
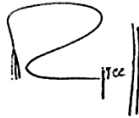






## Faculty of Health Sciences Ethics Office

ETHICS OFFICE		Standard Operating Procedure	
<b>Title</b>	SOP for the research ethics application process for external researchers with prior ethical approval by a NHREC registered REC wanting to conduct health or health-related research at the NWU or wanting to include staff or students from the Faculty of Health Sciences of the North-West University.		
<b>SOP no</b>	2.2.4_SOP_NWU-HREC_2.2	<b>Version no</b>	1
<b>Date of approval</b>	15 February 2018	<b>Revision date</b>	15 February 2021
<b>Web address</b>	<a href="http://health-sciences.nwu.ac.za/healthethics">http://health-sciences.nwu.ac.za/healthethics</a>	<b>Page no</b>	1 to 4

### 1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Wayne Towers		23 Nov 2017
Checked by:	Prof Minrie Greeff		27 Nov 2017
Authorised by:	Prof Minrie Greeff		28 Nov 2017

### 2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof Minrie Greeff		28 Nov 2017
Faculty of Health Sciences	Ms Leanie van Ronge		28 Nov 2017
Health Research Ethics Committee	Prof Wayne Towers		15 Feb 2018

### 3 DOCUMENT HISTORY

Date	Version no	Reason for revision
28 Nov 2017	1	Formulated the SOP

### 4 PURPOSE OF THE SOP

This SOP guides external researchers planning to do health or health-related research at the North-West University (NWU) or include staff or students from the Faculty of Health Sciences at the NWU and which has already obtained ethics approval from another NHREC registered REC, how to apply for ethics approval via an *expedited review process* to ensure a *contextual fit* of the research i.e. have the ethical aspects of the research within this specific context been addressed. It will guide the aforementioned external researchers in the process of first obtaining health research ethics approval needed from the *North-West University Health Research Ethics Committee (NWU-HREC)*. If *staff or students* of the *Faculty of Health Sciences* are to be included in the research, the external researchers will have to obtain further *gatekeeper permission* from the *Research Data Gatekeepers Committee (RDGC)*. The process whereby this can be achieved is indicated at <http://www.nwu.ac.za/research-support/ethics>.

### 5 SCOPE

This SOP is to be used by external researchers that have already obtained research ethics approval from another NHREC registered REC that plan to undertake health or health-related research or who would like to include staff and students of the Faculty of Health Sciences, NWU as participants. This SOP describes the process that should be followed to obtain ethics approval from the NWU-HREC of the NWU. In cases of wanting to include *staff and students*, *gatekeeper permission* will also have to be obtained from the *RDGC* as well. It guides the NWU-HREC in the *expedited review process* that should be followed to ensure that the *context of the research is applicable* to the NWU.

### 6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
External researcher	An external researcher is an individual that is not employed by the NWU and plans to undertake a research study that is health or health-related or includes staff and/or students from the NWU as participants.
NWU-HREC	North-West University Health Research Ethics Committee
NWU	North-West University
RDGC	Research Data Gatekeepers Committee. A committee within the Registrar's Office of the North-West University that acts as the gatekeeper for staff and/or students at the NWU
NHREC	National Health Research Ethics Council
REC	Research Ethics Committee
NHREC registered REC	A National Health Research Ethics Council registered REC that reviews health and health-related research studies that include humans as participants.
Health research	Research that contribute to biological, clinical, psychological or social welfare matters, including processes as regards humans; causes and effects of and responses to disease; effects of the environment; health care systems; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care (DoH, 2015: 7 1.1.3).
Health-related research	Refers to any research conducted by disciplines other than health disciplines about topics or participants within the field of health or

	investigating or striving to improve the bio-psycho-social wellbeing of human participants.
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## 7 RESPONSIBILITIES

There are numerous stakeholders involved in this process:

- The *external researcher* should follow the application process as outlined under Section 8 to ensure the timely approval of their request to conduct health or health-related research or access the staff and/or students of the Faculty of Health Sciences, NWU. The researchers have to ensure that the context of the NWU is well understood and correctly applied during the conduct of their research.
- It is the *responsibility of the NWU-HREC* to ensure that the external request is reviewed in an expedited manner, the context correctly described and applied and that any feedback is sent timeously to the external researcher.
- The *administrative staff of the NWU-HREC* are responsible for ensuring the effective processing of the external request, communicate effectively with the researcher, as well as timeously communicating the outcome of the review by the HREC to the researcher directly.
- The *RDGC* is responsible for ensuring the *both staff and students* at the NWU and *their data* are dealt with in a *legally appropriate* manner, when being included in research.

