LIFE HEALTHCARE RESEARCH GOVERNANCE STRUCTURES

Life Healthcare

Making life better

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1. INTRODUCTION

The research governance structure seeks to outline a framework which facilitates the institutional arrangements for research conducted by staff of Life Healthcare and external researchers who seek permission to conduct research at Life Healthcare. Furthermore, the governance has as its aim to provide clarity on the interactions of research structures, operational/functional offices, and the Life Healthcare Human Research Ethics Committee. This Governance structure ensures that the principles, requirements. and standards of research are upheld.

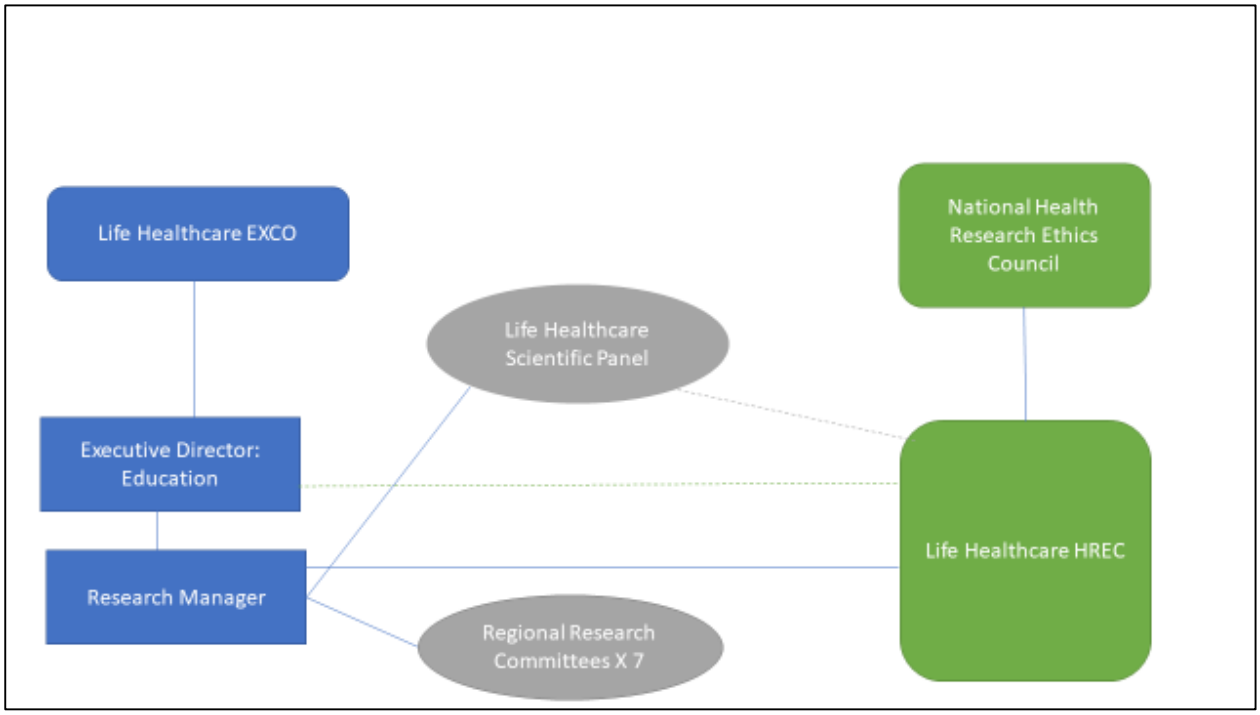

Figure 1: Life Healthcare Research Governance Structure

2. DEFINITIONS

In this document, unless the context indicates a contrary intention, the following words and expressions bear the meanings assigned to them and cognate expressions bear corresponding meanings:

"High Risk" refers to research that is expected to result in potential harm to participants' physical and/or mental wellbeing (Department of Health Ethics in Health Research. Principles, Processes and Structures, 2015)

"LHC HREC" means the Life Healthcare Health Research Ethics Committee

"LHC SP" means the Life Healthcare Scientific Panel

"Low-Risk" refers to research that is expected to result in no foreseeable risk, harm or discomfort to the mental, and/or physical well-being of the participants (Department of Health Ethics in Health Research. Principles, Processes and Structures, 2015)

"LHC" refers to Life Healthcare Group (Pty) Ltd.

