HUMAN RESEARCH ETHICS COMMITTEE



LIFE HEALTHCARE RESEARCH GOVERNANCE STRUCTURES



Making life better

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1. INTRODUCTION

The research governance structure ensures the smooth flow of proposal submissions from regional level, external organisations and universities to the National Research Committee (NRC) and Human Research Ethics Committee (HREC). It ensures that the principles, requirements and standards of research are upheld. The Life Healthcare research governance structure comprise the Regional Research Committee (RRC), National Research Committee (NRC), Senate Research Committee, Human Research Ethics Committee (HREC) and the Life Healthcare Clinical Governance Committee.



Figure 1: Life Healthcare Research Governance Structure

The RRCs review internal staff and student research proposals for non-degree purposes and provide feedback to the researchers who will affect the necessary corrections. The proposals are then submitted to the NRC who decides whether to waiver research ethics clearance by a full HREC committee and grant permission for studies to be conducted at LHC facilities or not. Studies where ethics clearance could be waivered are low risk studies that make use of secondary data which was intended for other use, for example, data collected for routine purposes at hospitals regarding patient care and patients' records data bases not intended for research at the time of data collection. All studies involving human participants require ethics clearance by a full HREC.

The NRC reviews all internal and external submissions of research proposals in accordance with the Department of Health: Ethics in Health Research. Principles, Processes and Structures (2015) and makes a decision regarding which proposals could be granted permission to conduct research at LHC facilities and which proposals require a full HREC review. The proposals that could be granted permission by NRC to conduct research at LHC facilities will include proposals that have been submitted from outside the organization (e.g. universities and other organisations) that are low risk research projects, are well written and have received ethics clearance from an ethics committee registered with the NHREC.

The HREC members review all proposals received and either grant ethics clearance or permission for research to be conducted at LHC facilities. The NRC and HREC informs the LHC Senate Research Committee who reports to Senate regarding all research conducted at LHC facilities. The HREC reports to the LHC Clinical Governance Committee quarterly regarding all research conducted at LHC facilities.

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:

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"College" means Life College of Learning.

"High Risk" means 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);

"HREC" means the Health Research Ethics Committee;

"Low-Risk" means 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);

"NRC" means the National Research Committee;

"RRC" means the Regional Research Committee;

"LHC" means Life Healthcare Group (Pty) Ltd;

"Senate" means the highest academic body of the College, and accountable to the College Council for the academic and research functions of the College.

"SRC" means the Student Representative Council of the College.

2. REGIONAL RESEARCH COMMITTEE (RRC) TERMS OF REFERENCE

2.1 INTRODUCTION

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, to be regarded as a leading Higher Education Institution not only in South Africa, but internationally.

2.2 PURPOSE OF THE REGIONAL RESEARCH COMMITTEE

- 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.
- Coordination of submissions to the LHC National Research Committee (NRC).
- Organising of research colloquiums.
- Identification of research training and skill building interventions.

2.3 COMPOSITION OF THE REGIONAL RESEARCH COMMITTEE

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 NRC 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.

2.4 PROCESSES AND PROCEDURES

2.4.1 General meetings

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

2.4.2 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.

2.4.3 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. Minutes may, at the discretion of the Chair, be available upon written request to the NRC.

2.4.4 Reporting

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

2.4.5 Reviewing of proposals

Proposals submitted from LHC nursing students and clinical staff for non-degree purposes are reviewed and approved by RRC. Thereafter, the proposals are submitted to LHC National Research Committee who decides whether the proposal should serve at a full HREC meeting. The proposals should be reviewed using the Reviewer Checklist which is attached hereto as Annexure "A".

3. NATIONAL RESEARCH COMMITTEE (NRC) TERMS OF REFERENCE

3.1 INTRODUCTION

The activities of the National Research Committees (NRC) of LHC take place in terms of the policies and procedures for research at LHC. The aim is to coordinate and report in the prescribed format on all research applications requesting ethics clearance and permission to conduct research at LHC facilities. A strategic objective of NRC is the screening of all external and internal proposals for degree and non-degree purposes and building of research capacity to increase both the quality and quantity of academic research, to be regarded as a leading Higher Education Institution not only in South Africa, but internationally.

3.2 PURPOSE OF THE NATIONAL RESEARCH COMMITTEE

- Enhancement of the research culture of the staff and students.
- To make some calculation of the risks and benefits of all proposed
- Research projects conducted at LHC.
- Coordination of the annual research report and its quality.
- Coordination of submissions to the LHC HREC
- Organising of research colloquiums.
- Identification of research training and skill building interventions.

3.3 COMPOSITION OF THE NATIONAL RESEARCH COMMITTEE

The National Research Committee shall comprise of the following persons:

- The Research specialist
- Two members from LHC HREC
- Four Regional Research Committee representatives
- Four representatives from the various clinical functions.
- Members of the NRC are appointed for a term of two years and will be able to renew for a further term.

- The committee shall be chaired by the Research Specialist. There should be a Deputy Chair who is elected by the NRC at the beginning of each academic year and acts in the absence of the chair.
- The NRC, may, at its discretion, invite such additional persons to the meeting at it deems fit.

3.4 PROCESSES AND PROCEDURES

3.4.1 General meetings

The NRC meets once a month on the dates as per the Research calendar agreed at the end of the previous academic year, or as needed.

3.4.2 Agenda

The agenda 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.

