



UNIVERSITY OF THE  
WITWATERSRAND,  
JOHANNESBURG

**Human Research Ethics Committee Non-Medical  
("HREC (Non-Medical)")**

**TERMS OF REFERENCE  
("TORs")**

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## Terms of Reference for the Human Research Ethics Committee Non-Medical

### 1. DEFINITIONS AND ABBREVIATIONS

Unless the context clearly indicates otherwise, the following terms will bear the following meanings:

- |       |                            |  |
|-------|----------------------------|--|
| 1.1.  | “Applicant”                | members of staff, registered students and affiliates of the University, and external applicants  |
| 1.2.  | “DVC: R&PGA”               | Deputy Vice-Chancellor: Research and Postgraduate Affairs  |
| 1.3.  | “HREC (Non-Medical)”       | Human Research Ethics Committee Non-Medical  |
| 1.4.  | “National Guidelines 2015” | Department of Health : Guidelines – Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2nd ed. 2015                      |
| 1.5.  | “National Health Act”      | National Health Act 61 of 2003   |
| 1.6.  | “NHREC”                    | National Health Research Ethics Council  |
| 1.7.  | “REC”                      | Research Ethics Committee  |
| 1.8.  | “SOP”                      | Standard Operating Procedures  |
| 1.9.  | “ToRs”                     | Terms of Reference   |
| 1.10. | “University” / “Wits”      | the University of the Witwatersrand, Johannesburg, a public higher education institution recognised as such in terms of the Higher Education Act 101 of 1997 |
| 1.11. | “URC”                      | University Research Committee, a committee appointed by the University Council   |

## **2. INTRODUCTION**

- 2.1. The University of the Witwatersrand, Johannesburg (“University” / “Wits”) has established a Human Research Ethics Committee (Non-Medical) (“HREC (Non-Medical)”) under the terms of the National Health Act 61 of 2003 (“National Health Act”) and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 (“National Guidelines 2015”).
- 2.2. The Terms of Reference (“TOR”) are designed to ensure that the HREC (Non-Medical) at the University is compliant with the requirements of the National Health Act and with the National Guidelines 2015.
- 2.3. The HREC (Non-Medical) is mandated to fulfil its function and mandate by the University Research Committee (“URC”) and the Deputy Vice-Chancellor: Research and Postgraduate Affairs (“DVC: R&PGA”) of the University.

## **3. PURPOSE OF TORS**

- 3.1. The overarching ethics guidance for the HREC (Non-Medical) will be the South African National Guidelines 2015.
- 3.2. Where relevant, major international guidelines (including, but not limited to: the Declaration of Helsinki, as amended, the Belmont Report, and the Council for International Organisation of Medical Sciences (“CIOMS”)) will apply. When strict compliance of a particular requirement of these declarations and codes is impossible, HREC (Non-Medical) will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.
- 3.3. The TOR is to provide guidelines and a minimum standard for the HREC (Non-Medical) operational management of the research process within the University.
- 3.4. The essential purpose of HREC (Non-Medical) is to protect the dignity, rights, safety, and well-being of all human participants in non-biomedical or non-medical research involving human subjects as participants. The HREC (Non-Medical) will do this through independent, prospective and ongoing ethics review of all non-

medical research projects involving human participants undertaken by members of staff, registered students and affiliates of the University, and external applicants (“Applicants”).

