Terms of Reference

Wits HREC-Medical

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Version Control

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Version numbering scheme:
0 = early rough drafts
1 = drafts that contain inputs from Wits HREC-(Medical)
2 = final drafts that are ready for approval
3 = Approved versions

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2. Definitions and Abbreviations

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

"Applicant"	Members of University staff, affiliates to the University, students registered with the University and people external to the University who apply to the Wits HREC (Medical) for an ethics clearance.
"Committee"	The Wits Human Research Ethics Committee focused on medical, biomedical, clinical and health science research projects. See Wits HREC (Medical) below.
"DVC: R&I"	Deputy Vice-Chancellor: Research and Innovation.
"Wits HREC (Medical)"	The Wits Human Research Ethics Committee focused on medical, biomedical, clinical and health science research projects. See Committee above.
"National Guidelines"	The Department of Health's Guidelines – Ethics in Health Research: Principles, Processes and Structures, 2nd edition 2015 (soon to be updated).
"National Health Act"	National Health Act, act 61 of 2003.
"NHREC"	National Health Research Ethics Council.
"SOP"	Standard Operating Procedure.
"ToR"	Terms of Reference.
"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.
"UR&IC"	University Research and Innovation Committee, a sub-committee of the University Senate and Council.

3. Introduction

The University of the Witwatersrand, Johannesburg ("University" / "Wits") will establish a human research ethics committee that reviews ethically responsible research in the broad fields of medicine, biomedicine, clinical and health sciences in terms of the National Health Act, 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"). This committee is referred to as the Wits Human Research Ethics Committee Medical ("Wits HREC Medical"), or the Committee, and must be registered with the National Health Research Ethics Council ("NHREC").

Thus established, the mandate of the Wits HREC (Medical) is conferred by the University Research and Innovation Committee ("UR&IC") and the Deputy Vice-Chancellor: Research and Innovation ("DVC: R&I").

4. Purpose

These Terms of Reference (ToR) are designed to describe the mandate of the Wits HREC (Medical) and, thereby, to ensure that it is compliant with the requirements of the National Health Act and the National Guidelines.

The essential purpose of Wits HREC (Medical) is to protect the dignity, rights, safety, and well-being of all human participants in medical, biomedical, clinical and health science research. The Committee will do this through independent, prospective and ongoing ethics reviews of all health and health-related research projects undertaken by members of University staff, registered students and affiliates of the University, and external applicants ("Applicants").

Research to be reviewed by the Committee will be in accordance with the provisions of the National Health Act. Although the overarching guidance for the Wits HREC (Medical) will be derived from the National Guidelines, where relevant, guidance will also be provided by 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")). When strict compliance of a requirement of these declarations and codes is impossible, the Wits HREC (Medical) will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

Applications for the review of the ethics related to conducting clinical trials involving human participants are also considered by the Wits HREC (Medical).

The Wits HREC (Medical) has a sub-committee that is established for the review of the ethics related to biobank activities, that is the collection and storage of biological samples (such as blood, tissue, etc.) and health information. This sub-committee is referred to as the Biobank Ethics Committee ("BEC").

The Wits HREC (Medical) may advise the DVC: R&I to initiate disciplinary steps against researchers who violate either legislation or National and University ethical guidelines.

The Chairperson of the Wits HREC (Medical) is required to provide all necessary information to inform the University in adjudicating complaints of the breach of research ethics and integrity standards and/or research misconduct by researchers whose research protocols have been approved by the Wits HREC (Medical).

These TOR must be read with the Wits HREC (Medical) Standard of Procedures ("SOP") document which is freely available on the Wits HREC (Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/.

5. Scope

All medical, biomedical and clinical research for degree and non-degree purposes, undertaken by an Applicant involving human participants must be submitted for review by the Wits HREC (Medical) or by the BEC, irrespective of the level of ethical risk and vulnerability of the research participants involved. Such research can only be initiated after a clearance certificate is provided by the Committee.

When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable[1] to undue influence and/or duress, for example, the poor and the marginalised, pregnant women, children, people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a clinic.

Such review of research ethics must be conducted before any research can commence. The Committee will not consider any applications for approval if it is apparent that the research has already commenced. Such applications will be rejected, and any date acquired must be discarded.

[1] 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.

6. Responsibilities

The NHREC stipulates the responsibilities of the Wits HREC (Medical) are to conduct rigorous ethics reviews of all medical, biomedical and clinical research proposals to ensure that the welfare and other interests of participants and researchers used in research are properly protected and that the research will be conducted in accordance with the required ethical norms, standards and legal requirements in terms of the National Health Act and the National Guidelines. Additionally, the Committee must confirm that all research proposals reviewed stand up to ethical scrutiny as is appropriate to the discipline or field concerned.

The review must ensure the maintenance of ethical standards to:

- Protect participants from harm by weighing the risk of harm against the prospect of benefit;
- Protect the safety and welfare of participants deemed to be in vulnerable categories;
- Hold researchers accountable for their research actions;
- Promote the highest ethical standards and best available techniques or approaches for optimal use of participating humans; and to
- Promote important social and ethical values to the research community.

The Wits HREC (Medical) must review research proposals prospectively and not retrospectively, to ensure that proposed research meets the accepted ethical norms and standards before research commences, using the National Guidelines as a minimum benchmark.

