



SUBMISSION REQUIREMENTS

**We respectfully request your attention to the schedule below to assist with your submission
Please note that one hard copy and one electronic copy is required. Please refer to collation schedule which follows**

| HARD COPY: LABEL AND DIVIDE EACH SECTION WHEN COLLATING YOUR DOCUMENTS. PLEASE STAPLE EACH DOCUMENT AND DO NOT USE PLASTIC RING BINDING | TOTAL QUANTITY OF HARD COPIES REQUIRED |
|--|---|
| PLEASE NOTE: AN ADDITIONAL COPY MAY BE REQUESTED AT OUR DISCRETION | |
| 1. COVER LETTER | 1 |
| 2. CHECKLIST | 1 |
| 3. SUBMISSION FEE <i>(an invoice/quote will be raised once the submission has been processed)</i> | 1 |
| 4. HREC APPLICATION FORM – Interventional / Non-Interventional (2026) | 1 |
| 5. SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR) - Proof of capture” Form - https://sanctr.samrc.ac.za/ <i>(if applicable)</i> | 1 |
| 6. SAHPRA Approval / Notification <i>(if applicable)</i> | 1 |
| 7. PROTOCOL REVIEW APPLICATION (when provisional facilities are used) <i>(if applicable)</i> | 1 |
| 8. INSURANCE CERTIFICATE <i>(if applicable)</i> | 1 |
| 9. PATIENT QUESTIONNAIRE, DIARY CARDS, ADVERTISEMENTS <i>(if applicable)</i> | 1 |
| 10. PROTOCOL (please version and date) | 1 |
| 11. PROTOCOL SUMMARY (INCLUDING STUDY FLOW DIAGRAM / ORANOGRAM) | 1 |
| 12. INVESTIGATOR’S BROCHURE <i>(if applicable)</i> / Package Insert <i>(if applicable)</i> | 1 |
| 13. PARTICIPANT INFORMATION LEAFLET & INFORMED CONSENT / ASSENT FORMS - <i>(please refer to Informed Consent Template and ICF Checklist)</i> | 1 |
| 14. SEPARATE PIL/ICON(S) - <i>(e.g. Focus Group Discussions, In-depth Interviews, Storage of samples, genetic testing, Parent/Legal Guardian etc. if applicable)</i> | 1 |
| 15. CV’S AND TRAINING CERTIFICATES: (Principal / Co-PI, Co/Sub Investigators in Wits / SAHPRA CV Format) – please include copy of SA GCP (2020) and Ethics Training Certificate – name and date of course attended – Investigators’ Meetings are not classified as formal GCP Training – Please ensure to submit updated CV’s | 1 copy of each |
| Essential Clinical Support Staff: Include copies of the Sub-Investigator Declaration, Statutory Body Registration, GCP Training Certificates, Ethics Training Certificates for essential clinical support staff (Senior and Back-up Pharmacist(s); Only Study Nurses / Study Co-Ordinator’s 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). CVs are not required. | |
| 16. WITS/SAHPRA DECLARATION <i>(Principal/Co-PI, Co/Sub-Investigators, Essential Clinical Support Staff to sign)</i> | 1 copy of each |
| 17. STUDY BUDGET INCLUDING (AS APPLICABLE): Total amount provided; Site/Investigator remuneration; Participant remuneration | 1 |

IN ADDITION TO THE HARD COPY REQUIREMENT ABOVE, AN ELECTRONIC SUBMISSION IS REQUIRED

| ELECTRONIC SUBMISSION OF NEW STUDY APPLICATION | QUANTITY OF COPIES REQUIRED |
|---|------------------------------------|
| PLEASE EMAIL THE FOLLOWING DOCUMENTS TO: EthicsRegulatory@witsethics.co.za | |
| 1. COVER LETTER | 1 |
| 2. SAHPRA Approval / Notification <i>(if applicable)</i> | 1 |
| 3. CHECKLIST | 1 |
| 4. HREC APPLICATION FORM – Interventional / Non-Interventional 2026 | 1 |
| 5. SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR) - Proof of capture” Form - https://sanctr.samrc.ac.za/ <i>(if applicable)</i> | 1 |
| 6. PROTOCOL REVIEW APPLICATION <i>(if applicable)</i> | |
| 7. INSURANCE CERTIFICATE <i>(if applicable)</i> | 1 |
| 8. PATIENT QUESTIONNAIRE, DIARY CARDS, ADVERTISEMENTS ETC <i>(if applicable)</i> | 1 |
| 9. PROTOCOL SUMMARY INCLUDING FLOW DIAGRAM / ORGANOGRAM | 1 |
| 10. PROTOCOL | 1 |
| 11. INVESTIGATOR’S BROCHURE / Package Insert <i>(if applicable)</i> | 1 |
| 12. STUDY BUDGET INCLUDING (AS APPLICABLE): Total amount provided; Site/Investigator remuneration; Participant remuneration | 1 |
| 13. PARTICIPANT INFORMATION LEAFLET & INFORMED CONSENT / ASSENT FORMS <i>(please refer to Informed Consent Template and ICF Checklist)</i> | 1 |
| 14. SEPARATE PIL/ICON(S) - <i>(e.g. FGD, IDI, Storage of samples, genetic testing, parent/legal guardian etc. if applicable)</i> | 1 |

