Human Research Ethics Committee: (Medical)

SECRETARIAT: Suite 189, Private Bag x2600, Houghton 2041, South Africa • Tel: +27-11-274 9278/9 •

Dear Applicants / Sponsors / Investigators

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

South African National Clinical Trials Registry (SANCTR)

The only point of trial data entry is the SANCTR database on this url: https://sanctr.samrc.ac.za/. Please follow this link for information on how to register.

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Email: sactradmin@mrc.ac.za
Website: https://sanctr.samrc.ac.za

ETHICS TRAINING REQUIREMENT

As per the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition, Research Ethics Training is a compulsory requirement for consideration of a research application nationally (in addition to Good Clinical Practice Training for Clinical Trials). Researchers have to provide proof of Research Ethics Training within the previous three years, in their HREC (M) [IEC] applications – without this, the application cannot be approved.

PRE-APPROVAL CHECKLIST

To eliminate unnecessary but time-consuming errors in your regulatory submissions to the Wits Human Research Ethics Committee (Medical), kindly ensure that the 'Pre-approval checklist' is completed and is included with your submission documents.

SUBMISSION FEE: (***Please refer to 'Payment Instruction Form'***)

- Approval Clearance Documents will only be processed once proof of the submission fee has been received by the Ethics Secretariat Office. Approvals will not be issued until ALL outstanding accounts have been settled.
- Payment can be made into the **Wits Health Consortium (Pty) Ltd - Management Account** - to the value of **R28 175.00** (VAT inclusive).
- When making an electronic transfer please quote your invoice number and ethics reference number or protocol number and inform us immediately to expedite your submission. Please submit payment instruction of electronic transfer as soon as the payment has been made to avoid any delays: Email to kmothiba@witshealth.co.za and ethicsregulatory@witshealth.co.za

SUBMISSION REQUIREMENTS DOCUMENT:

- To avoid any additional queries against your submission(s), we kindly request that you refer to the Submission Requirements and use this to facilitate the efficient processing of your submissions.
- Also, where applicable please submit the SAHPRA notification / approval

PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FORM (PIL/ICON):

- Please refer to the template for details required in the PIL/ICON
- The PIL should aim to be not more than 25 pages in length.
- The template is available to assist you in avoiding generic errors
- The tone of the Informed consent should be friendly, where the participant is ***'INVITED'*** to participate.
- Please check that all elements as per SA GCP, are present
- If 'Not Applicable'- please mark checklist 'N/A'

*(Please refer to **'Ethics Submission and Meeting Dates' for your convenience**)*

Your urgent attention to the above is appreciated, should you require any further information and/or assistance please do not hesitate to contact us.

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 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:	