



LIFE HEALTHCARE  
HEALTH RESEARCH ETHICS  
COMMITTEE

NHREC Registration Number  
REC251015-048

# LIFE HEALTHCARE HEALTH RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

## **1. INTRODUCTION**

In accordance with the National Health Act, No. 61 of 2003 and its regulations, the Life Healthcare Health Research Ethics Committee (hereafter REC) is registered with the National Health Research Ethics Council (NHREC) to fulfil the legal requirement that all health research involving human participants undergoes prior independent ethics review.

The Life Healthcare HREC Terms of Reference is aligned to the Life Healthcare Research Ethics Policy (LCL-POL-REC-002), National Health Act, No. 61 of 2003 and the South African Department of Health's Ethics in Health Research Guidelines (NDOH 2024 v3), that establishes the minimum national norms and standards for ethical health research. As a registered ethics committee, the Life Healthcare HREC operates in a manner that reflects the high standards of quality inherent with the Life Healthcare Group (Pty) Ltd and ensuring compliance with the governance, legal, and ethical frameworks mandated by the NHREC.

## **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, with the registration number: REC-251015-048.

The Life Healthcare HREC functions under the ambit of the Life Healthcare Group (Pty) Ltd Private Higher Education Institution (hereafter Nursing College) as per the Higher Education requisite. The Life Healthcare Nursing College's Senate and Council serve as the duly authorised governance structure responsible for the approval and ratification of the HREC's terms of reference, policies, and procedures, the HREC also has a reporting responsibility to the Life Healthcare Clinical Directorate. The Life Healthcare HREC is accountable to the National Health Research Ethics Council through annual reporting to maintain its registered status and demonstrate its ongoing compliance with national regulations.

## **3. MANDATE**

The Life Healthcare HREC is duly mandated to fulfil its functions in accordance with the

National Health Act, No. 61 of 2003 as outlined in the Department of Health's Ethics in Health Research: Principles, Processes and Structures, 3rd edition (NDoH 2024).

The HREC reviews research proposals from both Life Healthcare employees and external researchers for any health-related research conducted under the auspices of a Life Healthcare facility. The HREC reviews research proposals for both qualification and non-qualification purposes. Additionally, researchers not affiliated with a formally constituted, NHREC-registered ethics committee may approach the Life Healthcare HREC for review. The HREC reserves the right to exercise its discretion on a case-by-case basis to decide whether to review such proposals or refer the applicant to an alternative committee with appropriate expertise.

The HREC is authorised to conduct independent, prospective ethics reviews of all health or health-related research proposals. This function ensures that the welfare and interests of participants and researchers are protected and that the proposed research complies with the ethical norms and standards outlined in the Department of Health's Ethics in Health Research Guidelines (NDOH 2024). This includes, but is not limited to, any research that contributes to knowledge on:

- Biological, clinical, psychological, and social processes in human beings, including clinical trials and other health-related research.
- Human pathology and the understanding of human disease, including the causes, progression of pathogens, and internal dysfunction.
- The effects of the environment on the human body, including socioeconomic and environmental factors.
- Improved methods for the provision of health services, including aspects such as patient confidentiality, staff retention, and skills improvement plans.
- The development and application of new pharmaceuticals, medicines, related substances, and medical technology, which may have a positive impact on health. This includes, but is not limited to, the following areas:
  - Medical and nursing
  - Pharmacy

- Allied therapy (e.g., physiotherapy, occupational therapy, psychology)
- Engineering and facilities management
- Business administration (e.g., human resources, billing, record keeping)
- Environmental matters
- Quality, patient safety, and infection prevention
- Policy development and governance
- Management and executive functions

#### 4. SCOPE OF OPERATIONS

The Life Healthcare HREC is authorised to conduct rigorous, prospective ethics reviews of all health or health-related research proposals that fall within its mandate. The HREC's scope of authority includes the following responsibilities:

- **Review of Research:** The HREC reviews all research proposals to ensure they are scientifically sound, feasible, and compliant with ethical and scientific norms. The HREC can approve, require amendments, or reject proposals.
- **Reporting and Oversight:** The HREC ensures appropriate reporting and monitoring to safeguard the welfare and interests of participants. It also manages adverse events in line with NHREC processes, Life Healthcare PTY (Ltd) processes, Life Healthcare Research Policy and relevant legislation.
- **Governance and Structure:** The HREC is responsible for its own governance, including the establishment of an EXCO and a sub-committee for expedited reviews, and maintaining a transparent recruitment process for members. 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. 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's Ethics in Health Research Guidelines (NDOH 2024).

- at least one layperson
  - at least one member with knowledge of, and current experience in, the professional care, counselling, or health- related treatment of people, e.g., a social worker, nurse, psychologist, or medical practitioner
  - at least one member with professional training and experience in qualitative research methodologies
  - members with professional training and experience in quantitative research methodologies
  - a member with expertise in biostatistics (as per the NDoH 2024 guideline, the person need not be a professional biostatistician)
  - a member with expertise in research ethics (as per the NDoH 2024 guideline expertise means with great skill and knowledge in a particular field)
  - at least one member who is legally qualified and has extensive knowledge of family law, health law, and research ethics
- **Member Conduct:** The HREC ensures that all its members sign and adhere to a Code of Conduct, Confidentiality Agreement, and Conflict of Interest Declaration.
  - **Policy and Documentation:** The HREC develops and maintains standardised documentation, such as application forms and progress report forms, and reviews its Standard Operating Procedures (SOPs) regularly to ensure compliance with national and international guidelines. The SOPs are systematically reviewed every three years or sooner if necessary and are made accessible via the Life Healthcare websites under the Research domain and internal intranet platform and internal communications to ensure researchers have the latest information and guidance.
  - **Monitoring and Adherence:** The HREC provides a monitoring function to ensure that approved proposals are being adhered to. Research that does not comply with

regulatory requirements or ethical standards, or that causes harm to participants, may be terminated. To support this function, the HREC develops and maintains standardised documentation and SOPs that assist both researchers and the HREC in complying with national and international guidelines.

## 5. APPROVAL PROCESS

The Life Healthcare HREC Terms of Reference may only be revised after approval by the HREC, the College of Nursing Council and Senate approval.

### Approval History

Revision	Date	Revision description	Compiled by / Revised	Approved by
0	October 2017	New Document	P Naicker	Dr. S Vasuthevan
1	January 2021	Replacement Document	Dr. G Ure	Dr. S. Vasuthevan
2	January 2023	Replacement document	Prof. E. Ricks	Dr. S. Vasuthevan
3	November 2023	Replacement document	Prof. E. Ricks	Dr. N. Tathiah
4	September 2025	Replacement document	Prof. J Naidoo	Dr. N Tathiah