PLEASE NOTE THAT CV’S, DECLARATIONS, AND TRAINING CERTIFICATES DO NOT NEED TO BE INCLUDED IN THE ELECTRONIC SUBMISSION

SUBMISSION FEE – EFFECTIVE DATE 1 FEBRUARY 2026

The full fee amounts for pre-approval activities (ethics review) 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 |

Variable fees will be charged for grant funded pre-approval activities based on the total value of the project. There are five levels 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% |

UPDATED GUIDELINES

Please note updated guidelines:

- ◆ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024)
- ◆ World Medical Association, Declaration of Helsinki 2024
- ◆ ICH GCP E6(R3) 06 January 2025

SECRETARIAT OFFICE - TELEPHONE AND EMAIL ADDRESSES - PLEASE UPDATE YOUR RECORDS

Contact Details: Secretariat to the University of the Witwatersrand, Human Research Ethics Committee: (Medical):

Jennifer Palmer – Ethics Support Manager
011 274 9278 - email: jpalmer@witsethics.co.za

Kim Govender-Mothiba – Ethics Officer
011 274 9255 – email : kzgovender@witsethics.co.za

Thashin Reddy – Ethics Officer
011 274 3353 – email: treddy@witsethics.co.za

Yvonne Petersen – Ethics Administrator
011 274 9280 – email : ypetersen@witsethics.co.za

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011 274 9438 – email: nmthethwa@witsethics.co.za

Michaela Nadasen – Ethics Administrator
011 274 9279 – email: mnadasen@witsethics.co.za

Vuyiswa Maeki – Ethics Administrator
011 274 9433 – email: vmaeki@witsethics.co.za

Physical Address

Secretariat to Wits HREC (Medical) – for funded studies: 4th Floor, 31 Princess of Wales Terrace, Parktown, 2193

Please refer to the web page for Submission Documents Required. www.witshealth.co.za - click on 'Services' and then 'Research Ethics'
Be assured of our best attention at all times, we look forward to being of service to you in the processing of your research study applications.

Kind regards
Secretariat to Wits HREC (Medical)

CHECKLIST – HREC APPLICATION 2026 - SUBMISSION

| | PLEASE TICK | CHECKLIST | | Hard Copy Quantity |
|-----|--------------------------|---|--|--------------------|
| 1. | | South African National Clinical Trials Registry (SANCTR) Registration – Attach SANCTR “Proof of capture” form to Ethics Application Form – VIEW – https://sanctr.samrc.ac.za/ <input type="checkbox"/> Not Applicable | Date Of Issue | |
| 2. | <input type="checkbox"/> | Covering Letter | | |
| 3. | <input type="checkbox"/> | Completed HREC 2026 Application Form | | |
| 4. | <input type="checkbox"/> | Protocol including Synopsis | Version: Date: | |
| 5. | <input type="checkbox"/> | Patient Information Leaflet and Informed Consent Documents + Assent Forms <input type="checkbox"/> Not Applicable | Version: Date: Language: | |
| 6. | <input type="checkbox"/> | Investigator’s Brochure(s) <input type="checkbox"/> Not Applicable | Drug Name(s): Version: Date: | |
| 7. | <input type="checkbox"/> | Package Insert(s) (Local and International) <input type="checkbox"/> Not Applicable | Drug Name(s): Version: Date: | |
| 8. | <input type="checkbox"/> | Curricula Vitae of Investigators HREC / SAHPRA Format as per suggested CV template on Website. www.witshealth.co.za – Select Ethics. (Indicate Names In Fields To The Right) Please refer to Section 6.2 (HREC Form Interventional) or Section 5.2 (HREC Form Non-Interventional) and complete list of names and supporting documents | PI: Sub-Inv(s): 1. Sub-Inv 2. Sub-Inv | |
| 9. | <input type="checkbox"/> | Declaration of Investigator(s) in HREC / SAHPRA Format (PI and All Sub/Co-Investigators) | | |
| 10. | <input type="checkbox"/> | SAHPRA Approval Letter <input type="checkbox"/> / Letter of Application <input type="checkbox"/> / Notification <input type="checkbox"/> <input type="checkbox"/> Not Applicable | Date Of Letter: | |
| 11. | <input type="checkbox"/> | Insurance Certificate: Policy Number: <input type="checkbox"/> Not Applicable | Valid From: | Valid To: |
| 12. | <input type="checkbox"/> | Patient Questionnaire(s) And/Or Diary Cards; <input type="checkbox"/> Not Applicable | Version: Date: | |
| 13. | <input type="checkbox"/> | Advertisement(s); Please list mediums to be used: <input type="checkbox"/> Not Applicable | Version: Date: | |
| 14. | <input type="checkbox"/> | Protocol Review Application Form To be signed by Applicant, Principal Investigator and Head of Department (Please Note: If study is being conducted in Provincial Health facilities approval from Hospital CEO/Clinical Manager/District Research Committee (whichever is applicable) must be obtained by Sponsor/Investigator AFTER ethics approval) <input type="checkbox"/> Not Applicable | Province: | |
| 15. | <input type="checkbox"/> | Hospital / District Provincial / National DoH approval (when available) <input type="checkbox"/> Not Applicable | Date Of Letter | |
| 16. | <input type="checkbox"/> | Approvals by other IEC/IRBs Approval Letter <input type="checkbox"/> / Letter of Application <input type="checkbox"/> <input type="checkbox"/> Not Applicable | Date Of Letter | |
| 17. | <input type="checkbox"/> | Study Budget including (as applicable): - Total amount provided: - Site/Investigator remuneration: - Participant remuneration: | R R R | |