The Wits HREC (Medical) will:

- Function according to its code of conduct;
- Operate in accordance with the University's Research Integrity Policy and Research Integrity Procedures;
- Follow the Wits HREC (Medical) procedures as set out in its SOP;
- Formulate and approve a set of discipline-specific examples of risk level categories used to guide decision making whilst reviewing applications;
- Provide feedback on specific matters as requested by the UR&IC and/or the DVC: R&I;
- Ensure confidentiality of all information revealed to it;
- Ensure that all researchers applying for ethics approval sign the research ethics code of conduct, which an example of such Code of Conduct; and
- Ensure that all Wits HREC (Medical) members sign the research ethics code of conduct.

The Wits HREC (Medical) will uphold the necessary University's rules and regulations.

The primary responsibility of each member of the Wits HREC (Medical) is to decide independently whether the proposed research protects the interests of participants adequately and upholds the highest of standards. Such responsibility regarding participant interest will always take precedence over the interest of the research.

7. Procedures

7.1. Principles

The Wits HREC (Medical) and its sub-committees (e.g., BEC) are bound to adhere to the procedures described in the relevant Standard Operating Procedure (SOP) and the Code of Conduct for Wits HREC (Medical) Members. Beyond the requirements of the Code of Conduct, Committee members will be expected to:

- Agree to a term of office of five (5) years, which can be renewed for two (2) subsequent terms;
- Familiarise themselves with the University's relevant policy as well as national and international research ethics guidelines;
- Attend research ethics training sessions at least once every three (3) years to keep abreast with the latest developments in the field and provide proof of evidence of this training;
- Always act with integrity while conducting the business of the Committee;
- Although the submission of written reviews is permitted, members should regularly attend Committee meetings or, if this is not possible, provide a reasonable reason for any absence;
- Be punctual in the attendance of the Committee meetings;
- Diligently perform all responsibilities;
- Maintain all these responsibilities in compliance with the University's internal policies, directives, rules and regulations, national and international ethical and regulatory requirements;
- Declare any prior interest, any conflict of interest and/or involvement in any matter being discussed in a Wits HREC (Medical) meeting to avoid conflict of interest, either personal or financial interest; and
- Keep all matters discussed in Wits HREC (Medical) confidential.

7.2. Responsibility to Non-Affiliated Researchers and External Applications

Researchers with no affiliation to the University or who are considered to be external applicants can approach the Wits HREC (Medical) to review and approve their research proposals. The Committee may, on a case-by-case basis, decide whether it is able or appropriate to deal with the matter and whether the Committee is willing and has the capacity to evaluate the application. Part of this decision is the ability of the Committee to review progress of the research pasted clearance and, if necessary, to make interventions.

In such a case a review fee, which is payable upon submission of the application, will be levied for the service. The value of the review fee is subject to the Wits HREC (Medical) Chairperson's discretion, in consultation with the Secretariat and University Research Office, but should not be excessive. The review can be waived or discounted by the Wits HREC (Medical) Chairperson on a case-by-case basis.

7.3. Administration

The administration of the Wits HREC (Medical) is provided and managed by the University Research Office through the Legal Adviser and Research Compliance Manager, and the Director: Research Development. It is important that the administration and other support staff members work collaboratively with the Chairperson and the Wits HREC (Medical).

The University Research Office also serves to internally audit the Wits HREC (Medical) in terms of their operational mandate and standards, and where applicable, to ratify the HREC Non-Medical's decisions.

7.4. Collaboration

Although independent in its decision making, the Wits HREC (Medical), supported by the UR&IC, works in close collaboration with the management and staff of University's Faculties.

7.5. Audit and Reporting

The Wits HREC (Medical) must report annually on their activities to the NHREC via the UR&IC using the template provided. The NHREC will also organise and implement regular audits of the activities of the Wits HREC (Medical). If the Wits HREC (Medical) is dissolved for whatever reason, this must be reported to the NHREC, UR&IC and the DVC: R&I immediately.

7.6. Remuneration of Wits HREC (Medical) Members

Wits HREC (Medical) members, other than the Chairperson, who are on the payroll of the University are not remunerated for their services. This is to reduce conflict of interest and increase independence. Their services are recognised as part of their academic citizenship.

The services of members not on the payroll of the University (e.g., layperson, or attorney) should be viewed as community service. However, they may be compensated through an honorarium negotiated before the appointment to cover travel costs and other incidental costs provided they are:

- Not employed and might lose the opportunity to earn income for the day by attending to certain Wits HREC (Medical) duties;
- Employed but must add hours to their workday to serve on the Wits HREC (Medical); or
- In a private practice and their participation as a member of the Wits HREC (Medical) will lead to a loss of earnings, as they are not able to earn an income during the Wits HREC (Medical) meeting.

7.7. Amendments to the TOR

In all instances, amendments to the National Health Act and/or the National Guidelines will take immediate effect after they are published. Where necessary, this will lead to corresponding changes made to these ToR and to the SOP.

8. Relationship Between the Non-medical and Medical HRECs

It is possible that some applications may not have a clear distinction between the medical sphere and the non-medical sphere. For example, some social science research projects may be based in hospitals or clinics, but do not involve any clinical, diagnostic or therapeutic interventions. Instead they may use interviews or questionnaires with staff or patients focused on access to services, perceptions, values and cultures. In this case, staff or patients are merely a participant group.

Under these situations it is unclear which research ethics committee should review the application. Such cases will be resolved through informal discussions between the registered research ethics committees of the University to establish which is most appropriate to review the application.

The Wits HREC Non-Medical and the Wits HREC (Medical) are committed to continual dialogue working towards improving ethical practice across the University, including sharing best practice between them.

9. References

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

10. Acknowledgements

The following are acknowledged for their input into the development of these ToR; the North West University Research Ethics Committee and the University of Cape Town.

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