Statement by the Senate Ethics in Research Committee on the review of Health Research

Version 2.2 [June 2025]
Approved by the EiRC, 04 June 2025, quorate committee meeting

Table of Contents

1. Preamble 1
2. Provisions of the National Health Act (Act 61 of 2003), NHA 1
3. Position of the EiRC 2
4. NHREC-registered RECs at UCT 2
5. Health research using secondary data 3
6. Authorship and attribution 4
7. References 4

1. Preamble

The Senate Ethics in Research Committee (EiRC) is committed to upholding the highest national and international standards for research integrity and ethics and is obliged to follow any applicable national legal requirements in the review and approval of applications for research ethics clearance.

To this end, the EiRC brings the following provisions stipulated in the National Health Act (Act 61 of 2003) (NHA) and the current processes to facilitate implementation of the NHA to the attention of researchers at UCT.

2. Provisions of the National Health Act (Act 61 of 2003)

The NHA defines health research as follows:

> "health research" includes any research which contributes to knowledge of-
> (a) the biological, clinical, psychological or social processes in human beings;
> (b) improved methods for the provision of health services;
> (c) human pathology;
> (d) the causes of disease;
> (e) the effects of the environment on the human body;
> (f) the development or new application of pharmaceuticals, medicines and
> (g) the development of new applications of health technology;
>
> *NHA, Definitions, page 12*

Further, the NHA defines the role of a Health Research Ethics Committee as:

> 73.
> (1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.
>
> (2) A health research ethics committee must -
>
> (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
>
> (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee
>
> *NHA, Section 73, page 76*

3. Position of the EiRC

In light of the legal stipulations of the NHA and international best practice, **the EiRC requires that**:

a. All research conducted at the University of Cape Town (UCT), whether by academic or PASS[1] staff members or students (both undergraduate and postgraduate), and post-doctoral fellows (hereafter: UCT community), which meets the definition of health research, must undergo review by a UCT research ethics committee (REC) registered with the National Health Research Ethics Council (NHREC).
b. The review of health research must be done before any research activities (such as interviews or data collection) commence. Retrospective approval will not be granted.
c. No health research may be conducted until written approval from an NHREC registered REC has been received.

If there is in any doubt as to whether research constitutes **health research**, then a researcher must use the screening tool developed by the EiRC to determine which committee is most appropriate to review the proposed research.

This tool may be accessed here.

4. NHREC-registered RECs at UCT

UCT has two NHREC-registered RECs which will receive applications from the UCT community.

a. The Faculty of Health Sciences Human Research Ethics Committee (HREC), based in the Faculty of Health Sciences (FHS). Any research conducted by staff and students based in the FHS must be reviewed and approved by the HREC. Further information regarding their processes is available on their website, or via email to: hrec-enquiries@uct.ac.za.
b. The Inter-Faculty Human Research Ethics Committee (IFHREC), serviced by the Office of Research Integrity. All staff and students who plan to conduct health research (as per the definition) and who are based in the Faculties of Commerce, Engineering and the Built Environment, Humanities and Law; the Centre for Higher Education and Development and the Graduate School of Business must submit their applications to the IFHREC. This includes staff in

[1] PASS: Professional, Administrative and Support Staff at UCT.

PASS departments who may be conducting health research. Further information regarding their processes is available on their website, or via email to: ifhrec.enquiries@uct.ac.za.

5. Health research using secondary data

The National Department of Health, South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 (3rd edition) (hereafter NDOH 2024):

> … address **health** and **health-related research** broadly to achieve the specific goal of providing guidance for **all research involving human participants** … to be conducted in accordance with the ethical norms and highest standards. …
>
> … speak broadly to health research, i.e., research that relates to health or will have an impact on health. The effect of health research on the environment is also considered. The scope includes research carried out in a health care facility, as well as research conducted in any other environment where the wellbeing of humans is investigated, including research conducted in terms of disciplines such as anthropology, history, linguistics, i.e., research ethics is applicable to every discipline.
>
> … In general terms, research involving humans includes a wide range of activities conducted by many different disciplines that may use different methodologies and explanatory frameworks. In the physical and biological sciences, research may be described as a systematic study or inquiry, usually using quantitative data, seeking new knowledge. However, researchers are increasingly also using qualitative methodologies for health-related research, as is the case with the humanities, social and behavioural sciences, which use both qualitative and quantitative methods as well as analytical frameworks, all of which may be aimed at contributing to knowledge about being human in the environment and other contexts.
>
> *NDOH 2024, p. 4-5*

Section 4.1.5. of the NDOH 2024 considers "Secondary use of HBM[2] or data".

> Secondary use means using HBM or data* originally collected for another purpose. Surplus HBM samples may have been stored in a biobank or another type of repository. The importance of stored HBM and data as research resources cannot be overstated.
> ** Data are not limited to data associated with HBM but include all types of data, including questionnaires, interview records, images and audio records, collected for research or other purposes.*
>
> The ethical dilemma is whether later unanticipated use for research necessitates new informed consent and, if so, what should be done when a donor/participant is no longer available to provide consent for the further use of the HBM or the data.
>
> The content of the previously obtained consent determines whether subsequent usage was envisaged and, if so, whether the envisaged use falls within the scope of the current protocol. If so, new consent is not required.
>
> *NDOH 2024, p. 68*

Under the terms of the NHA and the NDOH 2024, research which uses secondary health data is considered to fall within the scope of the above definition of health research or health-related research, and **must be reviewed, or granted exemption from full review, by an NHREC registered REC**, as outlined in section 4 above. This is made clear in 3.4.3 "Data science research" (NDOH 2024 p. 59).

[2] HBM = human biological material

When reviewing applications, which propose to make use of secondary health-related data, the NHREC registered REC will carefully review the following:

a. The provisions of the informed consent initially provided by the participant, whether this included provision for future use and how the anticipated future use was described.
b. Whether the data or samples are anonymous or de-identified and the likelihood of risk for the individual participant or community if the data were to be reused.
c. Whether the data or samples are identifiable, and the associated risk of reuse.

This will be balanced by considerations such as:

a. The risk-level of the study.
b. The social value and relevance of the proposed research.
c. And the feasibility of the research using the secondary data or samples.

Based on the REC's evaluation it may choose to approve or not approve this type of research and, may either require that participants are re-contacted to obtain informed consent (if the new use of the data was not covered in the initial conditions of consent) or may waive the requirement to obtain new informed consent from the participants (for example, in the case of minimal risk studies, or where it is not practical or feasible to obtain new consent).

If a study is "not approved" researchers may engage with the relevant committee to understand the committee's concerns. Per the individual REC terms of reference, it may be possible to resubmit an application once measures to address concerns have been incorporated into the proposed research project.

This decision may only be taken by the REC although researchers/principal investigators and applicants may motivate for (a) the value of the secondary use of the data and (b) a waiver of informed consent.

6. Authorship and attribution

This document was developed by Mrs Paula Saner, Research Integrity Manager, for the Senate Ethics in Research Committee.

The document was reviewed, revised and approved by the EiRC.

7. References

- National Health Research Ethics Council (2024) ***South African Ethics in Health Research Guidelines: Principles, Processes and Structures***, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH. 137p. ISBN 978-0-621-52027-9. https://www.health.gov.za/nhrec-guidelines/
- National Health Act 61 of 2003. https://www.gov.za/sites/default/files/gcis_document/201409/a61-03.pdf

Version 2.2 (June 2025), developed by the ORI on behalf of the EiRC