3.4.3 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 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. Minutes may at the discretion of the Chair, be available upon written request by HREC.

3.4.4 Reporting

The committee submits a quarterly report to the LHC HREC.

3.4.5 Reviewing of proposals

Degree and non-degree proposals of researchers from outside and within LHC are reviewed for scientific rigor and ethics. Low risk well written proposals of researchers from external organisations who already received ethics clearance from a registered ethics committee at their organisation or university will be granted permission to conduct research at LHC facilities without having to serve at a full HREC. High-risk proposals submitted by researchers from external organisations and universities will serve at a full HREC irrespective whether they have already received ethics clearance from a registered ethics committee. All internal research to be conducted by students and staff among human participants will be submitted to a full HREC for ethics clearance.

4. SENATE RESEARCH COMMITTEE TERMS OF REFERENCE

4.1 INTRODUCTION

The LHC Senate Research Committee is a sub-committee of Senate. Its aim is to advise Senate on all aspects related to research within the College and the business.

4.2 COMPOSITION

The LHC Senate Research Committee will comprise the following:

- Five members nominated by NRC, at least two of whom shall be members of Senate.
- One SRC representative nominated by the College Head
- The LHC Senate Research Committee may invite such additional persons to the meeting as they deem necessary, provided the prior permission of the Chair is obtained.

4.3 CHAIRPERSON

The Chair of the LHC Research Senate Committee shall be an academic member of the LHC Senate Committee as nominated by the members of the LHC Senate Committee.

4.4 QUORUM

The quorum will be fifty percent of the membership, plus one member.

4.5 FUNCTIONS

The Committee is established to perform the following functions:

- Support and sustain the development of a research culture at LHC;
- Advise Senate on policies and programs that promote, support and celebrate high quality research and scholarly work and its dissemination at workshops, conferences and in the form of peer reviewed publications;
- Advise Senate on policies and practices on ethical, regulatory and other issues related to the conduct of research and scholarly work and its dissemination;

- Review annually the College's Strategic Research Plan and make recommendations to the Senate;
- Report annually to Senate on the College and regional research and scholarly activities; and
- Establish such sub-committees as may be needed to fulfil the Committee's responsibilities.
- Other duties as assigned by Senate.

4.6 PROCESSES AND PROCEDURES

- The Committee will meet bi-annually, and more regularly if necessary.
- Members will be notified at least two weeks before a meeting requesting submission of agenda items. Documentation should be circulated at least one week before a meeting.
- The Committee may appoint standing or ad hoc sub-committees for special assignments.
- The Committee may, at its discretion, co-opt any persons whose expertise is needed to deal with special assignments.

Prepared by Prof E.J. Ricks, Dr S. Vasuthevan and Ms B. Berning. 14 December 2021.

Annexure A: Reviewer Checklist



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HREC REVIEWERS FEEDBACK FORM AND SUGGESTED OUTCOME

Principal Researcher Name:

 Date:	
Title of Research:	
Reviewer:	
	••••••

Please mark with an X				
Approve	Approval with minor conditions	X Approval with major conditions and re-submission		
Decline	Waiver	Additional information required		

REVIEWERS COMMENTS

Criteria	Yes	No	Please comment if you have ticked no and recommend how it could be improved
TITLE: is concise, explicit, and congruent with research question, purpose, and objectives			
ABSTRACT is about 250-300 words, concise and is a true reflection of the whole proposal			
INTRODUCTION AND BACKGROUND: Address the research argument and has a logical flow. Supportive literature is relevant, recent and summarised logically			

PROBLEM STATEMENT: is stated clearly and is congruent with the title and introduction and background Image: Congruent with the title and introduction and background RESEARCH QUESTION: is congruent with title, purpose and objectives Image: Congruent with title, purpose and objectives RESEARCH PURPOSE: is congruent with research question and title Image: Congruent, concise, clear and achievable.				
title, purpose and objectives RESEARCH PURPOSE: is congruent with research question and title RESEARCH OBJECTIVES: are congruent, RESEARCH OBJECTIVES: are congruent,				
research question and title RESEARCH OBJECTIVES: are congruent,				
CLARIFICATION OF CONCEPTS is clear and operationalised				
DESIGN is clearly described and motivated for the study				
METHODS are described clearly under the following headings:				
RESEARCH POPULATION is clearly described				
SAMPLING METHOD is explicitly described				
MEASURING INSTRUMENT is clearly described in the study, can measure the objectives				
DATA COLLECTION process is explicitly described				
STATISTICAL ANALYSIS METHODS explicitly described				
RELIABILITY AND VALIDITY OF RESEARCH (Quantitative Studies) process are clearly described and strategies identified				
TRUSTWORTHINESS (Qualitative studies) is clearly described and strategies identified				

ETHICAL CONSIDERATIONS are adequately described and strategies identified for ensuring the principles of Respect for persons, Beneficence and justice		
TIME FRAME is adequately and logically described in the correct sequence		
BUDGET is complete and feasible		
WRITING STYLE academically acceptable, with minimum spelling and grammatical errors		
TECHNICAL ASPECTS such as 2.5 margins, 1.5 line spacing, full justification, complete table of contents, page numbering and general layout of the document complies with the norm		
REFERENCES in TEXT are correctly referenced and are all listed in the reference list		
REFERENCE LIST is complete, correct and in alphabetical order		

COMMENTS:

REVIEWERS SIGNATURE: ______

DATE: _____