

HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

HREC COMPOSITION AND QUORUM

SOP-HREC – 003 (VERSION 1)

REVISED AND UPDATED: FEBRUARY 2025

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| SUBJECT: | Wits HREC (Medical) Composition and Quorum |
| DIVISION / SCOPE: | University of the Witwatersrand, Human Research Ethics Committee (Medical) |
| AUTHOR: REVISION: | Ethics Secretariat |
| PURPOSE: | <p>This procedure describes the process to be followed by the Wits HREC (Medical) regarding composition and quorum, in compliance with the following requirements:</p> <ul style="list-style-type: none"> • Wits HREC-Medical SOP, Draft 3 Approved by UR&IC 23 Oct 2023 • South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) • South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024) |
| PREVIOUS VERSIONS / (REASON FOR REVISION) | SOP-IEC-003v12 Revised and updated |
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| APPROVALS: | <p>Signature of Chair / Co-Chair of Wits HREC (Medical):</p> <p style="text-align: center;"><i>Paul Ruff</i></p> <p>Date: 2025/02/19</p> |

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1. COMPOSITION OF THE WITS HREC (MEDICAL)

1.1 Committee Membership

Based on the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024) an ethics committee must have a minimum of 9 (nine) members including the Chair, to be properly constituted. There is however no upper limit on REC membership. The membership should ideally include, noting that all categories below are neither exhaustive nor intended to be exclusive of 1 (one) another, at least 1 (one):

- Laypersons, preferably from the community in which the research is to take place. A layperson is viewed as an ordinary person with no specific qualification in a given profession and/or does not have specific knowledge of a certain discipline / field, for example, a member of the community or someone with an interest in spiritual care*.
- Members with experience and expertise in a number of clinical areas including: Anaesthesia, Cardiovascular Disease, Critical Care, Endocrinology, Family Medicine, Gastroenterology, Haematology, Infectious Diseases/HIV/TB, Internal Medicine, Nephrology, Neurology, Obstetrics and Gynaecology, Oncology, Orthopaedics, Paediatrics, Pharmacy and Pharmacology, Pulmonology, Rheumatology and Surgery.
- Members with experience and expertise in a number of non-clinical areas including Artificial Intelligence, Biochemistry, Bioethics and Health Law, Human Anatomy, Pathophysiology, Pathology and Sociology.
- Members with experience and expertise in mental health including Psychology and Psychiatry.
- Members with experience and expertise in Allied Health Professions such as Nursing, Occupational Therapy, Physiotherapy, Social Work, Speech Pathology and Audiology.
- Members with professional training and experience in qualitative and quantitative research methodologies including biostatistics.
- Members with experience and expertise in molecular and cell biology and human genetics.
- Members with experience and expertise in radiation and radiation sciences including radiology, nuclear medicine and radiation oncology.
- Representatives of National, Provincial and Local Government healthcare structures.
- Members with experience and expertise in epidemiology and public health.
- Members with experience and expertise of health communication and education.
- Members with experience and expertise in health economics.
- Members who hold a legal qualification or are legally qualified.

The Committee should be representative of the research communities it serves within the University and, increasingly, reflect the demographic profile of the population of the Republic of South Africa as best and reasonably as possible. The Committee must include members of both genders, although not more than 75% (seventy five percent) should be either male or female.

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*Note that spiritual care does not necessarily mean religious care and must be non-denominational in nature.

1.2 The Committee can co-opt other members:

Specialist advisors to help review research proposals where the content of the proposed research is not within the areas of expertise of the Committee membership; and or Emeritus Advisors, namely, people with experience whose terms of HREC (Medical) membership have ended, but who can help with mentorship and capacity development.

Such co-opted advisors are not regarded as full members and will not be able to vote or to be counted in the quorum.

All Wits HREC (Medical) members including co-opted members and layperson / external members must:

- Protect the interests (safety, rights and welfare) of the Research Participants who volunteer to take part in scientifically sound research.
- Protect the interests (safety, rights and welfare) of Researchers, especially those who work in potentially high-risk environments, e.g. prisons, infectious disease wards.
- Decide independently whether the proposed research protects the interests of participants and the community adequately and keep to exemplary standards in all research activities
- Act in the best interests of the University and the Wits HREC (Medical). This obligation must be observed over any duty a member may owe to those electing or appointing him or her.
- Participate in the deliberations and decisions of the Wits HREC (Medical) with the object of promoting the best interests of the University and the Wits HREC (Medical), drawing on his or her knowledge and experience.
- Act in good faith, honestly and for a proper purpose.
- Exercise appropriate care and diligence in decision-making.
- Preserve the dignity of the research participants, the University and the Wits HREC (Medical) and respect and abide by and the Wits HREC (Medical) decisions.
- Spend as much time as is required to diligently perform their duties (this will normally mean devoting more time over and above that required for attending and the Wits HREC (Medical) meetings).
- Disclosure of all potential conflict of interests, whether personal, financial, academic, political or other.

