Red Cross War Memorial Children's Hospital
Department of Health and Wellness
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RESEARCH APPLICATION AND RENEWAL PROCESS

Steps to be taken for first time applications	**1.** Register your research on the National Health Research Database (NHRD). **Link for NHRD: https://nhrd.health.gov.za.** **Select the WCDoH Portal.** 2. Submit a letter requesting permission to conduct the study/ research and include the following details: a. Acknowledge that all patient information will be treated as confidential, and the study will be conducted as per the declaration of Helsinki. b. A detailed outline of the space, equipment, consumables (if not self-provided) and staff from facilities and the support required from the facilities and staff. Particularly, identifying how recruitment of study participants must be detailed. • Where in the hospital will your study be conducted? 1. Inpatients versus outpatients 2. Are you requesting additional space within an area of the hospital. This must be: a. Supported by the area involved in writing from the Head of Clinical Unit (HCU) and/or Operational Manager (OM). b. And approved by the research committee. • Please consider how this request may impact on the normal running of the service. ○ The study cannot negatively affect service delivery. c. Specify what consumables will be used in your study and who will provide these. d. Specify all additional items of cost e.g.: additional patient visits to the hospital, use of any consumables etc. – a change control form must be completed. • The Change Control Form will ensure the study is billed for these services and not the patients. • A copy of this form, if needed, can be accessed from Ms. Ellen Thomas in the G2 office. • Once completed this Change Control Form must be returned to Ms. Ellen Thomas who will send to fees. e. Specify if the NHLS will be used for specimen analysis and account for billing.

	• NHLS billing is separate from the Change Control Form and Hospital Fees department. • Submit approval to the NHLS and the account code issued. 3. Provide a copy of your HREC approval. http://www.health.uct.ac.za/fhs/research/humanethics/forms 4. Provide your research proposal. 5. Clinical trials must have Medicines Control Council (MCC) approval and be registered on the National Clinical Trials Register – proof of both must be provided. 6. Letter of registration at the University (if applicable) 7. Letter of support from your supervisor (if you are a student) 8. Approval from the head of department to be attached to the application. 9. Once approval is granted, a final patient list and their appointments distinguishing clearly between normal visit and services, research or trial visits and services, must be sent through to fees to ensure the study is billed for their respective visits and use of consumables timeously. 10. Patients attending visits for study purposes must have clear notes indicating the study visit.
Steps to be taken for renewal of applications	1. Submit a copy of your renewed HREC approval, including HREC application. 2. Annual Progress Feedback needs to be submitted along with the application. 3. Submit a letter requesting renewal of hospital approval with details as outlined above.
When to renew	• Renewal must be completed timeously on an annual basis before the expiration date of the initial approval has been granted. • Should you change your research protocol during the study, you will need to resubmit for hospital approval as per above process.
Completion	• Once the study is completed, please send feedback to ensure the study marked as complete on the NHRD and the Hospital database. This must be done within 6 months of completion of the study. • Please complete end of project feedback. • Researchers may be required to present the study to the relevant authorities and/or provincial health research committee (PHRC) and draft a summary of their research findings in the format of a research brief. • The relevant authorities reserve the right to deny access to further projects from any researchers that do not comply with this requirement. • Kindly submit copy of the final research.
Expiration of Approval	• Should approval expire and renewal not be granted, the study is to cease all activities with immediate effect, till such time as the new approval has been granted. • It remains the PI responsibility to seek renewal of approval in a timeous manner .