- 3.5. Research to be reviewed by the HREC (Non-Medical) will be in accordance with the provisions of the National Health Act. The University is to establish or have access to a Research Ethics Committee (“REC”), which is registered with the National Health Research Ethics Council (“NHREC”). This TOR must be read with the HREC (Non-Medical) Standard of Procedures (“SOP”) document which is freely available on the HREC (Non-Medical) website, <http://www.witsethics.co.za/Wits/index.aspx> and as Annexure 3 attached hereto.
- 3.6. A significant proportion of research conducted at the University constitutes Health Research, as defined by the National Health Act, and it is therefore appropriate for the HREC (Non-Medical) to be registered with the NHREC. Once registered with the NHREC, as currently the HREC (Non-Medical) has a provisional registration, the HREC (Non-Medical) may advise the Deputy Vice-Chancellor of Research and Postgraduate Affairs (“DVC: R&PGA”) to initiate disciplinary steps against researchers who violate either national or the HREC (Non-Medical)’s ethical guidelines and/or legislation.
- 3.7. The Chairperson of the HREC (Non-Medical) is required to provide all necessary information in order to inform the University in adjudicating complaints of research ethics and integrity violations and/or research misconduct by researchers whose protocols have been approved by HREC (Non-Medical).
- 3.8. The HREC (Non-Medical) has school sub-committees as categorised according to their specific faculty, school and field. These sub-committees will be referred to as “School sub-committees” of the HREC (Non-Medical).

#### **4. SCOPE**

- 4.1. Any research undertaken by any Applicant involving human participants or datasets of human non-medical data must be submitted for review by the HREC (Non-Medical) or by the appropriate School sub-committees, irrespective of the level of ethical risk and vulnerability of the research participants involved. The

School sub-committees of the HREC (Non-Medical) will only review applications which are of no risk and of minimal, low or negligible risk as defined by the HREC (Non-Medical).

- 4.2. When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable<sup>1</sup>, for example, the poor and the economic or socially marginalised, children (under 18 (eighteen) years old), people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a medical clinic.
- 4.3. The University requires applicants to obtain ethics approval from the necessary REC or School sub-committee before any research involving but not limited to human participants excluding animals may commence. The HREC (Non-Medical) will uphold all the University's necessary rules and regulations and in so doing reviewing applications for degree and non-degree purposes.
- 4.4. The HREC (Non-Medical) will only under exceptional circumstances consider any applications for retrospective ethical acknowledgment, which is not ethical clearance, if it is apparent that the research has already commenced.

## **5. RESPONSIBILITIES**

- 5.1. The NHREC stipulates the responsibilities of the HREC (Non-Medical) are as follows:
  - 5.1.1. The main responsibility of the HREC (Non-Medical) is to conduct rigorous ethics reviews of all non-biomedical and non-medical research proposals involving human participants to ensure that the welfare and other interests of participants and researchers are properly protected and that the research will be conducted in accordance with the required ethical norms and standards in terms of the National Health Act and the National Guidelines 2015.

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<sup>1</sup> includes, among others, children under 18 (eighteen) years old, orphans, prisoners, persons with cognitive or communication disorders, people who are traumatised or currently in traumatic situations.

- 5.1.2. The HREC (Non-Medical) must confirm that research proposals stand up to ethical scrutiny as is appropriate to the discipline or field concerned.
- 5.1.3. The review must ensure the maintenance of ethical standards to:
  - 5.1.3.1. protect participants from harm by weighing the risk of harm against the prospect of benefits;
  - 5.1.3.2. protect the safety and welfare of participants deemed to be in vulnerable categories;
  - 5.1.3.3. hold researchers accountable for their research actions;
  - 5.1.3.4. promote the highest ethical standards and best available techniques or approaches for optimal interaction of participating humans; and
  - 5.1.3.5. promote important social and ethical values to the research community.
- 5.2. HREC (Non-Medical) must review research proposals prospectively and not retrospectively, to ensure that the research proposal meet the accepted ethical norms and standards before research commences, using the guidelines indicated in the National Guidelines 2015 as a minimum benchmark, of which one important aspect is, but which is not limited to:
  - 5.2.1.1. the primary responsibility of each HREC (Non-Medical) member is to decide independently whether the proposed research study protects the interests of participants adequately and upholds the highest of standards.
- 5.3. Such responsibility regarding participant interest will always take precedence over the interests of the research.
- 5.4. The HREC (Non-Medical) will:
  - 5.4.1.1. function according to its Code of Conduct as appropriate as attached hereto as Annexure 1;