"RRC" means the Regional Research Committee

3. LIFE HEALTHCARE HUMAN RESEARCH ETHICS COMMITTEE (LHC HREC)

The Life Healthcare Human Research Ethics Committee is registered with the National Health Research Council of South Africa (NHREC) and as such, is directly accountable to the NHREC in terms of executing its mandate as an accredited Research Ethics Committee.
The Terms of Reference of the HREC 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).

3.1 Authority and Mandate

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.

3.1.1 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).

3.1.2 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

3.1.3 Aligned to the research policy an employee of Life Healthcare may approach the LHC HREC to submit proposed research for review; that is health-related research for non-degree purposes. Correspondingly, any person may approach Life Healthcare and request permission to conduct health related research at Life Healthcare facilities. Such submissions will be reviewed in terms of the HREC SOPs.

3.2 Terms of Reference

The LHC-HREC is constituted in alignment with its Terms of Reference as guided by the NHREC guidelines (DoH, 2015) and other relevant national and international benchmarks and guidelines.

3.3 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 three 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.

3.4 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:

3.4.1 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.

3.4.2 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.

3.4.3 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.

3.4.4 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.

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. ROLE OF LIFE HEALTHCARE EXECUTIVE COMMITTEE (EXCO)

The EXCO of Life Healthcare plays an integral role in the alignment of the organisation's vision for the research and its activities in the seven regions it operates within. The research activities of LHC are co-ordinated through the Regional Research Committees (RRC).

The EXCO of LHC is responsible for the institutional support for the mandate and operational requirements of the LHC-HREC as per the DoH guidelines (2015). This responsibility to support the functional requirements of the LHC-HREC are achieved through the infrastructure and support provided by the EXCO through the Research Office.

4.1 Relationship with LHC HREC

The EXCO of LHC acknowledges the independence of the HREC and its role in supporting the functioning of the HREC as an integral part of the LHC research eco-system.

In supporting the operations of HREC, EXCO is involved in the identification of nominees to fill vacancies on HREC with due consideration for the expertise and oversight function of the HREC. The names of nominees and their CVs are then presented to HREC and after due consideration and deliberation, HREC appoints the selected nominee(s) as members of HREC.

5. ROLE OF REGIONAL RESEARCH COMMITTEES

The activities of the Regional Research Committees (RRC) of the College take place in terms of the policies and directives for research at LHC. The aim is to coordinate and report in the prescribed format on research related activities of the College and health care facilities within LHC, whilst measures are put in place to support research by means of mentorship and training courses. A strategic objective of the Committee is the building of research capacity to increase both the quality and quantity of academic research in each region, to be regarded as a leading Higher Education Institution not only in South Africa, but internationally.

5.1 Purpose

The main purpose of the Regional Research Committees is:

- Enhancement of the research culture of the staff and students.
- Introduction of incentives to promote research endeavours.
- Coordination of the quarterly research report and its quality.
- Organising of research colloquiums.
- Identification of research training and skill building interventions.

5.2 Composition

The Regional Research Committee consists of:

- The Regional Education Manager, Regional Clinical Manager and Regional Clinical Pharmacist.
- All nurse educators.
- LHC staff, approved by the Chair, who are passionate about research and have at least a Masters or PhD degree.

- At least one (1) member from the local university who should have at least a PhD in Nursing.
- All new members shall be appointed by majority agreement of the existing members.
- Members of the Committee are appointed for a term of two years and will be able to renew for an additional term.
- The committee is chaired by an academic nominated by the committee for a term of two years and will be able to renew. There should be a Deputy Chair who acts in the absence of the Chair and is designated by the Committee at the beginning of each academic year.