1.3 Duration of Membership

Members including the Chair and Co-Chairs of the Wits HREC (Medical) are appointed for a period of 5 (five) years and can be re-appointed for a second 5 (five) year term. The maximum period of service is therefore 10 (ten) years.

2. SELECTION OF WITS HREC (MEDICAL) MEMBERS

2.1 Recruitment and Appointment of Members

The number of new members to be recruited each year will depend on the needs of the Committee and the number of members resigning or retiring.

Applications, including a brief motivation and CV, must be submitted to the Wits HREC (Medical) Secretariat. These applications, including those from people seeking re-appointment, will be reviewed by HREC members and Secretariat. The selected candidates will be approved and appointed by the Deputy Vice-Chancellor for Research and Innovation (DVC: R&I). Any potential new members are to

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attend a minimum of 2 (two) monthly Wits HREC (Medical) meetings as observers before being appointed to the Wits HREC (Medical).

Each new member and reappointed member will receive an appointment letter, signed by the DVC: R&I, referring to the ToRs, the Wits HREC-Medical SOPs, Confidentiality Declaration, Code of Conduct and Declarations of Interest. The appointment letter will also provide the assurance by the University that the Committee members are indemnified from any personal liability against claims that may arise in the course and scope of ordinary business of the Committee.

2.2 Induction of New Members

All the new members will take part in an induction programme that will introduce them to the functioning of the Committee and their responsibilities. The induction programme will be arranged by the Committee and Secretariat. They will receive an introductory pack of information which will include the following, but not limited to: Letter of Appointment, University Research Ethics Policy, Wits HREC (Medical) ToRs and SOPs, Wits Code of Conduct, Confidentiality Declaration (to be signed by the members yearly and returned to the Secretariat), South African Ethics in Health Research Guidelines, Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024), , SAGCP (2020), ABPI (2014) and other documents that maybe required. After an initial briefing, training will be achieved through observation, mentoring and “on the job” experience.

All members are required to complete an accredited Ethics Content Course and provide proof of completion to the Secretariat within 6 (six) months of joining the Committee. This training must be renewed every 3 (three) years. Members who review clinical trials must complete an accredited SAGCP training course, to be renewed every 3 (three) years.

Upon appointment to the Wits HREC (Medical), new members must sign an applicable Confidentiality Declaration (renewable annually), the University’s Code of Conduct, Conflict of Interest Declaration (renewable annually) and any other relevant documentation that may be required in future.

All Wits HREC (Medical) members will receive an acknowledgment of service at the end of each year that they have served. This certificate will indicate the member’s involvement with the Committee and serve as evidence of their academic citizenship in the University.

2.3 Appointment of the Chairperson and the Co-Chairpersons

The Chairperson of the Wits HREC (Medical) is a paid position normally at the level of 50% (fifty percent) of a full-time professorial equivalent. The recruitment of the Chairperson will follow normal University recruitment processes and policies, including advertising of the position. The selection committee for the recruitment process will include 2 (two) representatives of the Wits HREC (Medical), 2 (two) members of the academic leadership within the Faculty of Health Sciences, a Chairperson from another Wits research ethics committee and 2 (two) members of the University Research Office. Additional members may be required by the Wits Human Resources Department as per their policies. The selection criteria will include, at least, a deep knowledge of ethically responsible research and experience on an ethics review committee.

The appointment of the Chairperson will be for a period of 5 (five) years. In the fifth year the position will be advertised, and the incumbent can reapply. No 1 (one) person will be allowed more than 2 (two) 5 (five) year terms as Chairperson and Co-Chairperson. Previous terms as a member will not impact on this term. Once a Chairperson has served their full term as a Chairperson, they are not permitted to be appointed as Co-Chairperson but may continue as an ordinary Member.