- 5.4.1.2. operate in accordance with the University's Research Integrity Policy and Research Integrity Procedure as attached hereto as Annexure 2 and amended from time to time;
  - 5.4.1.3. follow the HREC (Non-Medical) procedures as set out in its SOP as attached hereto as Annexure 3, in reviewing ethics applications;
  - 5.4.1.4. formulate and seek approval for a set of research discipline-specific examples of risk level categories, in order to have a guide to make a suitable classification of the risk levels of research studies whilst reviewing ethics applications which such risk levels can be found the HREC (Non-Medical) SOP;
  - 5.4.1.5. provide feedback on specific matters as requested by the URC and /or the DVC: R&PGA;
  - 5.4.1.6. ensure confidentiality of all information revealed to it;
  - 5.4.1.7. ensure that all researchers applying for ethics approval sign the research ethics Code of Conduct, which is attached hereto as Annexure 1; and
  - 5.4.1.8. ensure that all HREC (Non-Medical) members sign the research ethics Code of Conduct as attached hereto as Annexure 1.
- 5.5. The HREC (Non-Medical) will uphold the necessary University's rules and regulations.

## **6. PROCEDURES**

- 6.1. Formal Character of the HREC (Non-Medical) and School sub-committees" of the HREC (Non-Medical):
  - 6.1.1. The HREC (Non-Medical) is provisionally registered with the NHREC registered committee, and the HREC (Non-Medical) will endeavour to be a fully registered REC. For further details of the HREC (Non-Medical)



member selection, appointment and functioning, please see the HREC (Non-Medical) SOP as Annexure 3 attached hereto.

6.1.2. As stated above, the HREC (Non-Medical) has “School sub-committees” of the HREC (Non-Medical) which have the same processes and procedures as the HREC (Non-Medical) and as such they are bound by the HREC (Non-Medical) SOP, University Ethics Policy and this TORs. For further information, selection, appointment and function of these School sub-committees” of the HREC (Non-Medical), please see the HREC (Non-Medical) SOP as Annexure 3 attached hereto.

6.2. Code of Conduct for HREC (Non-Medical) Members

6.3. The HREC (Non-Medical) members will be expected beyond the Code of conduct to:

- 6.3.1. agree to a term of office of five (5) years, which can be renewed for two (2) subsequent terms;
- 6.3.2. familiarise themselves with the University’s relevant documentation as well as national and international research ethics guidelines;
- 6.3.3. attend research ethics training sessions to keep abreast with the latest changes in this field and the HREC (Non-Medical) members will need to provide proof of evidence of training at least once every three (3) years to the HREC (Non-Medical);
- 6.3.4. always act with integrity in the capacity as members of HREC (Non-Medical);
- 6.3.5. regularly attend HREC (Non-Medical) meetings and provide a reasonable reason if they do not attend such meetings but they are permitted to still provide written reviews of applications if applicable;
- 6.3.6. be punctual in the attendance of the HREC (Non-Medical) meetings;
- 6.3.7. diligently perform all responsibilities delegated to them;

- 6.3.8. maintain all of these responsibilities in compliance with the University's internal policies, directives, rules and regulations, national and international ethical and regulatory requirements;
- 6.3.9. consider and declare any prior interest, any conflict of interest and/or involvement in any matter being discussed at a HREC (Non-Medical) meeting to avoid potential conflict of interest, either personal or financial interest; and
- 6.3.10. keep all matters coming to the HREC (Non-Medical) member's attention during HREC (Non-Medical) meetings confidential.

