UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Human Research Ethics Committee: (Medical)
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GENERAL NOTICES FROM THE HREC (MEDICAL), INCLUDING THE USE OF NEW HREC MEDICAL APPLICATION FORMS:

1. External/Private Research Sites outside of Gauteng

The HREC (Medical) hereby notifies Investigators/Researchers and Sponsors/Applicants that it has unfortunately had to decide that it will no longer be able to approve External/Private Research Sites outside of the Gauteng Province. This decision is due to monitoring pressures and difficulties in oversight.

As per South African Ethics in Health Research Guidelines: Principles, Processes and Structures 2024, Third Edition, Chapter 5, Section 5.5.1.4 a):

"The South African ethico-legal framework requires that PIs or research leaders must obtain approval from their institutional REC. In principle, this means that RECs have authority to review and approve research protocols only for research sites or geographic areas within their own South African jurisdiction. Thus, when a protocol proposes a research study or project that is to collect data from multiple sites or geographic areas within South Africa, more than one REC may be involved in the review and approval processes."

Therefore External/Private Research sites outside of Gauteng should be submitted to HRECs within their own geographical area.

This applies to all new applications with immediate effect.

The HREC (Medical) will however continue to provide ethics support for previously approved External/Private Research Sites outside of Gauteng, until the expiry of the existing HREC (Medical) approval (either initial approval or recertification).

For now, External/Private Sites due for recertification will be provided with HREC approval for one year only, thereafter the site will have to obtain HREC approval elsewhere.

Please be advised that all external sites affiliated with the HREC (Medical) will be considered for approval regardless of their location in South Africa, but outside Gauteng.

All sites, regardless of their location in South Africa, must have SOPs in place to deal with medical emergencies, including immediate access to functioning resuscitation equipment and hospital admission.

The HREC (Medical) is committed to ensuring that all Wits affiliated sites in South Africa meet the necessary ethical standards and requirements for research approval.

2. Grant Funded and Commercial Studies Processed Through Ethics Secretariat at Wits Health Consortium

The HREC (Medical) requests that all studies with significant grant or commercial funding be submitted through the Ethics Secretariat Office based at the Wits Health Consortium. These studies normally have financial implications involved such as insurance, indemnity, financial contracts, and participant reimbursement. Grant or Contract funded research requires more specific attention to documentation, finance, retention of records, and are often of high risk to participants.

3. Withdrawal of Applications where Queries are not Responded to Within Six (6) Months

The HREC (Medical) hereby requests that Investigators and Sponsors/Applicants respond to queries raised by the committee within 14 days.

If it is not possible to respond within 14 days, the Investigator/Sponsor/Applicant are requested to provide a reason why they cannot respond in this time frame.

Should no responses be received within six (6) months of the meeting, the application will be withdrawn from the review process and will require a new submission.

4. HREC (Medical) Review of Essential Support Staff

The HREC (Medical) hereby requests that the following essential support staff be submitted to HREC (Medical) for notification:

• 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.

For these Pharmacists and Study Nurses we would require a copy of their CV's, a signed Declaration by Sub-Investigator, relevant statutory body registration and GCP Training certificates.

Other support staff members who have an administrative role and who are not clinically involved with participants in a significant fashion, would not need to be submitted to HREC (Medical) for notification.

Please note:
1. This request does not apply retrospectively.
2. This request will be implemented from 1st of October 2024

5. Insurance and Non-Interventional Studies Where Samples Are Taken

The HREC (Medical) has recently debated when a study is interventional or not interventional, particularly where blood samples are being taken.

The committee is concerned that there are still risks, albeit limited, with blood samples being taken, and believes that there needs to be some form of protection for participants if something goes wrong.
The committee understands that it is not always possible to get clinical trial insurance linked to ABPI 2014 for a non-interventional study. That does not obviate the institution from having protection for participants, and the individual healthcare practitioner from being a member of the Medical Protection Society or equivalent, for their own personal liability cover.

The committee therefore agreed that, while insisting on study insurance is not always possible, it would like to stress that there is still a responsibility to the participants, and liability on the part of the Investigators, if there is an injury.

Participants must therefore be adequately protected. Sites must have plans/SOPs in place to protect participants in all instances, should injuries occur.

6. Length and Complexity of Participant Information Leaflets (PIL)

The HREC (Medical) has recently discussed the length of the PIL documents being submitted for review and is concerned about the length of these documents, and the burden this is placing on participants.

The committee agreed that while it is critical to maintain the integrity of the PIL with regards to important international and local information and legal requirements that needs to be provided to participants, the document needs to be more manageable and user friendly for participants with various degrees of literacy.

