent or 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 respondent or 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 respondent or 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 respondent or participant cannot speak English:
    - An interpreter, fluent in English as well as the language understood by the respondent or 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 respondent or participant in such a manner that the respondent or 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 respondent or participant to discuss or consider the information given to him/her
- Verify the information provided to the respondent or participant by checking whether the respondent or 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)
- LHC Research Policy

17. 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-LHC-REC-002
Date of Approval	
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	14/12/2021
Pages	4

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L Roets**	**14.05.2018**	**L. Roets**
Checked 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 December 2021	002	Document revised

17.1 PURPOSE OF THE SOP

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

17.2 SCOPE

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

17.3 RESPONSIBILITIES

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

17.4 PROCEDURE

17.4.1 Conflict of interest

- Members of the LHC 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 LHC HREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided.
- The LHC HREC members must sign a standard conflict of interest agreement regarding review procedures, including meetings, deliberations and applications for ethics approval at the time of appointment, annually renewable. The signed agreements are securely stored by the administrator of the LHC HREC for record purposes
- Only members without conflict of interest may participate in the review, deliberations or voting process.
- LHC 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 LHC HREC member (his/her spouse or immediate family member) is the principal researcher or co-researcher of the research under review by the LHC HREC.
    - Financial interest: The LHC HREC member has a financial interest related to the research that could be affected by the outcome of the research under review by the LHC 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 LHC HREC member has a personal relationship with the principal researcher, peers, subordinates or superiors involved in the research under review by the LHC HREC.
- Business relationship or affiliation: The LHC 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 LHC 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 LHC HREC.

- The chairperson of the LHC HREC requests members to declare conflicts of interests at the start of all meetings.
- When a member of the LHC 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 offer to 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.
- Should the member be allowed to remain for the discussion at the discretion of the chairperson, the members may not participate in the final decision-making on the application in question.
- 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.
- LHC HREC members who have a conflicts of interest related to any research that the LHC 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 LHC 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 LHC 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.
- All reviewers sign a conflict of interest declaration which is part of the review form. LHC HREC members assigned as a primary or secondary reviewer for a research project or related matters, with respect to which a conflict of interest has been identified, will notify the chair so that the protocol can be reassigned.

17.4.2 Confidentiality

- All LHC HREC members and administrator should sign a standard confidentiality agreement on appointment to the LHC HREC, annually renewable
- The signed agreements are securely stored by the administrator of the LHC HREC for record purposes

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.

18. COMPLAINTS PROCEDURE

Life Health Care Research Ethics Committee	
Title	SOP for complaints procedure
SOP	SOP 17-LHC-REC-002
Date of Approval	
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	14/12/2021
Pages	5

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**L. Roets**	**19.05.2018**	**L. Roets**
Checked 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 December 2021	002	Document revised

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

18.2 SCOPE

This SOP covers the responsibilities and procedure(s) to be followed by the LHC 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.

18.3 RESPONSIBILITIES

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

18.4 PROCEDURE

18.4.1 Procedure for complaints from researchers about a LHC HREC – issue

18.4.1.1 Should a researcher experience a problem with a LHC HREC member's behaviour regarding the application of management procedures or reviewer report(s), they have the opportunity to lodge a complaint.

18.4.1.2 The complaint should be lodged in writing to the Chairperson LHC HREC. Should the complaint be against the LHC HREC Chair, the complaint should be lodged in writing to the Deputy Chair of HREC and then Chief Executive Officer.

18.4.1.3 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 LHC 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 LHC 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 LHC HREC Chairperson shall convene a meeting as soon as possible with the complainant/s and the Chief Executive Officer to discuss the complaint in an

attempt to find an amicable solution. The chairperson will compile a written report of this meeting to chairperson of LHCERC, 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.

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

18.4.2.1 The LHC 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 LHC HREC.

18.4.2.2 The complainant may lodge a complaint with the chairperson of LHC 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.

18.4.2.3 The chairperson of the LHC HREC shall immediately notify the Chief Executive Officer of the complaint. Within a week of receiving the complaint, the chairperson of the LHC HREC shall call a meeting with the complainant and thereafter with the researcher.