6.4. Relationship to Non-Affiliated Researchers / External Applications

- 6.4.1. Researchers with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such a REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.
- 6.4.2. A cost ("Review Fee") will be levied for such service only for researchers who are non-affiliated to the University and external applicants to the amount of R15 000,00 (fifteen thousand Rand) plus VAT as per the Value Added Tax Act as amended from time to time, which Review Fee is payable upon submission. The Review Fee is subject to the HREC (Non-Medical) Chairperson's discretion, in consultation with the Secretariat and Research Office. The review can be waived or discounted by the HREC (Non-Medical) Chairperson on a case-by-case basis.

6.5. Accountability and Responsibilities of RECs

- 6.5.1. The HREC (Non-Medical) is to function within the legislative framework of the National Health Act No. 61 of 2003 and the National Guidelines 2015, which requires a University at which research is being conducted to have an NHREC-registered REC. The REC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of the proposal.

6.6. Mechanisms for Reporting by HREC (Non-Medical)

6.6.1. The HREC (Non-Medical), managed and supported by the URC, function directly under the DVC: R&PGA. The University Research Office has oversight of all the RECs at the University. The Director: Research Development and the Legal Adviser and Research Compliance Manager conduct this function with the REC Chairpersons and the Research Office administrative officers and other support staff members. The HREC (Non-Medical) works in close collaboration with the University's Faculties, the Faculty Deans and Assistant Deans for Research and Postgraduate Affairs structures involved in non-biomedical, non-medical and non-health-related research. The Research Office also serves to internally audit the HREC (Non-Medical) in terms of their operational mandate and standards, and where applicable, to ratify the HREC (Non-Medical)'s decisions. The HREC (Non-Medical) must report annually on their activities to the NHREC and the URC in the form of an annual report.

6.7. Mechanisms for Remuneration of HREC (Non-Medical) Members

6.7.1. HREC (Non-Medical) members who are on the payroll of the University are not remunerated for their services as HREC (Non-Medical) members, in order to reduce conflict of interest and increase independence, being a member of the HREC (Non-Medical) forms part of the University's academic citizenship. Should the services of a HREC (Non-Medical) member not on the payroll of the University be required (e.g. layperson, attorney, and psychologist), then their services should be viewed as part of their contribution to their community but may be remunerated according to an honorarium negotiated before the appointment, where they are compensated for time, travel costs, inconvenience and expenses provided they are:

- 6.7.1.1. not employed and might lose the opportunity to earn income for the day by attending to certain HREC (Non-Medical) duties;
- 6.7.1.2. employed but have to add hours to their workday to serve on the HREC (Non-Medical) and do its work; or

6.7.1.3. in a private practice and their participation as a member of the HREC (Non-Medical) will lead to a loss, as they are not able to earn an income during the HREC (Non-Medical) meeting.

6.7.1.4. An honorarium has been introduced by the University to the Chairperson/s as a part of their academic service to the University as they may need to add hours to their workday to serve on the HREC (Non-Medical) and do its work.

6.8. Authority of the HREC (Non-Medical)

6.8.1. The National Health Act provides statutory authority for the governance of “health research through the registered RECs, as well as the necessary ethics regulatory infrastructure through the NHREC. Non-biomedical, non-medical and non-health-related research.”

6.8.2. The HREC (Non-Medical) receives its authority from the minimum standards and guidelines for research ethics of the NHREC, National Guidelines 2015, as well as from the URC and the DVC: R&PGA of the University:

6.8.2.1. The National Health Act, which requires the University to establish HREC (Non-Medical) which are registered with the NHREC;

6.8.2.2. The Department of Health’s minimum national benchmark of norms and standards for conducting responsible and ethical non-biomedical, non-medical and non-health-related research in the National Guidelines 2015.

6.8.2.3. The University Research Ethics Policy and the HREC (Non-Medical) SOPs.

6.8.3. In all instances the amendments of the National Health Act, regulations or standards will take immediate effect as they are published or promulgated, where this TOR and the HREC (Non-Medical) SOP will then be amended as soon as reasonably possible to reflect the latest amendments.

