UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Human Research Ethics Committee: (Medical)
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UPDATED GENERAL NOTICES FROM THE WITS HREC (MEDICAL)

TABLE OF CONTENTS

TITLE	PAGE
1. Introduction	1-2
2. Ethics and GCP Training	2-3
3. Insurance, Indemnity and Malpractice Cover	3-4
4. Length of Documents	4
5. Informed Consent and Assent	4-5
6. Duration of Approval	5-7
7. Biobanks and Biorepositories	7-8
8. Reciprocity with other RECs	8
9. Wits Affiliated And Non-Affiliated Investigators Including Foreign Investigators	8
10. HREC (Medical) Review of Essential Support Staff	8-9
11. Application Forms - General	9
12. Types of HREC Application Forms	10-12
13. Reimbursements	12-13
14. SOPs For Invasive Procedures	13
15. Queries To HREC (Medical)	13
Addendum 1: Investigator Workload Form (To be completed by all clinical investigators)	15
Addendum 2: Fee Structure for Commercial and Grant-Funded Research (effective 1st of February 2026)	16-17

1. INTRODUCTION

1.1 Background

The Human Research Ethics Committee (HREC) (Medical), is an independent committee which provides ethics approval and oversight for all research at the University of a medical nature involving human beings, and has two secretariats with differing roles, one for university-based research for degree and non-degree purposes, based in the PV Tobias Building, and one for complex grant-funded and commercial research, based at the Wits Health Consortium (WHC). Both secretariats form part of HREC (Medical) and are not two separate HRECs (Medical).

1.2 Faculty Cover

Although HREC (Medical) predominantly covers medical research from the Faculty of Health Sciences, it also deals with research from the other four Faculties at the University, including Science; Humanities; Engineering and the Built Environment; and Commerce, Law and Management.

1.3 Meetings

The HREC (Medical) meets on the second last Friday (commercial and grant funded applications) and last Friday (research for degree and non-degree purposes) of every month, from 12 noon to 5 pm, except December. In very busy months the meeting starts at 11am to enable the committee to deal with the extra load. The meetings are held face-to-face one month in three, and virtually for two months in three.

1.4 Membership

HREC (Medical) has 55 members at present, including the Chair, and four co-Chairs. The membership includes 45 full members based at Wits; 5 full members not affiliated with Wits; and 5 advisory members who don't form part of the meeting's quorum but advise on specific areas of expertise. Expertise on HREC (Medical) includes clinical trials (10), regulatory affairs (5), pharmacology and pharmacy (4), public health (3), health economics (4), occupational therapy (1), physiotherapy (1), psychology & psychiatry (3), legal (2), statistics (16), surgery (3), internal medicine (8), paediatrics (3), O&G (3), engineering (1), microbiology and ID (6), dentistry (2), human genetics (3), oncology (4), anatomical pathology (3), nephrology (1), pulmonology (1), nursing (1); speech & hearing therapy (1); human anatomy (1), haematology (5), and radiation affairs (2) as well as 2 members of the lay public. Members must attend two months of meetings as an Observer before they are eligible to become a full member.

1.5 Responsibilities

All studies involving research grants, funding, budgets, insurances, reimbursements, collaborators, etc., being of medium to high risk to very high risk, go through the WHC-housed secretariat due to their obvious complexity, allowing the faculty-based secretariat to deal with all the university based degree and non-degree studies. The faculty-based research office deals with approximately 100 applications per month, mainly for under- and postgraduate research but also non-degree-research. The more complex funded projects which fall under the WHC-housed secretariat deals with an average of 14 applications (range 8 -28) per month.

- Link to the website for Faculty-based applications:

https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/

- Link to website for Funded applications:

https://www.witshealth.co.za/Services/Research-Ethics

2. ETHICS AND GCP TRAINING

All **HREC members**, **HREC administrators**, **researchers**, **supervisors** and **students** must complete theoretical research ethics training to ensure they are familiar with expectations, especially those set out in the National Health Research Ethics Council (NHREC), South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition (NDoH 2024), and for clinical trials, SA GCP (2020). Both GCP and Ethics Training must be renewed every three years.

The expectation is that researchers, and especially students, both under and post-graduate, should complete the institutionally required research ethics training before conducting any research. Any research conducted without HREC approval will be considered invalid and may not be used for any publication or presentation.