The Chairperson will be regarded as a Member of the Wits HREC (Medical) and will carry the responsibilities of presiding over the Committee’s work and responsibilities, ensuring the smooth and efficient running of the Committee and to provide leadership both on a strategic and operation level. To

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this end, the incumbent will work closely with the Secretariat and with the University Research Office tasked to administer the Committee.

The Wits HREC (Medical) may have several Co-Chairpersons, at least 2 (two), but more if necessary. They will be selected from the membership by the Committee, through a nomination and decision-making process by the Wits HREC (Medical). The Co-Chairpersons remain members of the Committee and have the additional responsibility of supporting the Chairperson and representing the Chairperson during periods of absence. The role of the Co-Chairpersons is seen in a development light, thus preparing them to compete competently for the role of Chairperson as described above. Their membership term is as for normal members of the Committee.

2.4 Termination of Membership

If a member, including a co-Chairperson, is absent from 2 (two) consecutive scheduled Committee meetings without a legitimate explanation, or attend less than 80% of annual HREC meetings without a legitimate explanation, then the absence must be addressed by the Chairperson in writing and may result in the termination of the membership. Virtual attendance by members is however fully acceptable.

In situations where a member is on sabbatical leave, maternity leave, is seriously ill, or under circumstances where they cannot fulfil the requirements of membership, the membership of the person concerned can be put into abeyance until they are able to continue serving normally.

Membership can be terminated for good cause including but not limited to poor performance or inappropriate performance.

For purposes of this paragraph good cause includes *inter alia* decision-making in bad faith or failure to declare conflicts of interest. Such decisions must be decided by a specially constituted independent sub-committee chaired by the Chairperson of the Wits HREC (Medical) and communicated in writing to the member. People whose membership is terminated in this manner may appeal the decision by writing a motivation to the University Research and Innovation Committee (UR&IC). The UR&IC will consider the matter and call for all necessary inputs before making a decision. The decision of the UR&IC in this matter will be regarded as full and final.

Should the Chairperson miss 2 (two) consecutive scheduled meetings without explanation or if the Committee considers the Chairperson's performance less than adequate, then they can bring this to the attention of the UR&IC in writing. The UR&IC will consider the matter and call for all necessary inputs before making a decision on the way forward. If they uphold the decision, then the DVC(R&I) will refer the matter to the University's Employee Relations to institute disciplinary procedures against the Chairperson using the University's normal disciplinary procedures and in line with the Labour Relation legislation.

3. MANAGING CONFLICTS OF INTEREST

Wits HREC (Medical) members must disclose all conflicts of interest, no matter how small or apparently insignificant, before they have a bearing on decision making which is in line with the University's Conflict of Interest Policy.

Wits HREC (Medical) members are required to declare any conflict of interests at the start of every year by signing a declaration of interest. Members are to further declare any conflicts of interests before and in meetings. Members should not review or make decisions about research proposals in which they are involved academically, personally or financially or where they may receive any benefit from the approval of the ethics related to a research proposal. When such a proposal is discussed, the member concerned must declare the potential conflict and must then recuse himself / herself from the meeting while that matter is being discussed. This absence must be minuted. The specific member will be invited back to

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re-join the meeting after the review has been complete. Members are required to declare if they have a relationship with an applicant in order for the Committee to decide if there are any conflicts that need to be addressed.

In the case of a conflict impacting on the Chairperson, a Co-Chairperson will preside over the meeting and the Chairperson must recuse himself / herself while the matter is being discussed and decided upon. This absence must be minuted. The Chairperson will be invited back to re-join the meeting after the review has been complete.

4. QUORUM

As per South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024) where the number of members is more than 15, the quorum may be 33%.

5. DEFINITIONS AND ABBREVIATIONS

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| ABPI | Association of British Pharmaceutical Industries |
| DVC | Deputy Vice-Chancellor |
| GCP | Good Clinical Practice |
| HREC | Human Research Ethics Committee |
| NDoH | National Department of Health |
| REC | Research Ethics Committee |
| R&I | Research and Innovation |
| SAGCP | South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) |
| UR&IC | University Research and Innovation Committee |
| WITS | University of the Witwatersrand |

6. REFERENCES

- ◆ Wits HREC-Medical SOP, Draft 3 Approved by UR&IC 23 Oct 2023
- ◆ South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
- ◆ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024)
- ◆ Declaration of Helsinki 2024
- ◆ ICH Harmonised Guideline for Good Clinical Practice E6(R3) Final version, 06 January 2025