GUIDELINE FOR OBTAINING APPROVAL FROM THE NORTH WEST DEPARTMENT OF HEALTH (NWDOH)

This guideline is setup in response to a need by the Faculty of Health Sciences to have a clear process description which can be followed when applying for approval to access NWDoH facilities to conduct the following types of research studies:

1. Research studies that will be undertaken in public health facilities
2. Clinical trial research that will be undertaken in both public and private healthcare facilities that requires the recruitment of patients
3. Research studies that make use of personnel or any other asset of the NWDoH

These research studies must have *undergone a process of ethics approval* by an *appropriately registered authority* i.e. a *National Health Research Ethics Council (NHREC)-registered research ethics committee* (REC), before being submitted to the NWDoH for approval. In the case of the *Health Research Ethics Committee (HREC)* of the Faculty of Health Sciences at the North-West University, the researchers will be *furnished with a letter* indicating that the research is ethically sound, but that approval will only be granted once *approval from the Department of Health is obtained,* and the individual healthcare facilities have provided goodwill permission.

Please note: The National Department of Health can only give permission for research that is commissioned at *the National Department of Health itself,* which involves their *staff or resources*.

STEPS TO OBTAIN APPROVAL FROM THE NORTH-WEST DEPARTMENT OF HEALTH

If a study requires access to *numerous provincial facilities*, each *individual province has to give permission* for the research to take place within the provincial facilities.

Research studies (as previously indicated) that will be *undertaken in the North West province* should be *submitted via the National Health Research Database* or NHRD (http://nhrd.hst.org.za/). *Before submitting* the application:

1. The *researcher should first register a profile* on the NHRD website. This can be done by *going to the aforementioned website* and *clicking on the "Register" tab* in the top, right-hand corner of the website.
2. The researcher should provide the necessary information as indicated by the website.
3. Once the profile has been registered, the researcher can *submit the application for review*, by going to the aforementioned website and *clicking on the "Submit new proposal" tab* on the top, left-hand of the screen.
4. The website will then ask you to log-in.
5. Once the researcher's login details have been accepted, *the website will proceed* to a webpage where the researcher can choose between *submitting their proposal* either to the *National Department of Health* or to any of the nine *provincial Departments of Health*.
6. In order to submit the proposal, the researcher should click on the "Request access to a provincial facility" button. The researcher will then be taken to a webpage, where the following information must be entered:
   a. *Researchers involved* in the study
   b. *Title* and the *field* of study
   c. *Study design* and the manner in which the *data will be collected*
   d. *Sample* and *data tools* to be used
   e. Project time frame
   f. Ethics time frame
   g. *Funding source* and *budget*

h. *Province and facilities to be included* in the research
i. *Additional* facility requirements
j. *Support documents* e.g. approved proposal, approval letter from ethics committee etc.

7. Under the "Support documents" heading it is requested that the following documentation should be included:
   a. A *cover letter* from the *principal investigator* indicating the *nature of the request* e.g. if it is for academic purposes or as part of a commercial endeavour, the *type of research study* to be undertaken, an *indication of the support* i.e. equipment, infrastructure and staff, that will be required at each of the facilities to be included and the manner in which this *support will be managed* to ensure that normal operations will continue, as well as the *contact details* of the researchers
   b. The *ethically approved research proposal*
   c. The *prior to approval letter* and the *letter to the gatekeepers* from the NHREC-registered REC (Ethical approval certificate)
   d. An *approval letter from the Medicines Control Council* (MCC) if the research study is a clinical trial of a pharmaceutical agent or some form of health technology equipment

8. Research studies that are being undertaken by postgraduate students must be accompanied by
   a. A *cover letter from the supervisor* to indicate that the *proposal has been approved*
   b. The *prior to approval letter* and the *letter to the gatekeepers* from the NHREC-registered REC (Ethical approval certificate)

9. The researcher should remember to *save their progress* when moving from heading, by *clicking on the "Update and save proposal" button* before moving on to the next heading.

10. Once it is completed, the researcher should *proofread the final page* i.e. "Review and submit"

11. Once the researcher is satisfied, they can *submit the application by pressing the "Submit" button*.

12. Once the application is submitted, it is directed by the NHRD to *the NWDoH, Directorate: Policy Planning Research Monitoring and Evaluation or PPRME* for review for studies to be undertaken in the NWDoH facilities.