Researchers are expected to ensure they have the appropriate knowledge, skills, expertise, competence, including discipline-appropriate scientific background and research ethics training to conduct studies involving human participants.
Current Research Ethics Training certificates that do not reference NDoH 2024 guidelines, but rather NDoH 2015 guidelines, will be accepted until expiry, after which refresher training must include reference to the NDoH 2024 guidelines.

The HREC (Medical) will accept TRREE training provided that the South African Regulatory Framework Modules 1, 2 and 3 are completed. These three modules together will be viewed as valid ethics training.
- Module 1 – Introduction to Research Ethics
- Module 2 - Research Ethics Evaluation
- Module 3 – Informed Consent

Please Note:
- TRREE Ethics Training **Module 1** completed **before the 30th of September 2025** will be valid as is, **until expiry, after which Modules 2 and 3 must be done**.
- TRREE Ethics Training **Module 1** completed **after 1st of October 2025** will be required to also complete Modules 2 and 3 to be valid.

Other online South African based ethics training, including Academic Advance, incorporating NDoH 2024 will also be accepted.

GCP Training, which must reflect SA GCP (2020) requires an initial face-to-face or virtual, live training programme over two days, while refresher courses, which must be completed every three years, may be done online.

3. INSURANCE, INDEMNITY AND MALPRACTICE COVER

Due to the increasing high-risk nature of clinical research, especially clinical trials, it is important that adequate cover is provided for participants, investigators and study sites. It is therefore essential that the following be provided on all studies which have more than minimal to low risk:

1. **No-fault insurance** based on The Association of the British Pharmaceutical Industry (ABPI 2014) guidelines. All clinical trials require this form of insurance to cover medical and related expenses for participants on a no-fault basis. It must be noted that there is no burden of proof on the participant to show that the injury was due to the investigational product (IP). Indeed, this insurance must cover any event that would not have happened if the participant was not on a clinical trial.
2. **Indemnity** – This insurance normally provided by the Sponsor or Institution i.e. Wits or WHC, covers participants and study sites for any serious adverse events / adverse events which may result in litigation.

3. **Personal Malpractice Insurance** - All Investigators must have personal liability protection from the MPS or an alternative organisation in the case of negligence or malpractice. Only Investigators who are working full time for the state or province are covered by the employer in the case of malpractice in their routine course of work. As clinical trials usually fall outside the ambit of routine work, it is imperative that all Investigators, whether employed by state or university, have their own personal malpractice insurance. It is suggested that you contact the MPS for further advice as to what would be the best cover to obtain. Please note that MPS for full-time state employees only covers HPCSA matters and does not cover any potential litigation by study participants.

4. LENGTH OF DOCUMENTS

4.1 Length and Complexity of Participant Information Leaflets/Informed Consent (PIL/ICON)

The committee asks Applicants to apply their minds when developing the PIL/ICON for South African purposes, by **avoiding cutting and pasting** from the protocol, and to summarise important information into simple, plain English, which is readable and literacy-level appropriate.

The PIL should aim to be not more than **25 pages** in length.

4.2 Length of Completed HREC Application Forms

The committee asks Applicants to **avoid cutting and pasting** from the protocol, and to summarise important information into simple, plain English. Applicants must please avoid changing the format of the HREC Application Forms.

In addition please make sure that all of the sections of the application form are completed even if they are Not Applicable.

The completed HREC Application Form should aim to be not more than **25 pages** in length.

Also, please note that handwritten application forms or poorly scanned application forms will not be accepted and will be returned to the Applicant.

5. INFORMED CONSENT AND ASSENT

All clinical studies involving adults >18 years of age require Participant Information Leaflet and Informed Consent Form (PIL/ICON) to be signed, dated and witnessed. Informed consent should be taken under the auspices of a trained person who ideally should be a healthcare professional but may be a non-healthcare professional provided that evidence of GCP, Ethics, Protocol and Informed Consent training is available.

Minors <18 years of age may not sign informed consent forms. This is because informed consent forms are legal documents and cannot be signed by minors. As a result, parent/legal guardian consent is mandatory.