## 8 PROCEDURE/S

The external researcher sets up the following documentation for the application request:

- a. A *clear and systematic cover letter* addressed to the chairperson of the NWU-HREC indicating:
  - the title of the study
  - the names of the researchers involved
  - that it is a request with *prior NHREC registered REC approval for an expedited review process*
  - that the request is for health or health-related research or to include staff and/or students from the Faculty of Health Sciences
  - listing the documents that are attached to the application
  - any further explanation needed to clarify the submission
- b. A copy of the *ethically approved proposal* of the research study
- c. A copy of the *initial completed ethics application form* that was submitted to the first REC
- d. A copy of the *ethics approval certificate* obtained from the external NHREC registered REC
- e. A copy of the *informed consent form* that will be used in the study
- f. A copy of the questionnaire(s) or interview schedule(s)
- g. Copies of *any other documentation* that will be used in the recruitment process e.g. advertisements, recruitment flyers
- h. Checklist for the submitted documentation.



The application request, addressed to the chairperson of the NWU-HREC, should be sent to [Ethics-HRECApply@nwu.ac.za](mailto:Ethics-HRECApply@nwu.ac.za) with the email subject line indicating “**Research ethics application for the expedited review of a prior approved study**”. Each of the aforementioned documents should be attached as separate documents to the e-mail.



The application will be handled via the ***expedited review process***.



The administrative staff of the NWU-HREC, *within three working days*, sends the application request to the chairperson of the NWU-HREC.



The chairperson of the NWU-HREC, within three working days, assigns *at least two reviewers* and returns it to the administrative staff.



The administrative staff, *within two working days*, distributes the application accordingly to the assigned reviewers.



The reviewers have *three working days* to complete the review and send their feedback back to the administrative staff of the NWU-HREC.



The administrative staff within *three working days* sends the feedback to the NWU-HREC chairperson, who in turn consolidates the feedback into a formal response and sends this to the administrative staff of the NWU- HREC.



The administrative staff of the NWU-HREC *within three working days* sends the formal response to the external applicant researcher.



If corrections are requested, the external researcher should make the suggested changes and as soon as possible send the amended documentation to [Ethics-HRECProcess@nwu.ac.za](mailto:Ethics-HRECProcess@nwu.ac.za).

A *rebuttal letter* should be included indicating:

- what changes have been made,
- how the queries have been addressed and
- where the changes were made in the documentation.

Furthermore the changes should be **highlighted in yellow highlight** in all the amended documents as well.



The NWU-HREC administrative staff will re-distribute the amended application to the same reviewers that were previously assigned, who will be given *three working days* to complete the review of the corrections.



The reviewers will again send their feedback to the administrative staff of the NWU-HREC who will, in turn, send it to the NWU-HREC chairperson.



The NWU-HREC chairperson will consolidate the feedback and will send a formal response to the administrative staff of the NWU-HREC.



The administrative staff of the NWU-HREC, *within three days*, sends the formal response to the external researcher.



A. If the application is for *health or health-related research*, a letter will be sent to the researcher indicating approval of the study that will be followed by the issuing of an ethics approval letter by the Research Ethics Regulatory Committee (RERC).

B. If the application has been approved for research that *includes staff or students of the Faculty of health Sciences*, the scientist must also obtain approval from the **Research Data**

**Gatekeepers Committee (RDGC)** <http://www.nwu.ac.za/research-support/ethics>. The external researcher will be furnished with a “*letter to the gatekeepers*” indicating that the study has been approved, but that the aforementioned permission letter is required. The approval letter obtained from the NWU-HREC must be attached to the application for obtaining permission from the RDGC. The researcher is guided to the web page of the RDGC to follow their guidelines as well as obtain permission to conduct research including staff and/or students of the Faculty of Health Sciences of the NWU.

- C. Once the NWU-HREC receives a copy of the *permission letter from the RDGC* and a copy of the permission letter from the director of the School in which the staff and/or students to be included in the study reside, ethics approval will be granted.



Once these *permission letters* have been obtained, they should be submitted to [Ethics-HRECProcess@nwu.ac.za](mailto:Ethics-HRECProcess@nwu.ac.za).

There should be a clear cover letter attached, indicating:

- the title of the study
- the names of the researchers involved
- the documents that are being submitted in order to obtain the final approval by the NWU-HREC
- any further explanation to clarify the submission



The administrative staff of the NWU-HREC will send the final documents to the NWU-HREC chairperson, who in turn, will check the documentation and will setup an approval letter that will be sent to the administrative staff, who, in turn, will send it to the external researcher.



The researcher can then continue to recruit participants as per the approved proposal.



This decision is ratified during the next NWU-HREC meeting.

### Checklist for the application documentation

Items	Attached (tick the box)
A clear and systematic cover letter	
A copy of the ethically approved proposal of the research study	
A copy of the initial completed ethics application form that was submitted to the first REC	
A copy of the ethics approval certificate obtained from the external NHREC registered REC	
A copy of the informed consent form that will be used in the study	
A copy of the questionnaire(s) or interview schedule(s)	
Copies of any other documentation that will be used in the recruitment process e.g. advertisements, recruitment flyers. Please mention:	
Checklist for the submitted documentation	

## 9 REFERENCE DOCUMENTS

None

## 10 ADDENDA

No	Document name
1	Checklist to attach to the application

Original details: (12686417) C:\Users\12686417\Documents\Ethics\Ethics office\SOPs\External applications SOP\_23 Nov 2017.docm  
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