Pages 1-8	HREC	**Compiled/Revised by**: ***E Ricks***
Effective Date: January 2023	Revision 2	***Approved by**: Sharon Vasuthevan*
Title: LHC HREC Terms of Reference		***Approver's* Signature and Designation:** ***HREC Chairperson***

4.1 Standard

The Life Healthcare (LHC) Human Research Ethics Committee (HREC) Terms of Reference are aligned to the LHC Research Policy, Life Healthcare Code of Conduct for researchers as well as with the National Health Act, No. 61 of 2003 and the Department of Health's Ethics in Health Research Guidelines (March 2015). The essential purpose of LHC HREC is to protect the dignity, rights, safety, and well-being of all human participants in health-related research. HREC will do this through independent, prospective and ongoing ethics review of all health research projects applications for either ethics clearance and/or permission to conduct research studies at Life Healthcare facilities. All activities of the 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.

4.2 Scope

In line with the National Health Act s73, all health institutions are required to establish Health Research Ethics Committees (HRECs) which will rigorously 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 and commitment to the ethical principles laid down in the following documents 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, 3rd edition (2020)
- 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)

4.3 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 Chief Medical Officer, SA. Administrative support is managed by LHC Research office.

4.4 Mandate

4.4.1 The LHC HREC is mandated to fulfil its functions in accordance with the National Health Act No 61 of 2003 as outlined in the DoH "Ethics in Health Research" Guidelines 2015. It reports annually to the National Research Ethics Council (NHREC).

4.4.2 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:

i) 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.

ii) 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.

iii) human pathology and the understanding of human disease. These studies can include experimental pathology, and other means to aid the diagnosis of disease.

iv) 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.

v) 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.

vi) 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.

vii) 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:

   a) Medical and nursing
   b) Pharmacy
   c) Allied therapy – physiotherapy, occupational therapy, psychology, social work, dietetics, speech therapy
   d) Engineering and facilities management
   e) Business administration, including human resources, billing and record keeping

f) Environmental matters

g) Quality, patient safety and infection prevention

h) Policy development and governance

i) Management and executive functions

4.4.3 A person who is an employee of Life Healthcare may approach the LHC HREC for a review of a health-related research proposal for non-degree purposes. Correspondingly, any person may approach Life Healthcare and request permission to conduct health related research at a Life Healthcare facilities.

4.4.4 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.

4.5 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 via email, 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.

4.6 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.

4.7 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:

4.7.1 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.

4.7.2 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.

4.7.3 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.

4.7.4 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.

4.7.5 Ethics approval must be obtained before a study commences. LHC HREC will not consider projects for approval if it is apparent that the research has already been conducted.

4.8 Monitoring and adverse event management

4.8.1 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.

4.8.2 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.

4.9 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.

4.10 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.

4.11 Composition and membership

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

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

4.11.2 Members should be representative of active research disciplines including both clinical and non-clinical fields.

4.11.3 The term of membership is four years, which is renewable for a second consecutive cycle.

4.11.4 The LHC HREC must comprise of at least nine members. Additional members may be co-opted as deemed necessary. New members may be appointed as required.

4.11.5 Each of the following categories should be represented in the membership of the committee and include those specified by the Department of Health in 'Ethics in Health Research: Principles, Processes and Structures, 2nd Edition, Department of Health, Republic of South Africa, 2015:

- i) At least one lay person who does not have specialised or professional knowledge or is a non-expert in the health sciences disciplines
- ii) At least one member with knowledge of, and current experience in the professional care, counselling or health related treatment of people. Such a member may be a medical practitioner, psychologist, social worker or nurse.
- iii) At least one member with professional training and experience in qualitative research methodologies.
- iv) At least one member with professional training and experience in quantitative research methodologies.

v) At least one member with expertise in bio-statistics.

vi) At least one member with expertise in research ethics.

vii) At least one person who has a qualification in law.

viii) Ethnically and diverse members and appropriate mix of males and females.

ix) At least one member from the Research Scientific Committee.

4.12 Meetings

4.12.1 At least 10 meetings will be held per year, one every last Tuesday of the month from February to November.

4.12.2 Meeting dates will be available on the Gateway in the Research folder as well as on the LHC Research webpage.

1.14 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***
2	***January 2023***	***Replacement document***	***E. Ricks***	***S. Vasuthevan***

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- National Health Act, Act No 61 of 2003
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- 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.
- Nelson Mandela University. Terms of Reference