In addition, minors over the age of 7 years must sign Assent Forms. These participants are usually divided into 7-11 year olds and 12-17 year olds who would require separate assent forms. This is particularly important in interventional studies that involve significant risk.

Assent Forms should also be adequately summarised and appropriate for minors of applicable ages and literacy-levels.

Templates for informed consent and assent forms can be obtained from both HREC (Medical) websites.

6. DURATION OF APPROVAL

6.1 Expiry Dates of Initial Ethics Approval Letters And Recertification Approvals

HREC (Medical) hereby requests that Investigators and Sponsors/Applicants regularly review their initial ethics approval letters to determine the expiry date of the ethics approval.

As per the initial ethics approval letters provided by the HREC, approval is valid for 5 years. Where the 5-year approval is set to expire, a recertification application should be submitted before the expiry date. **A maximum of six (6) months grace period will be allowed once the approval has expired.**

The committee reminds Investigators and Sponsors/Applicants of the potential implications resulting from a lapse in ethics approvals, such as discarding of data collected during the lapse period.

6.2 Recertifications and Memorandum of Agreement (MoA) for External/Private (non-Wits) Research Sites <u>inside of the Gauteng Province</u>

The National Ethics Committee regulations require direct legal supervision of the research sites by the HREC (Medical) including monitoring visits to the site and the authority to intervene should there be an identified risk of ethical misconduct. The HREC (Medical) developed a Memorandum of Agreement (MoA) for External/Private Research Sites/Principal Investigators based **inside** of Gauteng. Applications for these sites may be submitted to the HREC (Medical) for review and approval, however 1) there must be at least one Wits affiliated Site/Investigator involved in the study, and 2) the MoA for the external/private sites must be completed and submitted with applications.

The MoA is an agreement between the University of the Witwatersrand, the Sponsor/Applicant and the External Site/Principal Investigator and will give the HREC (Medical) proper jurisdiction to oversee these external/private sites. This MoA is required for all external/private site applications (i.e., new applications and additional sites added to ongoing studies).

External/private sites based **inside** of the Gauteng Province that have previously been approved by the HREC (Medical) will be supported until the initial 5 year ethics approval expires, after which they may be recertified for an additional five years, but on condition that they complete MoAs.

6.3 Studies previously approved by the HREC (Medical) for sites <u>outside of the Gauteng Province</u>, that require annual recertification

These will be reviewed under the following categories:

6.3.1 An ongoing study where participant enrollment and follow-up is ongoing will be considered for a single recertification to provide the investigators with an opportunity to approach a local or private ethics committee for further approval. This recertification will require the institution, site and principal investigator to sign the MoA referenced above. Category 6.3.1 is subject to application by the principal investigator and should be accompanied by a cover letter motivating the required period of recertification while awaiting review from the local institutional or private ethics committee.

6.3.2 An ongoing study where the participant enrollment and follow-up has been completed but the study remains open under the Wits HREC (Medical) for the completion of the data, secondary analysis, laboratory investigations or sample storage may be recertified by the Wits HREC (Medical) as required.

6.3.3 A study that is closed to participant follow-up and where the primary database has been closed, but the study remains registered with the HREC (Medical) for the maintenance of laboratory samples stored in a biorepository may be recertified by the HREC (Medical).

6.3.4 Studies conducted at sites under the supervision of a Principal Investigator that are affiliated by an appointment to the University of the Witwatersrand may continue to under the recertification of the HREC (Medical). Should this affiliation cease, the Wits HREC will no longer be able to provide ethics cover for the applicable site/PI.

6.4 External/Private (non-Wits) Research Sites outside of Gauteng

The HREC (Medical) no longer approves external/private research sites **outside** of the Gauteng province. This decision is due to monitoring pressures and difficulties in oversight.

As per South African Ethics in Health Research Guidelines: Principles, Processes and Structures 2024, Third Edition, Chapter 5, Section 5.5.1.4 a):
*"The South African ethico-legal framework requires that PIs or research leaders must obtain approval from their institutional REC. In principle, this means that RECs have authority to review and approve research protocols only for research sites or geographic areas within their own South African jurisdiction. Thus, when a protocol proposes a research study or project that is to collect data from multiple sites or **geographic areas** within South Africa, more than one REC may be involved in the review and approval processes."*

Therefore external/private research sites outside of Gauteng should be submitted to HRECs with jurisdiction in their own geographical area.
The HREC (Medical) will however continue to provide ethics support for previously approved external/private research sites outside of Gauteng, until the expiry of the initial 5 year approval, after which they will be provided with HREC approval for a maximum of one year only, until either the study closes, or to provide support until an alternative ethics approval can be obtained elsewhere, should the study continue for a number of additional years. These sites must complete and submit MoAs with the annual recertification application.

