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. JUSTIFICATION OF PLACEBO ARM, 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. **FINANCIAL AGREEMENT – Tripartite Agreement between the Wits Academic Research Unit (Syndicate) the relevant Company and Wits Health Consortium (Pty) Ltd- Draft copy acceptable – original to follow once draft has been approved (submit to WHC Contracts Office)**	
18. **BUDGET & PAYMENT SCHEDULE / GRANT AWARD / NOTICE OF AWARD**	**1**

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

ELECTRONIC SUBMISSION OF NEW TRIAL 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. **JUSTIFICATION OF PLACEBO ARM, 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. **FINANCIAL AGREEMENT – Tripartite Agreement - Draft copy acceptable**	**1**
13. **BUDGET AND PAYMENT SCHEDULE / GRANT AWARD / NOTICE OF AWARD**	**1**
14. **PARTICIPANT INFORMATION LEAFLET & INFORMED CONSENT FORM** *(please refer to **Informed Consent Template and ICF Checklist**)*	**1**
19. **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:

R28 175.00 inclusive of VAT.

Please submit payment advice for direct transfers / deposits

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

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

Contact Details: WHC Secretariat to the 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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Thashin Reddy – Ethics Officer
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Nathi Mthethwa – Ethics Administrator
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Michaela Nadasen – Ethics Administrator
011 274 9279 – email: mnadasen@witshealth.co.za

Vuyiswa Maeki – Ethics Administrator
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Physical Address
WHC Ethics Secretariat Office: C/o Wits Health Consortium (Pty) Ltd, 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 clinical trial applications.

Kind regards
WHC Ethics Secretariat

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/	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.	☐	Patient Information Leaflet and Informed Consent Document for Collection and Storage of Genetic Material for Future Use ☐ Not Applicable	Version: Date: Language:	
7.	☐	Patient Information Leaflet and Informed Consent Document for Blood or Tissue Collection and Storage for Future Use ☐ Not Applicable	Version: Date: Language:	
8.	☐	Investigator's Brochure(s)	Drug Name(s): Version: Date:	
9.	☐	Package Insert(s) ☐ Not Applicable	Drug Name(s): Version: Date:	
10.	☐	Justification Document for **Placebo Arm / Control**		
11.	☐	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 Appendix A and complete list of names and supporting documents***	PI: Sub-Inv(s): 1. Sub-Inv 2. Sub-Inv	
12.	☐	Declaration of Trialists' In HREC / SAHPRA Format (PI and All Sub-Investigators)		
13.	☐	SAHPRA Approval Letter ☐/ Letter of Application / Notification ☐	Date Of Letter:	
14.	☐	Insurance Certificate (if applicable) Valid	From:	To:
15.	☐	Patient Questionnaire(s) And/Or Diary Cards; ☐ Not Applicable	Version: Date:	
16.	☐	Advertisement(s); Please list mediums to be used: ☐ Not Applicable	Version: Date:	
17.	☐	**Protocol Review Application Form** To be signed by Applicant, Principal Investigator and Head of Department (Please Note: If trial 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:	