Western Cape Government

Department of Health and Wellness
Health Research
Health Intelligence
Health.Research@westerncape.gov.za

Frequently Asked Questions

1. **What is the research application process?**
   The current research application process is as follows:
   1. Register and login on the National Health Research Database (NHRD) - https://nhrd.health.gov.za/
   2. Create a new application.
   3. Select the appropriate province.
   4. Upload all your supporting electronic documents.
   5. Select the facilities you wish to conduct your research.
   6. Review that you have completed all required fields, save, and submit your application.
   7. When following up on the progress of your application, please ensure that the NHRD reference number (WC_yyyymm_xxx) is in the subject line of all communication to the Department's Health Research Unit.

2. **What documents are required for the NHRD application?**
   The following documentation is required when submitting your application on the NHRD:
   1. Ethical clearance (from a Human Health Research Ethics committee registered with the South African National Health Research Ethics Council (NHREC).
   2. A protocol/ proposal.
   3. A completed research summary form for managers.
   4. A completed Annexure A/data request form (if you are requesting access to data from the Provincial Health Data Centre (PHDC)).
   5. Any other supporting document (if relevant) e.g., Clinical trials registration letter.
   6. Once the research is concluded you must complete a short summary of the findings (Annexure 9) which is uploaded onto a SharePoint site for internal staff (and facilities) to access. You can also attach articles or conference proceedings.

3. **What is the research approval process?**
   The current research application and approval process is as follows:
   1. The Health Research Unit downloads applications on the NHRD.
   2. The application then goes through the reviewing process.
   3. Our internal team reviews the documents and is particular about checking informed consent, POPIA issues concerning how data is shared and used, the feasibility of the research, etc. If we pick up issues, we will liaise with the researcher to resolve them before the next stage. We also have subject experts to co-review your application if we pick up issues.
   4. If you request access to data from the provincial health data centre (PHDC), the Annexure A form that you submit will be forwarded to the PHDC to conduct a feasibility assessment of the research request. Where named data are required, you will need informed consent from your participants.
   5. The Health Research Unit will issue a feasibility letter for the researcher if the research is deemed feasible by the PHDC. Please note that this letter does not guarantee that the data will be released.

6. For facility requests your application will be sent to the districts and/or facility for review. The average processing time is 6-8-weeks.
7. Once the requested facility approves, we will issue a provincial approval letter.

4. **When should I query my application?**
   The application process usually takes 6-8 weeks after it has been submitted to the facilities for further processing approval. Follow up after the 8 weeks if you have not yet received feedback by then.

5. **Should I apply to NHRD while waiting for documents such as ethics or the clinical trial no.?**
   No, if your application is not completed, your application will not be processed. Applications dormant on the NHRD for 3 months will be deleted and you will need to reapply.

6. **How to make an amendment on the NHRD?**
   If you need to amend your application, you will need to alert the Health Research Unit to revert your application on the NHRD. The NHRD does not notify us once amendments are made, thus you will have to notify us when your amendment is completed.
   When applying for an amendment, the following documents are required:
   1. annexure 8 (progress report) – template available on the health research website
   2. updated summary form
   3. a valid ethical clearance letter

7. **How to apply for an extension on a study?**
   If you need an extension on your application, you will need to alert the Health Research Unit and submit the following documents:
   1. annexure 8 (progress report) – template available on the health research website
   2. updated summary form
   3. a valid ethical clearance letter

8. **What happens if I submit an application with missing information, an incomplete application, and/or the researcher does not respond to review queries and emails sent from the WC Health Research Unit?**
   All applications undergo review at the provincial level before being forwarded to the districts/sub-structures and facilities for feasibility assessment and review. If there are queries or outstanding information, a six-month period will be provided for resolution. Failure to address these issues within this timeframe will result in the application being withdrawn from the NHRD.

9. **When will approved applications be withdrawn from the NHRD?**
   If you make significant changes to your protocol and receive a new ethics approval letter, your research application will be withdrawn because it will be considered a new study. In that case, you will need to submit a new application through the NHRD.

10. **What happens if I receive provincial approval but have been unable to start my study?**
    If you do not commence data collection within two years from the date of the approval letter, the approval will no longer be valid. You will then need to submit a new application on the NHRD, and your current application will be withdrawn.

11. **What information is often missing or incomplete on the NHRD application?**
    The Ethical clearance letter: We often receive partial ethics approval letters which we do not accept or ethics letters from an ethics board that is not registered with the South African

Health Human Research Ethics Committee (SA HREC) and/or if the ethics approval letter has lapsed. Please check the SA HREC's website for the updated list of registered HRECs. https://www.health.gov.za/nhrec-registration/

The Clinical Trial documentation: We often receive applications with an application form to the SA Clinical trials registry. We do not accept such applications and require the NDOH approval letter with the clinical trial registration number and the SAPHRA approval letters.

Incomplete applications will take longer to process as the applicant will need to be contacted to provide the missing information. This delays the research approval process.

12. **What happens if I do not submit the results of the research (Annexure 9) to the Health Research Unit, 6 months after the research has ended?**
    This may negatively influence your next research application with the Western Cape Department of Health and Wellness.

13. **What is the process for requesting access to a tertiary hospital?**
    There are 3 tertiary hospitals, namely: Groote Schuur Hospital, Tygerberg Hospital, and Red Cross War Memorial Children's Hospital. Each tertiary Hospitals manage its own application process which is separate from the provincial health research process. To enquire about the status of your application, please refer to the contact details provided below:
    - Groote Schuur Hospital - GSHResearch.Request@westerncape.gov.za
    - Tygerberg Hospital - Dawn.Marwood@westerncape.gov.za
    - Red Cross War Memorial Children's Hospital - Ellen.Thomas@westerncape.gov.za