Note: WITS affiliated sites and Investigators outside of Gauteng will be accepted for HREC review and approval as they fall under the jurisdiction of the University of the Witwatersrand.

6.5 Withdrawal of Applications where Queries are not Responded to Within Six (6) Months

The HREC (Medical) hereby requests that Investigators and Sponsors/Applicants respond to queries raised by the committee within 14 days. If it is not possible to respond within 14 days, the Investigator/Sponsor/Applicant are requested to provide a reason why they cannot respond in this time frame. Should no responses be received within six (6) months of the meeting, the application will be withdrawn from the review process and will require a new submission.

7. BIOBANKS AND BIORESPOSITORIES

7.1 Transport, Storage and Future Research on Human Biospecimens for Future Laboratory Research, including Genetic Testing

When human biospecimens are collected from research participants, the participants must be made aware that no future testing, beyond the overall scope of the original study may be undertaken, unless the participant specifically consents to future research using the biospecimens. Participants may consent to the use of their biospecimens in future studies but only on the basis that the HREC (Medical) will approve the research on a project specific basis at the applicable time.

The HREC (medical) will approve the use of these biospecimens for future research provided that the interests of the participants are protected and that the research is in the public interest.

The participants may also consent to storage of their biospecimens in a Biobank inside or outside of South Africa (see section on biobanks below).

As per the SOP on future research:

Scenario 1: Participant consents to research on samples/data in the current study/protocol only. No future testing beyond the scope of the study/protocol will be done. This requires no further approval by the HREC (Medical).

Scenario 2: Participant consents to research on samples/data for the current study/protocol, and also stored for future studies that are within the broad scope of the disease(s) being studied. HREC (Medical) must approve these future studies at the applicable time.

Scenario 3a) Participant consents to non-genetic research on samples/data for as yet 'ill-defined' future analysis not related to the current study/protocol/scope of the disease(s), but in the public's best interest. HREC (Medical) must approve these future studies.

Scenario 3b) Participant consents to genetic research on samples/data for as yet 'ill-defined' future analysis not related to the current study/protocol/scope of the disease(s), but in the public's best interest. HREC (Medical) must approve these future studies. In this case, the participant must have been clearly informed about genetic testing (present and future) in the original PIL.

7.2 Biobanking

If a study collects human biospecimens as a component of the primary study, it should not be considered to be Biobanking. Such a facility should rather be considered as a Biorepository.

If any human biospecimen samples are stored for future secondary/unrelated research, and/or commercial use, then it is considered to be Biobanking, and will need to be stored in a formal biobank facility. Biobank Ethics applications are dealt with by the Biobanks Ethics Committee (BEC), a Subcommittee of the HREC (Medical).

BEC requires application forms to be submitted for:

- BEC 1 Form*: Approval of a **Local** Biobank for sample storage
- BEC 2 Form: Storage/Retrieval/Transfer of HBM (Human Biomedical Materials) for a specific study from an approved Biobank
  * International Biobanks do not require a formal BEC1 but BEC will need to be informed via a notification of documentary evidence confirming their Biobank approval status in their own jurisdiction
  BEC Contact details: Tanya Coetzee (Tanya.Coetzee@wits.ac.za) or (Rhulani.Mkansi@wits.ac.za) / 011 717 2816/1234) / https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/

8. RECIPROCITY WITH OTHER RECS

The HREC (Medical) has taken the decision not to implement reciprocity recognition with other RECs, either inside or outside of South Africa, at this point in time. Should the need arise in the future, SOPs will be created first, in conjunction with the relevant institution.

Any benefits or arrangements available to students or staff at other institutions may therefore not apply to Wits and its HREC (Medical).