18.4.2.4 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 LHC HREC will finalise the complaint.

The chairperson of the LHC HREC shall keep a written record of the meeting and its outcome and shall communicate it to the Chief Executive Officer.

18.4.2.5 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.

18.4.2.6 A detailed written report of the aforementioned processes and outcomes will be compiled by the chairperson of the LHC HREC and circulated for correctness and fairness. 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 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.

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

18.4.2.8 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].

19. CONDUCTING A ROUND ROBIN

Life Health Care Research Ethics Committee	
Title	SOP for conducting a round robin
SOP	SOP 18-LHC-REC-001
Date of Approval	August 2019
Web address	https://www.lifehealthcare.co.za/careers/life-college-of-learning/human-research-ethics-committee/
Revision Date	December 2021
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**G. Ure**	**August 2019**	**G. Ure**
Checked by:	**E. Ricks**	**14.12.2021**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

Date	**Version no**	**Reason of the document**
August 2019	001	Development of the document

19.1 INTRODUCTION

In the absence of a quorum being available for a Life Healthcare Health Research Ethics Committee or a Science and Research committee meeting, 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.

19.2 Scope

The scope of this procedure is to gain a majority decision on medium and high risk research proposals submitted for approval to the LHC 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.

19.3 PROCESS

19.3.1 Indications

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

a) When there is an absence of a quorum for a regular LHC 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 random event, or not often seen phenomenon which might occur rarely, for example, a natural disaster.

c) 19.3.2 Extenuating circumstances

In the case of a request to accelerate a review outside of the usual academic rigor and the ethics review process due to time limitation, or an unforeseen circumstance, the researcher must provide a written motivation 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 LHC 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.

19.3.3 Process

The full document application pack submitted for approval is made available to LHC HREC members for their respective meeting, either through access to the Gateway, or via email for members who are unable to access the Gateway.

Each committee member is allocated the responsibility of reviewing the submissions for either academic rigor or for ethical concerns, legal compliance and the potential for risk and harm to the participants for the LHC HREC. LHC HREC members will also be required to review academic rigor on a limited scale, and the S and R committee evaluation is attached to the LHC HREC pack for this purpo**se.**

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 relevant convenor, who then collates the information into a composite resolution to be ratified at the following meeting of the LHC HREC.

The decision reached by the round robin will be considered as carrying the same weight as a discussion at a meeting as all of the members will participate.

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

Related forms (Internal and external)

- RESEARCH-FORM-001b Round Robin Feedback Form. Rev 0. August 2019
- RESEARCH-FORM-001a Round Robin Feedback Form. Rev 0. TBD

20. CONDUCTING AN EXPEDITED REVIEW

Life Health Care Research Ethics Committee	
Title	SOP for conducting an expedited review
SOP	SOP 19-LHC-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
Pages	3

COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	**G. Ure**	**August 2019**	**G. Ure**
Checked by:	**E. Ricks**	**22.01.2022**	
Authorised by:	**S. Vasuthevan**		

DOCUMENT HISTORY

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

20.1 INTRODUCTION

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

20.2 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.

20.3 DEFINTION

Expedited review is a review which occurs using a component of the S & R or LHCHREC, usually one person, and the Chairperson. The review occurs in the same way as a full review but, because it does not fulfil the criteria for a full review, the process of approval can be accelerated.

20.4 PROPOSALS FOR EXPEDITED REVIEW

20.4.1 Proposals included for expedited review

- Low risk proposals may include, but are not limited to the below categories:
    - Research which does not involve human or animal subjects.
    - Research which does not include vulnerable subjects or special groups.
    - Research which does not use 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.
    - The research involves observing people in public places behaving naturally.
    - 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.

20.4.2 Proposal 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 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 put at risk of personal damage, whether reputational or financial.
    - Any risks related to invasion of privacy, or breach of confidentiality due this this research must be minimal.

- Any research that involves human or animal subjects/participants whether it is low risk.

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

20.5 PROCESS

- An HREC member will be tasked to review the proposal for ethical content once it has been reviewed for academic rigor by the Science and Research committee.
- 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.
- The results of the review will be ratified at the next 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 the full process of the S & R or LHC HREC.

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