



SECRETARIAT: Suite 189, Private Bag x2600, Houghton 2041, South Africa • Tel: +27-11-274-9200 • Fax: +27-11-274-9281

28 JUNE 2021

UPDATED REQUIREMENTS FOR SUBMISSION OF DOCUMENTS TO WHC ETHICS SECRETARIAT

Please note the following updated requirements for the submission of documents to the Wits Health Consortium, Ethics Secretariat Office:

1. Wits HREC (Medical) COVID-19 Recommendations:

- Please submit a formal request to restart studies/enroll for studies. These will be reviewed on a case by case basis and require a COVID plan to mitigate risk.

2. HREC Submission Dates

Please refer to our website for the meeting and submission dates for new applications. Unfortunately, late applications will not be accepted.

<https://www.witshealth.co.za/Services/Research-Ethics/Application-Forms>

3. Please note the following processes for submission of documents will apply from Monday, 28 June 2021:

PRE-APPROVAL:

New Trial Applications

- Please refer to the **SUBMISSION REQUIREMENTS** (dated March 2021) on our website: <https://www.witshealth.co.za/Services/Research-Ethics/Application-Forms>.

- Please submit **only one hard copy** to Reception

- Please also email the submission to EthicsRegulatory@witshealth.co.za and include confirmation of delivery

- Please note that **both** the electronic and hard copy must be submitted on Submission Day

Responses to Reviewer Queries for new trial applications

- Please email the responses to Ty Reddy (treddy@witshealth.co.za) and Jennifer Palmer (jpalmer@witshealth.co.za)

- Submit the responses in MSWord format and accompanying documents in PDF

- The subject title of the email should include the Type of application, protocol number and ethics reference number

(Depending on the volume of printing, **we may** request hard copies if required)

POST-APPROVAL:

Recertifications

- Please email to Ty Reddy (treddy@witshealth.co.za) and Jennifer Palmer (jpalmer@witshealth.co.za)
- The subject title of the email should include 'Recertification', protocol number and ethics reference number
(Depending on the volume of printing, **we may** request hard copies if required)

Notifications, Deviations, Violations, Advertisements, Questionnaires, Investigators Brochures, SAEs, Safety Line Listings, and Translations:

- Please email EthicsRegulatory@witshealth.co.za
- The subject title of the email should include the Type of application, protocol number, version/date of document, and ethics reference number

Amendments to Protocols, Informed Consent forms, Additional Sites and Investigators:

- Please submit a hard copy to Reception
- Please email EthicsRegulatory@witshealth.co.za and include confirmation of delivery
- The subject title of the email should include the Type of application, protocol number, version/date of document, and ethics reference number

(PLEASE NOTE: Hard copies are required for high/large volume submissions (>100 pages), however we will print submissions <100 pages).

Please don't hesitate to contact the WHC Ethics Secretariat for any queries and/or assistance:

- Jennifer Palmer – jpalmer@witshealth.co.za / (011) 274 9278
- Kim Govender-Mothiba – kzgovender@witshealth.co.za / (011) 274 9255
- Ty Reddy - treddy@witshealth.co.za / (011) 274 3353
- Tania Booysen - tbooyesen@witshealth.co.za / (011) 274 9279
- Yvonne Petersen - ypetersen@witshealth.co.za / (011) 274 928

Please 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