9. WITS AFFILIATED AND NON-AFFILIATED INVESTIGATORS INCLUDING FOREIGN INVESTIGATORS

a) Studies done at Wits Academic Circuit Teaching Hospitals by non-Wits affiliated Investigators do not need Wits HREC approval unless there will be a Wits affiliated Investigator involved on the study.

b) If a Wits affiliated Investigator is doing a study in any another jurisdiction, they will need Wits HREC approval plus Facility/Provincial Approval from that Facility/Province.

c) Each South African University is responsible for providing ethics approval for all investigators affiliated with that University in South Africa.

d) Foreign Investigators will need HPCSA registration, Ethics and South African Good Clinical Practice (SA GCP 2020) training if they are active clinical investigators in South Africa. If they do not have HPCSA registration and appropriate ethics and/or GCP training, they may be non-Clinical Investigators or Collaborators only.

10. HREC (MEDICAL) REVIEW OF ESSENTIAL SUPPORT STAFF

The HREC (Medical) requests that the following essential support staff be submitted to HREC (Medical) for notification:

• Medical Practitioners with HPCSA registration
• Senior and Back-up Pharmacist(s) with SAPC registration
• Only Study Nurses / Study Co-Ordinator's, with SANC registration, who have a direct clinical involvement with participants i.e., who are actively involved in the treatment of participants e.g., administering participants treatment with the investigational product, or independently taking Informed Consent or In-depth Interviews.
• Non-healthcare professionals taking informed consent under the auspices of a healthcare professional provided that they have evidence of GCP, Ethics, Protocol and Informed Consent training.

For these support staff we would require a copy a signed Declaration as Sub-Investigator, GCP and Ethics training certificates. We do not require a copy of their CV's.

Other support staff members who have an administrative role and who are not clinically involved with participants in a significant fashion, would not need to be submitted to HREC (Medical) for notification.

11. APPLICATION FORMS- GENERAL

11.1 Completion of HREC Forms

Please note that the HREC forms must be filled in completely, otherwise the committee will not be able to adequately review the submission. No handwritten or poorly scanned applications will be accepted.

11.2 Signatures on HREC Applications

Please note that a Supervisor/Principal Investigator who is also Head of Department (HoD) cannot sign an HREC application form as HoD. In this case, the signature of another senior member of the department will be required as HoD.

11.3 Study start and end dates

These should not be confused with the period for which data is to be collected, especially in a retrospective study. The start date for the study must be at least a month after the meeting HREC.

11.4 Expedited Reviews

All reviews will follow the normal channels as above. The only time that reviews will be truly expedited will be in cases of emergency situations such as a pandemic.

11.5 Phased Study Applications

Studies done in multiple phases may be submitted as one application or as multiple applications as the Investigator proceeds through their research. It is essential that the Applicant refers back to the initial application when applications for subsequent phases are submitted to HREC (Medical).

11.6 College of Medicine of South Africa (CMSA) Qualifications

Please note that projects for CMSA qualifications are not considered to be for university degrees.

Any study done specifically for a CMSA project, especially those for sub-speciality certificates e.g. Certificate in Pulmonology, must therefore be submitted to HREC (Medical) as being for non-degree purposes.

Candidates for CMSA qualifications done in conjunction with an MMed or MSc are considered to be for degree purposes. These applications to HREC (Medical) must be submitted as a post-graduate degree e.g. MMed (Int Med) and not FCP (SA).

11.7 Workload document
All Investigators involved in clinical research should submit a workload document demonstrating that they have enough time to complete the planned project(s).

12. TYPES OF HREC APPLICATION FORMS

12.1 DEGREE AND NON-DEGREE HREC APPLICATIONS

Full HREC Application Form
This is for all HREC (Medical) applications for degree and non-degree purposes, that are not case reports, sub-studies, retrospective record reviews, secondary data analyses, de-identified human bio-specimen studies, waivers or amendments.

The HREC (Medical) request that all Full applications be submitted through the Ethics Management System (EMS)8 - https://www.witsethics.co.za/Login.aspx.
These applications are all reviewed by two members of the HREC (Medical) and presented and discussed at the monthly meeting.

Retrospective Record Reviews
These studies, which are usually of low risk, require the submission of the HREC Retrospective Data Review Application Form and not a full HREC application, unless there is a prospective component. The HREC (Medical) request that all Retrospective Record Review based research only, be submitted through the office email - HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting. All reviews must go through the normal HREC channels.

