UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Human Research Ethics Committee: (Medical)

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 NOTE: AN ADDITIONAL COPY MAY BE REQUESTED AT OUR DISCRECTION**	**TOTAL QUANTITY OF HARD COPIES REQUIRED**
1. COVER LETTER	**1**
2. CHECKLIST	**1**
3. SUBMISSION FEE *(an invoice/quote will be raised once the submission has been processed)*	**1**
4. HREC APPLICATION FORM – 2025	**1**
5. SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR) - Proof of capture" Form - https://sanctr.samrc.ac.za/ *(if applicable)*	**1**
6. SAHPRA Approval / Notification *(if applicable)*	**1**
7. PROTOCOL REVIEW APPLICATION *(if applicable)*	**1**
8. INSURANCE CERTIFICATE *(if applicable)*	**1**
9. PATIENT QUESTIONNAIRE, DIARY CARDS, ADVERTISEMENTS *(if applicable)*	**1**
10. PROTOCOL	**1**
11. PROTOCOL SUMMARY ***(INCLUDING STUDY FLOW DIAGRAM / ORGANOGRAM)***	**1**
12. INVESTIGATOR'S BROCHURE *(If applicable)* **/ *Package Insert*** *(if applicable)*	**1**
13. PARTICIPANT INFORMATION LEAFLET & INFORMED CONSENT- *(please refer to* ***Informed Consent Template and ICF Checklist)***	**1**
14. SEPARATE PIL/ICON(S) - *(e.g. FGD, IDI, Storage of samples, genetic testing etc. if applicable)*	**1**
15.* CV'S** (Principal / Co-PI, Co/Sub Investigators, Essential Clinical Support Staff in **Wits / SAHPRA CV Format) – *please include copy of GCP 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 **Essential Clinical Support Staff:** Include copies of CV's, the SI Declaration, Statutory Body Registration and GCP 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)	**1 copy of each**
16. WITS/SAHPRA DECLARATION *(Principal/Co-PI, Co/Sub-Investigators, Essential Clinical Support Staff to sign)*	**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 **PLEASE EMAIL THE FOLLOWING DOCUMENTS TO: EthicsRegulatory@witshealth.co.za**	**QUANTITY OF COPIES REQUIRED**
1. COVER LETTER	**1**
2. SAHPRA Approval / Notification *(if applicable)*	**1**
3. CHECKLIST	**1**
4. HREC APPLICATION FORM – 2025	**1**
5. SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR) - Proof of capture" Form - https://sanctr.samrc.ac.za/ *(if applicable)*	**1**
6. PROTOCOL REVIEW APPLICATION *(if applicable)*	
7. INSURANCE CERTIFICATE *(if applicable)*	**1**
8. PATIENT QUESTIONNAIRE, DIARY CARDS, ADVERTISEMENTS ETC *(if applicable)*	**1**
9. PROTOCOL SUMMARY INCLUDING FLOW DIAGRAM / ORGANOGRAM	**1**
10. PROTOCOL	**1**
11. INVESTIGATOR'S BROCHURE / Package Insert *(if applicable)*	**1**
12. STUDY BUDGET INCLUDING (AS APPLICABLE): Total amount provided; Site/Investigator remuneration; Participant remuneration	**1**
13. PARTICIPANT INFORMATION LEAFLET & INFORMED CONSENT FORM *(please refer to **Informed Consent Template and ICF Checklist**)*	**1**
18. SEPARATE PIL/ICON(S) - *(e.g. FGD, IDI, Storage of samples, genetic testing etc. if applicable)*	**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 2025

Submission Fee for Pharmaceutically Sponsored Studies:
R28 175.00 inclusive of VAT.
Please submit payment advice for direct transfers / deposits

A sliding pricing scale will apply for grant funded applications

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@witshealth.co.za

Kim Govender-Mothiba – Ethics Officer
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Vuyiswa Maeki – Ethics Administrator
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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 2025 - 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/ ☐ Not Applicable	Date Of Issue	
2.	☐	Covering Letter		
3.	☐	Completed HREC 2025 Application Form		
4.	☐	Protocol including Synopsis	Version: Date:	
5.	☐	Patient Information Leaflet and Informed Consent Documents + Assent Forms ☐ Not Applicable	Version: Date: Language:	
6.	☐	Investigator's Brochure(s) ☐ Not Applicable	Drug Name(s): Version: Date:	
7.	☐	Package Insert(s) (Local and International) ☐ Not Applicable	Drug Name(s): Version: Date:	
8.	☐	Curricula Vitae of Investigators HREC / SAHPRA Format as per suggested CV On Website. www.witshealth.co.za – Select Ethics. (Indicate Names In Fields To The Right) ***Please refer to Section 6.3 and complete list of names and supporting documents***	PI: Sub-Inv(s): 1. Sub-Inv 2. Sub-Inv	
9.	☐	Declaration of Investigator(s) in HREC / SAHPRA Format (PI and All Sub/Co-Investigators)		
10.	☐	SAHPRA Approval Letter ☐/ Letter of Application ☐ / Notification ☐ ☐ Not Applicable	Date Of Letter:	
11.	☐	Insurance Certificate: Policy Number: ☐ Not Applicable	Valid From:	Valid To:
12.	☐	Patient Questionnaire(s) And/Or Diary Cards; ☐ Not Applicable	Version: Date:	
13.	☐	Advertisement(s); Please list mediums to be used: ☐ Not Applicable	Version: Date:	
14.	☐	**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) ☐ Not Applicable	Province:	
15.	☐	**Hospital / District Provincial / National DoH approval (when available)** ☐ Not Applicable	Date Of Letter	
16.	☐	**Approvals by other IEC/IRBs** Approval Letter ☐ / Letter of Application ☐ ☐ Not Applicable	Date Of Letter	
17.	☐	**Study Budget including (as applicable):** - Total amount provided: - Site/Investigator remuneration: - Participant remuneration:	 R R R	