13. The mechanism by which approval is obtained consists of:
   a. A *review of the proposal by a minimum of three NWDOHRC members and an appropriate directorate* within the department using a specific internal research evaluation form.
   b. These committee members will *provide a recommendation to the NWDOHRC* regarding the research study, which will in turn *submit this feedback to the researcher*:
      - *Accept without changes*
      - *Accept with minor changes*
      - *Accept after extensive revision*
      - *Not suitable*.

14. This process can take up to four *weeks*. If the research study is *approved*, the researcher will *receive an approval letter.*

Please note: If the researcher has any queries, they can contact the following individuals at the PPRME:

   a. Tshiamo Mokate (Tel: +27 (0)18 391 4504; E-mail: TMokate@nwpg.gov.za
   b. Nancy Mangonyane (Tel: +27 (0)18 391 4124; E-mail: nmangonyane@nwpg.gov.za)
   c. Chairperson of the NWDoH Research Committee (NWDOHRC) is Dr Frikkie Reichel (FReichel@nwpg.gov.za), who is also the Director: Policy, Planning, Research Monitoring & Evaluation.)

STEPS TO OBTAIN GOODWILL PERMISSION FROM STAKEHOLDERS

Once the *approval letter* has been obtained from the NWDOHRC via the NHRD website or by email, the *researchers can approach:*

a. the *district-level institutions* and
b. the *individual healthcare facilities* to obtain *goodwill permission* for the research to be undertaken in these entities.

This must *occur well before* the researchers would want to enter these facilities i.e. the researcher cannot just enter the facility without prior approval by the management of the facility. This process will, however in general, be *fast-tracked* as the *NWDOHRC has already provided approval*.

The *request for goodwill permission* will consist of the *submission of the following documentation*:

1. A *cover letter from the principal investigator* indicating the *nature of the request*:
    a. If it is for academic purposes or as part of a commercial endeavour
    b. the *type of research study* to be undertaken
    c. An *indication of the support* i.e. equipment, infrastructure and staff, that will be required at the specific facility to be included
    d. The manner in which this support will be managed to ensure that normal operations will continue, as well as the *contact details of the researchers*
2. The *ethically approved research proposal*
3. The *prior to approval letter* and the *letter to the gatekeepers* from the NHREC-registered REC
4. The *approval letter* from *the NWDOHRC*

These documents *should be sent* to the *appropriate individuals* as indicated in the supplementary document entitled, "*Contact details for District and District Managers, Sub-District Managers and Hospital CEOs"*.

Please note: These requests should be sent to the C*hief Directors of the district* when obtaining *goodwill permission at district level* whereas the appropriate sub-district managers should be approached for permission from the sub-districts or clinical entities.

SUBMITTING DOCUMENTS FROM GATEKEEPERS TO HREC FOR APPROVAL

In order to obtain ethics approval from the HREC for your study:

1. Submit the *approval letter* that has been obtained from *the PPRME* and the *goodwill permission letters* that have been obtained at both the *district level* and the *individual healthcare facilities electronically* to Ethics-HRECProcess@nwu.ac.za
2. These documents should be submitted for review BEFORE approval can be provided, and should be accompanied with a *cover letter* with a *specific subject titl*e indicating, "Submission of Final Version: NWU-XXX-XXX."
3. The *cover letter* should include the following:
    a. The title of the approved study
    b. The *names of the researchers* involved
    c. That the documents are being *submitted in order to obtain approval* by the HREC
    d. The *nature of the documents*
    e. Any further *explanation to clarify the submission*
4. The *e-mail*, to which you attach the documents that you send, should have *a specific subject line* indicating the *nature of the submission*, as well as the nature of the document being sent e.g. "Submission of Final Version: NWU-XXX-XXX.

COMPULSORY REPORTING TO NWDOH AFTER COMPLETION OF STUDY

Six months following *completion* of the research study, it is expected of the researcher

1. To *provide a copy of the research report* that is generated, *to the PPRME*.
2. This is a *non-negotiable requirement* of the permission provided by the PPRME.
3. This report should be sent electronically to Tshiamo Mokate (Tel: +27 (0)18 391 4504; E-mail: TMokate@nwpg.gov.za).
4. The NWDoH reserves the right to *deny approval* of any *future research studies undertaken by a specific researcher* or the *entire research institution* if this requirement is *not adhered* to by a researcher.
5. This will also be *monitored by the Ethics Office* via *review of the monitoring report*.