Case Reports
Any study involving 3 or less participants will be considered to be a case report, requiring submission of the Case Report HREC Form, and not a Full HREC or Retrospective Record Review Application. HREC request that Case report applications be submitted through the office email - HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting.

De-identified Human Biospecimens
These studies require the submission of this HREC form if they involve the use of left over stored human biospecimens. HREC request that all De-identified Human Biospecimens applications be submitted through the office email - HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting.

Sub-studies and Secondary Data Analysis
Sub-studies and Secondary Data Analysis of a previously HREC approved study require submission of the HREC Sub-study Form. The expectation of "blanket" HREC approvals of such studies is not acceptable. All applications for sub-studies and secondary data analysis, must reflect details of the primary study, as well as the HREC number MXX/XX/XX (year/month/date).
HREC request that all sub-studies and secondary data analysis study applications be submitted through the office email - HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting.

PhD Applications
Please note that all HREC applications for PhDs must be reviewed by two members of the HREC and discussed at the monthly meeting regardless of whether they are full applications, retrospective record reviews, waivers, sub-studies or secondary data analyses.
We will however provide waivers outside of the committee for the initial literature/scoping review component of the PhD. A full HREC application will however be required for the rest of the PhD. Forms for retrospective record review, sub-studies/secondary analyses or de-identified human biospecimen studies may be used for a PhD application if applicable, but will still need to be seen by the full HREC (Medical) following review by two members.

Amendments and New Investigators
Minor and Major Amendments require completion of the Amendment Application Form and not just a letter to the HREC (Medical). Please note that very substantial amendments such as the addition of a new IP, arm on a clinical trial, will require a full new submission and not just an amendment.
HREC request that all Amendments and New Investigators applications be submitted through the office email - HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting.

Waivers
These will only be given for reviews of data in the public domain, *in vitro* or microbiology laboratory studies, environmental surveillance studies, and observational studies of people in public places.
All such studies require the submission of the HREC Waiver Form before starting the research.
HREC request that all Waiver applications be submitted through the office email – HREC-Medical.ResearchOffice@wits.ac.za. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting. Waivers will not be given for full PhDs but may be given for the initial scoping review only.

NOTE: SUBMISSION DEADLINE
The submission deadline for Full Applications is 5pm on the Monday following the HREC (Medical) meeting held on the last Friday of the month (except December – deadline is the last Friday at 5pm before 16th December).

There are no submission deadlines for Retrospective Record Review, Sub-study/Secondary analyses, Case reports, De-identified human biospecimen studies, Waivers, and New investigator and Amendment applications, except for PhDs, as discussed above, which must be submitted by 5pm on the last Monday of the month before the meeting.

12.2 COMMERCIAL AND GRANT FUNDED HREC APPLICATIONS

The HREC (Medical) requests that all studies with significant grant or commercial funding be submitted through the HREC (Medical) – Email address: EthicsRegulatory@witsethics.co.za. These studies require extra scrutiny and oversight, both ethically, medically, and financially. Typically, these applications involve multiple investigators, collaborators, and sites at Wits, or broader throughout South Africa or across the world. These applications often involve complex material or data transfer agreements and other memoranda of agreement. Another class of complex studies includes those with financial complexities that involve reimbursements to participants and investigators or have complex insurances and indemnities. All of these types of studies are also required by National Health Research Ethics Council (NHREC) to have active monitoring programmes, which adds to the cost structure. Indeed, it is important to understand that the role of the HREC (Medical) is not only to approve ethics applications, but also to provide ethics oversight throughout the duration of the research. This is of particular importance in high-risk studies with potential to cause physical, psychological, and even financial harm to study participants, as well as to the investigators and to the University itself.

Full HREC Application Forms:

- **Interventional Studies**

This includes all studies of an interventional nature, including the use of medicines, medical devices, kits, interviews, questionnaires as well as any medical procedure including surgery, biopsies, imaging and blood sampling.

- **Non-Interventional Studies**

This includes observational studies, surveys, cohort studies, case-control studies, surveillance studies and registry studies, where there is no direct intervention involving study participants.

