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| Pages 1-8 | HREC | **Compiled/Revised by**: *Esmeralda Ricks* |
| Effective Date: November 2023 | Revision 2 | ***Approved by**: Nerisha Tathiah* |
| **Title: Life Healthcare HREC Terms of Reference** | | ***Approver's* Signature and Designation:** <br> ***HREC Chairperson*** |

## 1. STANDARD

The Life Healthcare Human Research Ethics Committee (HREC) Terms of Reference are aligned to the Life Healthcare 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 National Health Act s73, requires institutions to establish research ethics committees (RECs) which are registered with the National Health Ethics Council (NHREC) and requires all 'health research' involving human participants to undergo prior ethics review by a registered ethics committee. Committees are registered with NHREC after an assessment of eligibility and compliance with the governing legal and ethics framework, function seamlessly with the operations of Life Healthcare Group and should maintain the same levels of quality expected of the group.

## 2. AUTHORITY

The Life Healthcare 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 Life Healthcare HREC is mandated to carry out its activities in line with those outlined in the National Health Act, 61 of 2003. The Life Healthcare HREC reports to the National Health Research Ethics Council, and to the Life Healthcare Head: Clinical Directorate and the Chief Nurse Officer. Administrative support is managed by Life Healthcare Research office.

## 3. MANDATE

The Life Healthcare 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 Health Research Ethics Council (NHREC) and Life Healthcare Clinical Governance. This is done to ensure that there is ongoing monitoring of wellbeing and welfare of all participants.

The Life Healthcare 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

A person who is an employee of Life Healthcare may approach the Life Healthcare HREC for review of a health-related research proposal for non-degree purposes.

Researchers with no affiliation to or affiliation with institutions that do not have a REC that is registered with NHREC may approach Life Healthcare HREC to review their research proposals. The Life Healthcare may exercise its discretion on a case-by-case basis to decide whether to review the proposal or whether to refer the applicant elsewhere to access appropriate expertise and capacity to evaluate the application.

## 4. SCOPE OF OPERATIONS

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

The Life Healthcare HREC is authorised to:

- Conduct rigorous ethics reviews, prospectively of all health or health related research proposals to ensure that the welfare and other interests of participants and researchers are correctly protected and that the proposed research complies with ethical norms and standards outlined in the national ethics guidelines (Note: retrospective review is **not** permitted).
- Ensure that research proposals are scientifically sound and feasible.
- Decide whether to approve, to require amendments or to reject the proposals for lack of compliance with scientific or ethics norms and standards.
- Ensure appropriate reporting occurs to fulfil the oversight obligation of Life Healthcare HREC to monitor welfare interests of the participants.

The Life Healthcare HREC should establish an EXCO to deal with matters between meetings, duly authorize by the full committee (See SOP 23).

The Life Healthcare HREC may establish a sub-committee to deal with expedited reviews. The sub-committee is authorised to approve applications and report to a full committee for noting (See SOP 19).The life Healthcare HREC must establish and make accessible a Code of Conduct for its members that describes what is expected of members, a Confidentiality Agreement, and a Conflict of Interest Declaration. The Code of Conduct and Confidentiality Agreement is signed upon

appointment as an HREC member which must be adhered to throughout their term of office. The members are requested to declare any conflict of interest at the start of all HREC meetings and are excused if necessary.

The Life Healthcare HREC establishes and ensures that the recruitment process for members are transparent and inclusive and include paying attention to achieving demographic representivity, and succession planning. Members should be representative of active research disciplines including both clinical and non-clinical fields. The term of membership is four years, which is renewable for a second consecutive cycle. The LIFE HEALTHCARE HREC must comprise of at least nine members. Additional members may be co-opted as deemed necessary. New members may be appointed as required. Each of the following categories should be represented in the membership of the committee and include those specified by the Department of Health in 'Ethics in Health Research: Principles, Processes and Structures, 2nd Edition, Department of Health, Republic of South Africa, 2015:

- At least one lay person who does not have specialised or professional knowledge of the health sciences disciplines.
- At least one member with knowledge of, and current experience in the professional care, counselling or health related treatment of people. Such a member may be a medical practitioner, psychologist, social worker or nurse.
- At least one member with professional training and experience in qualitative research methodologies.
- At least one member with professional training and experience in quantitative research methodologies.
- At least one member with expertise in bio-statistics.
- At least one member with expertise in research ethics.
- At least one person who has a qualification in law.
- Ethnically and diverse members and appropriate mix of males and females.

(See SOP 2: Selection, Appointment and responsibilities of Members).

Life Healthcare HREC develops SOPs to inform researchers and the business of research processes, obligations, operational requirements, and reporting requirements. These SOPs are systematically reviewed every three years, or sooner if necessary. These SOPs are designed to assist both researchers and the Life Healthcare 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.

The Life Healthcare HREC develops and make accessible appropriate documentation that are standardised and in line with required legislation. This is to enable the Life Healthcare 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 application forms, process guidance documents, reporting templates and review templates among others, to facilitate appropriate processing of applications to assist researchers to comply with requirements. 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 (See SOP 20: Documents and Records Management and Control).

The Life Healthcare HREC must provide a monitoring function to ensure adherence to approved proposal and that research is conducted in line with accepted scientific and ethical principles. 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 Life Healthcare HREC. If it is necessary, these projects will be referred to NHREC or any other oversight bodies for sanction if necessary.

Life Healthcare HREC must 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.

The Life Healthcare HREC must have at least 10 meetings per year, and the meeting dates will be available in the research folder on the Gateway and also on the Life Healthcare Research webpage.

## 5. APPROVAL PROCESS FOR TERMS OF REFERENCE

These terms of reference were approved by the Chairperson, Dr N. Tathiah on the 26 March 2024.

## 6. 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*** |
| ***3*** | ***November 2023*** | ***Replacement document*** | ***E.Ricks*** | ***N. Tathiah*** |

## REFERENCES


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- HPCSA. (2016). Guidelines for Good Practice in the Healthcare Professions. Booklet 11: Guidelines on over servicing, perverse incentives, and related matters. Pretoria: Health Professions Council of South Africa.
- Nelson Mandela University. Research Ethics Terms of Reference