- 6.8.4. The HREC (Non-Medical) is supported by the University's Research Office and the HREC (Non-Medical) act independently. If the HREC (Non-Medical) is dissolved for whatever reason, it must be reported to the NHREC, URC and the DVC: R&PGA.

## **7. MANDATE BETWEEN HREC (NON-MEDICAL) AND HREC MEDICAL**

- 7.1. Many inquiries are received from applicants regarding the most suitable REC to obtain ethics clearance, for social science projects. This is because some studies may be based in hospitals or clinics, but do not involve any clinical, diagnostic or therapeutic interventions. Examples may include interviews or questionnaires with staff or patients about phenomena such as access to services, perceptions, values and cultures. In this case, staff or patients are merely a participant group.
- 7.2. Under such situations, informal enquiries will be made between the registered RECs of the University, in order to establish which REC is most appropriate to review such study under question.
- 7.3. The University is committed to continual dialogue and working towards improving ethical practice across the University , including sharing best practice between RECs and their constituent members..

## **8. REFERENCES TO OTHER RELATED DOCUMENTS**

- 8.1. National Health Act 61 of 2003;
- 8.2. Department of Health, Guidelines – Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015;
- 8.3. University Research Ethics Policy; and
- 8.4. Delegation of Authority Document (DOAD).

## **9. ACKNOWLEDGEMENTS**

- 9.1. The following sources are acknowledged for their input into the development of this SOP:

9.1.1. North West University Research Ethics Committee; and

9.1.2. UCT

**10. APPROVAL HISTORY OF THE TOR**

<b>STRUCTURE CONSULTED</b>	<b>Target date for discussion**</b>	<b>Date approved/ discussed#</b>	<b>Date noted#</b>
HREC (Non-Medical)	20 October 2017	20 October 2017	-
University Research Committee	09 November 2017	November 2018	
University Research Committee	28 February 2020	28 February 2020	
University Research Committee	29 January 2021	29 January 2021	

**\* Outline which structures will be consulted on this issue, and in which order**

**\*\* Indicate which meeting of each structure is being targeted.**

**# This date is only filled in when the specific body has dealt with the issue.**

**10.1. SUBMISSION CONTENT**

10.2. Proposal (Complete the sentence: This body is requested to approve the draft Standard Operating Procedures of the Human Research Ethics Committee Non-Medical (“HREC (Non-Medical)”):

10.2.1. University Research Committee (“URC”) is requested to approve new Terms of Reference and Standard Operating Procedures for the HREC (Non-Medical) at the University of the Witwatersrand, Johannesburg (“University” / “Wits”).

10.3. Motivation (Please put down the reasons why this decision should be reached, that is, why this should be supported):

10.3.1. The proposed Terms of Reference and Standard Operating Procedures are designed to ensure that the Human Research Ethics Committee (NON-MEDICAL) HREC (Non-Medical) at the University of the Witwatersrand, Johannesburg is compliant with the requirements of the National Health Act 61 of 2003 (“National Health Act”) and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 (“National Guidelines 2015”) at the University, Johannesburg is compliant with the requirements of the National Health Act (Act 61 of 2003) and with the Department of Health Guidelines for Health Research (2004).

10.4. Financial Implications (Outline what it will cost)

10.4.1. Researchers with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such an REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

10.4.2. The HREC (Non-Medical) can review research proposals / Protocols / applications of researchers that are not affiliated to University, or external applications subject to payment of a cost (“Review Fee”) levied for such service in the current amount of R15 000,00 (fifteen thousand Rand) plus VAT (currently at 15%) as per the Value Added Tax Act as amended from time to time, which Review Fee is payable upon submission. The Review Fee may change from time to time. The Review Fee is not for any Researchers within the University. The Review Fee is subject to the HREC (Non-Medical) Chairperson’s discretion, in consultation with the Secretariat and Research Office.

**ANNEXURE 1**

1. Wits Code of Conduct for Researchers
2. University Research Integrity Policy
3. SOP for HREC (Non-Medical)