- **Amendments and New Investigators:**

Minor and Major Amendments require completion of the Amendment Application Form and not just a letter to the HREC (Medical). Please note that very substantial amendments such as the addition of a new IP, arm on a clinical trial, will require a full new submission and not just an amendment. These applications are reviewed by the committee and secretariat outside of the monthly meeting but are ratified at the monthly meeting.

NOTE: SUBMISSION DEADLINE

The submission deadline for Full applications is 5pm on the Monday after the HREC (Medical) meeting held on the second last meeting of the month, (except December – deadline is the last Monday at 5pm before 16th December).

There are no submission deadlines for Amendments and New Investigator applications.

13. REIMBURSEMENTS

13.1 Reimbursement of Participants

Participant reimbursement/remuneration should not be confused with a payment, perverse incentive or inducement/coercion.

As per the National Health Research Ethics Council, South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition (NDoH 2024) and SAGCP (2020), based

on SAHPRA'S TIE (Time, Inconvenience and Expenses) guidelines, participants should not incur expenses to take part in research.

Researchers should budget to reimburse participants a fair rate, calculated using the TIE method, to determine the expenses incurred by the participant for:

- Time expended i.e. time taken to get to the study site, time spent at the site and time taken to get home
- Inconvenience should also be based on time taken to get to the study site, time spent at the site and time taken to get home and on study activities associated with research participation
- Expenses i.e. travel, petrol, taxi fares, meals and refreshments

Reimbursement for time and inconvenience is based at an hourly rate equivalent to the minimum wage for unskilled labour in South Africa of approximately R30.00 per hour (currently R28.79 per hour, but expected to increase to R30.23 after the 1st of March 2026). **This is regardless of the type of study and financial status of the individuals**.

Transport should be remunerated based on the current AA rate of R4.75 per kilometre, x by a minimum of 25km.

In addition, participants should receive modest increases in amount for increasing degrees of inconvenience that are associated with participation i.e. more inconvenience should merit a little more reimbursement that is given for minimal inconvenience.

At present the minimum participant reimbursement from SAHPRA should be R400.00 per visit, although this will be increased in 2026 based on inflation.

Note: if a participant has to come to the study site for more than one day in a row, they should be remunerated for each day individually.

13.2 Caregivers

Caregivers including those for children, the elderly or infirm, should be remunerated at the same rate as the study participant i.e. currently R400.00 per visit.

13.3 In-patients

In-patients recruited to the trial need not be compensated for distance travelled, but the inconvenience, expense and time beyond in-patient stays need to be taken into consideration. A minimum of R150 per visit is usually recommended depending on whether informed consent or other investigations and/or patient reported outcome questionnaires are being done.

The SAHPRA TIE guidelines can be downloaded from the SAHPRA website: https://www.sahpra.org.za/guidelines/

13.4 Reimbursement / Remuneration of Participants who are state employees

Although payment of state employees by study sites is not permitted, they may still be reimbursed/remunerated for their inconvenience and expenses as above. This may in the form of a token of appreciation rather than an actual payment.

14. SOPS FOR INVASIVE PROCEDURES

All studies involving invasive procedures e.g. liver biopsies, lumbar punctures, colonoscopies, require a SOP to demonstrate what measures are put into place to prevent and manage any potential adverse events/serious adverse events that may occur. This may include hospitalisation overnight following the procedure.

15. QUERIES TO HREC (MEDICAL)

All queries to the HREC (Medical) must be specific to a study rather than general, vague queries/questions. As each study is different, it is impossible to give a general answer as this may lead to misinterpretation and confusion.

Regards,

Prof P Ruff

Prof P Ruff (Jan 21, 2026 11:25:02 GMT+2)

Professor Paul Ruff
Chair, Wits HREC (Medical)

Professor Brett Bowman
Senior Director: Research Development

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

ADDENDUM 1: INVESTIGATOR WORKLOAD FORM

Study Title:				
Protocol/Project/Study Number:				
Investigator (Title, Name, Designation (PI, Co-PI, Co-I, SI)				
NUMBER OF CURRENT CLINICAL STUDIES OF INVESTIGATOR'S INVOLVEMENT				
Role (Principal Investigator/Co-PI, Co-Investigator or Sub-Investigator)	**Number of participants responsible for in actively recruiting clinical studies**	**Number of participants responsible for in follow-up clinical studies**	**Number of actively recruiting clinical studies**	**Number of clinical studies in follow-up clinical studies**
Principal /Co-Principal Investigator				
Co/Sub-Investigator				