The committee asks Applicants to apply their minds when developing the PIL/ICON for South African purposes, by **avoiding cutting and pasting** from the protocol, and to summarise important information into simple, plain English, which is readable and literacy-level appropriate.

The PIL should aim to be not more than **25 pages** in length.

Assent Forms should also be adequately summarized and appropriate for minors of applicable ages and literacy-levels.

7. Length Of Completed HREC Application Forms

The HREC (Medical) has recently discussed the length of the completed HREC Application Forms being submitted for review and is concerned about the length of these documents.

The committee asks Applicants to **avoid cutting and pasting** from the protocol, and to summarise important information into simple, plain English.

Applicants must please avoid changing the format of the HREC Application Forms.

The completed HREC Application Form should aim to be not more than **25 pages** in length.

8. Expiry Dates of Initial Ethics Approval Letters And Recertifications For All Research / Studies / Projects

The HREC (Medical) hereby requests that Investigators and Sponsors/Applicants regularly review their initial ethics approval letters to determine the expiry date of the ethics approval.

As per the initial ethics approval letters provided by the committee, approval is valid for 5 years. Where the 5-year approval is set to expire, a recertification application should be submitted before the expiry date. **A maximum of three (3) months grace period will be allowed once the approval has expired.**

The committee reminds Investigators and Sponsors/Applicants of the potential implications resulting from a lapse in ethics approvals, such as discarding of data collected during the lapse period.

9. Additional Tests on Stored Biological Specimens For Future Research

The HREC (Medical), would like to clarify the following requirements regarding requests for additional tests on stored biological specimens for future research:

Where an Applicant plans to store biological specimens for future research:

• Future research must be within the scope/area of the disease initially being studied.

• If any future work is planned, a study should not be closed completely with the HREC (Medical) but should remain open through Recertification (5 yearly or annually if required by the Sponsor).

• Applications for Additional tests on stored biological specimens (research based on previously approved study) submitted within 5 years of expiry of prior ethics approval/recertification will be accepted for processing.

• Applications for Additional tests on stored biological specimens (research based on previously approved study) submitted after 5 years of expiry of prior ethics approval/recertification will need to be discussed at a meeting with the HREC before being processed. These applications will be processed on a case-by-case basis.

• When applying for additional tests on stored biological specimens, the committee requires Applicants to complete the 'Application Form for Amendment to Approved Study', Page 2 and section 3.9.

10. Reciprocity

Please be advised that the HREC (Medical) does not have reciprocity agreements with other institutions/universities at present. As such, any benefits or arrangements available to students or staff at other institutions may not apply to Wits and the Wits HREC (Medical).

This may change in the future if reciprocity agreements are made with other institutions, especially those in Gauteng.

11. Reimbursement of state employees

Reimbursement of state employees by study sites, is not permitted, but they may be given a small token of appreciation by the Investigator(s).

12. Wits Affiliated and non-Affiliated Investigators including Foreign Investigators

a) Studies done at Wits Academic Circuit Teaching Hospitals by non-Wits affiliated Investigators do not need Wits HREC approval unless there is a Wits affiliated Investigator involved on the study.

b) If a Wits affiliated Investigator is doing a study in another province/jurisdiction, they will need Wits HREC approval plus Facility/Provincial Approval from that Facility/Province.

c) Each South African University is responsible for providing ethics approval for all investigators affiliated with that University in South Africa.

d) Foreign Investigators need HPCSA registration + Ethics and South African Good Clinical Practice (SA GCP 2020) training, to become clinical investigators in South Africa. If they do not have HPCSA registration, they may be non-clinical Co-PI or Co/Sub Investigator only.

13. Case Reports

Any study involving 3 or less participants will be considered to be a case report, requiring submission of the new Case Report HREC Form, and not a Full HREC Application.

14. Waivers

These will only be given for reviews of data in the public domain, *in vitro* laboratory studies, environmental surveillance studies, and observational studies of people in public places.

All such studies require the submission of the new HREC Waiver Form before starting the research.

15. De-identified Human Materials

These studies require the submission of this new HREC form if they involve the use of left over stored human materials.

16. Sub-studies

Sub-studies of a previously HREC approved study require submission of the new HREC Sub-study Form. The expectation of "blanket" HREC approvals of such studies is not acceptable.

17. Retrospective Record Reviews

These studies require the submission of the new HREC Retrospective Data Review Application Form and not a full HREC application, unless there is a prospective component.

18. Amendments and New Investigators

These also require completion of the new specific HREC Forms and not just a letter to the HREC (Medical).

19. Completion of HREC Forms

Please note that the HREC forms must be filled in completely, otherwise the committee will not be able to adequately review the submission.

Regards,

Paul Ruff

Paul Ruff (Sep 9, 2024 16:50 GMT+2)

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Chair, Wits HREC (Medical)

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