5.3 Processes and procedures

5.3.1 General meetings

The Research Committee meets once a month on the dates agreed at the beginning of the year, or as needed.

5.3.2 Agenda

The agenda is to be circulated at least three (3) days before a general meeting and at least one (1) day before a special meeting, and should contain amongst others, the date, time and place of the meeting and the points of discussion. In the case of a special meeting, the Chairperson determines the manner of notification, with the proviso that only the matters necessitating the special meeting may be deliberated.

5.3.3 Minutes

A general meeting starts, after constitution, when the Chair of the meeting ratifies, with his/her signature, the minutes of the previous general meeting and the minutes of any special meetings held thereafter. The minutes may be considered as read, provided a copy was circulated beforehand to all committee members. Minutes not circulated before the meeting shall be reviewed at the meeting. Any objections to the minutes are raised to be raised on review and settled before ratification. On approval and adoption of the minutes, the Chair of the meeting shall affix their signature to the minutes so approved.

5.3.4 Reporting

The RRC shall submit a quarterly report to the LHC Research Manager.

6. LIFE HEALTHCARE SCIENTIFIC PANEL

The Scientific Panel was established for providing an opinion/review on clinical content of proposals or for more than minimal risk studies submitted by applicants requesting

permission to conduct their studies at LHC facilities. The Scientific Panel could also assist the LHC HREC members in reviewing low risk study proposals in expediting the review process.

6.1 ROLE/PURPOSE

The role of the Scientific Panel is to provide expert opinion regarding the specialised content of the proposal and/or input for more than minimal risk proposals if requested by Life Healthcare HREC. The Scientific Panel could also assist LHC HREC with expedited reviews.

6.2 MEMBERSHIP

The Scientific Panel will comprise nine members who represent the following departments/units/services because of their expert knowledge of their functional area and expertise:

- Clinical Directorate
- Clinical Pharmacy
- College/Nursing
- Human Resources
- Legal Life Health Solutions
- Nkanyisa

6.3 ROLES AND RESPONSIBILITIES

The roles and responsibilities of the Scientific Panel 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 Scientific Committee must carry out the following:

6.3.1 Conduct prospective reviews of research proposal referred to the Scientific Panel by the LHC HREC, including clinical trials, proposals where expert input regarding the specialised content of the proposal and/or input for more than minimal risk proposals are requested by Life Healthcare HREC.

6.3.2 The Scientific Panel could also assist LHC HREC with expedited reviews.

6.3.3 The Scientific Research Committee provide feedback to Life Healthcare HREC regarding the content, scientific and ethical rigour of the proposal.

6.4 ATTENDING LIFE HEALTHCARE HREC MEETINGS

An invitation could be extended to panel members to attend specific Life Healthcare HREC meetings to deliberate specific submissions which they may have reviewed or in the event of other relevant agenda items.

6.5 REPORTING

The Scientific Panel reports to the Life Healthcare HREC on matters relating its purpose.

7. RESEARCH OFFICE

The Research Office was established at Life Healthcare to co-ordinate and manage all research activities within LHC and to provide administrative support to the HREC. The Research Office is resourced by the Research Manager and an Administrative Assistant.

7.1 Research Co-ordination Function

The research co-ordination function is operationalized through interaction at the regional level through the Research Committees as outlined.

7.2 HREC Support Function

The Research Office provides administrative support to the Chairperson of LHC-HREC and supports the day-to-day operations of the HREC. All internal researchers, as well as researchers from external organisations/institutions submit their applications to the Research Office via email. The Research Manager together with the Chairperson of HREC will screen all proposals and make a decision regarding which proposals should be expedited or referred to a full HREC.

Only proposals that are regarded as low risk proposals and have received full ethics clearance from a research ethics committee registered with and accredited by the NHREC will be expedited. The process for expediting review of proposals submitted is described in the SOP for expedited reviewing of proposals and the SOP for candidates who previously received full ethics clearance from a registered NHREC research ethics committee,

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