ESTIMATED TIME PER WEEK (AS APPLICABLE)		Hours
Clinical studies	Clinical work (patient contact)	
	Administrative work	
University work / Hospital work	Clinical / Routine work	
	Teaching/Research	
	Administrative work	
Private Work	Clinical / Routine work	
	Teaching / Research	
	Administrative work	
Total		
Investigator Signature:		**Date:**

ADDENDUM 2:

FEE STRUCTURE FOR COMMERCIAL AND GRANT FUNDED RESEARCH

(EFFECTIVE 1ST OF FEBRUARY 2026)

The Human Research Ethics Committee (Medical) provides ethics approval and oversight for all research at the University of a medical nature involving human beings. It has two secretariats with differing roles, one for university-based research for degree and non-degree purposes, based in the PV Tobias Building, and one for complex grant-funded and commercial research, housed within the Wits Health Consortium (WHC). Both secretariats support the work of a single HREC (Medical). Although this committee predominantly covers medical research from the Faculty of Health Sciences, it also deals with research from the other four Faculties at the University.

As mentioned above, applications are routed through two different secretariats based on the type and size of the grant. This system ensures efficiency as under- and postgraduate student applications are not delayed by the more complex applications.

All studies involving research grants, external funding, budgets, insurances, reimbursements, collaborators, etc., being of medium to high risk, go through the WHC-housed secretariat due to their obvious complexity. They typically need approval in addition to regular oversight, including report and reviews from both the investigators and sponsors, AEs and SAEs, GCP and ethics violations, and even site visits and audits.

Commercial projects and large grant-funded projects require extra scrutiny and oversight, both ethically, medically, and financially. The HREC (Medical), in line with other Research Ethics Committees in South Africa, has introduced a charge schedule for reviews based on the risk of the research and the funding available. Typically, these applications involve multiple investigators, collaborators, and sites at Wits, or broader throughout South Africa or across the world. These applications often involve complex material or data transfer agreements and other memoranda of agreement. Another class of complex studies includes those with financial complexities that involve reimbursements to participants and investigators and / or have complex reimbursements, insurances and indemnities. All of these types of studies are also required by the NHREC to have active monitoring programmes, which adds to the cost structure. The role of the HREC (Medical) is not only to approve ethics applications, but also to provide ethics oversight throughout the duration of the research. This is of particular importance in high-risk studies with potential to cause physical, psychological, and even financial harm to study participants, as well as to the investigators and to the University itself.

The full fee amounts for pre-approval activities (e.g., ethics reviews) and post-approval activities (e.g., amendments, renewals, monitoring, site visits, audits, GCP and ethics violations and other changes to approved studies) are listed below.

Fee Values for Pre-Approval Activities

Activity	Price including VAT
Ethics Review – Wits Academic sites	R 35 000.00
Ethics Review – Resubmission for Category 5 Rejected Studies	R 22 750.00
Ethics Review – Combined Wits Academic & Private Sites	R 62 000.00
Ethics Review – Epidemiology / Observational Studies	R 22 750.00

Fee Values for Post-Approval Activities

Activity	Price including VAT
Amendments – Major	R 6 500.00
Amendments – Minor	R 3 500.00
Annual Recertification	R 2 000.00
Five-Year Recertification	R 6 500.00
Major Administrative Charges	R 2 000.00
Minor Administrative Charges	R 1 090.00

Variable fees will be charged for pre-approval activities and post-approval activities based on the total value of the project.

There are <u>five levels</u> of discounts described below.

Category	Value of project	Discount
1	> R 10 million	0%
2	> R 5 million, < R 10 million	25%
3	> R 1 million, < R 5 million	50%
4	> R 0.5 million, < R 1 million	75%
5	< R 0.5 million	100%

Commercial and grant-funded projects that recover all or some indirect costs, as described by the **Wits CORY Policy**, will not be charged over and above CORY. In these cases, the fees described above will be paid from the CORY income.