






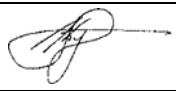




Faculty of Health Sciences Ethics Office for Research, Training and Support









ETHICS OFFICE		Standard Operating Procedure	
Title	SOP for the establishment of SOPs in the Faculty of Health Sciences Ethics Office		
SOP no	2.2.4_SOP_Ethics_1.1	Version no	2
Date of approval	1 November 2023	Revision date	November 2026
Web address	http://health-sciences.nwu.ac.za/healthethics	Page no	Page 1 to 6

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof M Greeff		18 Aug 2016
Updated by:	Prof GW Towers		27 July 2023
Checked by:	NWU-HREC		24 Aug 2016
			27 July 2023
	NWU-AnimCareREC		24 Aug 2016 27 July 2023
			24 Aug 2016
	Ethics Office		27 July 2023

	Faculty Management Committee		9 Nov 2016 2 August 2023
Authorised by:	Head of the Ethics Office		9 Nov 2016
	Head of the Ethics Office		1 November 2023

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof M Greeff		10 Nov 2016
	Prof GW Towers		27 July 2023
Chairperson on behalf of NWU-HREC	Dr GW Towers		10 Nov 2016
	Prof P Bester		27 July 2023
Chairperson on behalf of NWU-AnimCareREC	Prof CB Brink		10 Nov 2016 27 July 2023
Executive Dean of the Faculty of Health Sciences	Prof AF Kotzé		10 Nov 2016 2 August 2023
Faculty of Health Sciences	Ms L van Ronge		10 Nov 2016
	Ms L Sengati		27 July 2023

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2016	1	First document
1 November 2023	2	Second document

4 PURPOSE OF THE SOP

The purpose of this SOP is to provide a framework for the establishment of all SOPs relating to ethics matters, within the Faculty of Health Sciences Ethics Office for Research, Training and Support (referred to as the Ethics Office), as well as for the North-West University Health Research Ethics Committee (NWU-HREC) and the North-West University Animal Care, Health and Safety in Research Ethics Committee (NWU-AnimCareREC) further referred to as Research Ethics Committees (RECs) in all associated documents. Important procedures and processes within the aforementioned structures should be documented to ensure standard and uniform practices, so that activities are reproducible and transparent.

5 SCOPE

The scope of this document covers the establishment of all new SOPs in the Ethics Office and RECs of the Faculty of Health Sciences. It covers the responsibilities and procedure(s) to be followed, the essential elements to be included, as well as a template to be used for the establishment of a SOP.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
FMC	Faculty Management Committee
NWU-AnimCareREC	North-West University Animal Care, Health and Safety in Research Ethics Committee
NWU-HREC	North-West University Health Research Ethics Committee
REC	Research Ethics Committee
SOP	Standard Operating Procedure

7 RESPONSIBILITIES

All staff members of the Ethics Office and the REC members should be aware of the procedure to be followed for the establishment of any SOP relating to ethics matters within the Faculty of Health Sciences, to ensure a standardised approach.

8 PROCEDURE(S)

- 8.1 Should the need arise for the establishment of a new SOP for either the Ethics Office or one of the RECs, a request must be submitted to the Head of the Ethics Office via email.
- 8.2 The Head and the Academic Advisor of the Ethics Office will review the request and authorise/decline the establishment of the SOP.
- 8.3 The decision of approval/disapproval will be communicated to the requestor via email.
- 8.4 On receipt of approval, the requestor will then write the SOP in accordance with **2.2.4 SOP_Ethics_1.1: SOP for the establishment of SOPs in the Faculty of Health Sciences Ethics Office** and use the provided template.
- 8.5 SOPs are numbered by the Ethics Office using the following prefixes:
 - 8.5.1 For SOPs of the Ethics Office – **2.2.4 SOP_Ethics_1.XXX**
 - 8.5.2 For SOPs of the Ethics Office administration – **2.2.4 SOP_EthicsAdmin_4.XXX**
 - 8.5.3 For SOPs of the NWU-HREC – **2.2.4 SOP_NWU-HREC_2.XXX**
 - 8.5.4 For SOPs of NWU-AnimCareREC – **2.2.4 SOP_NWU-AnimCareREC_3.XXX**
- 8.6 The approval process for the various SOPs will differ:**
 - 8.6.1 When the first draft of the SOP has been written, the draft must be sent electronically to the Head of the Ethics Office. The version number of this draft will be indicated as Draft X.
 - 8.6.2 The SOP will be distributed according to the process indicated below.

- 8.6.2.1 In the case of SOPs specifically regarding the management and administration in the Ethics Office, it is first reviewed by and discussed with the Head and Academic Advisor of the Ethics Office and then tabled at the next personnel meeting of the office where it is discussed and can be approved.
- 8.6.2.2 If the SOP has greater relevance to the Faculty of Health Sciences as a whole, it is first reviewed by and discussed with the Head and Academic Advisor of the Ethics Office, after which it will be discussed during a personnel meeting of the Ethics Office, followed by a discussion at the appropriate REC meeting(s), and then taken to the Faculty Management Committee (FMC) of the Faculty of Health Sciences. During the FMC, a decision can be taken of whether the SOP should go to the Research and Innovation Committee (RIC) and/or the Faculty Board for approval.
- 8.6.2.3 In the case of an SOP specific to one of the RECs, it is first reviewed by and discussed with the Head and Academic Advisor of the Ethics Office, then at the appropriate REC meeting/s, followed by the same process of approval at FMC, where a decision can be taken of whether the SOP should go to the RIC and/or the Faculty Board for approval.
- 8.7 Any changes received via any of the aforementioned channels, will be sent to the Head of the Ethics Office to implement with the requestor.
- 8.8 Once all changes have been agreed upon and made, the SOP is finalised, approved and signed by all relevant parties.
- 8.9 The SOPs for general use and for the RECs are placed on the webpage of the Ethics Office and a notice is sent to all in the Faculty of Health Sciences, via the appropriate communication channels i.e. P-HealthSciences email address.
- 8.10 A database of all SOPs is kept in the Ethics Office.
- 8.11 A record of all SOPs is kept in the Ethics Office.
- 8.12 SOPs are revised as indicated on the specific SOP, following the same process that was followed during its development.
- 8.13 SOPs must be adhered to stringently.
- 8.14 When a SOP becomes redundant it should be withdrawn from the webpage and this withdrawal should be widely communicated.

9 ESSENTIAL ELEMENTS TO BE INCLUDED

- 9.1 All approved SOPs must contain the following essential elements:
 - 9.1.1 SOP identification:
 - 9.1.1.1 Title
 - 9.1.1.2 SOP no
 - 9.1.1.3 Version no
 - 9.1.1.4 Date of approval
 - 9.1.1.5 Revision date
 - 9.1.1.6 Web address
 - 9.1.1.7 Page no
 - 9.1.2 Compilation and authorisation
 - 9.1.3 Distribution
 - 9.1.4 Document history
 - 9.1.5 Purpose of the SOP

- 9.1.6 Scope
- 9.1.7 Abbreviations and/or definitions
- 9.1.8 Responsibilities
- 9.1.9 Procedure(s) to be followed
- 9.1.10 Essential elements to the specific SOP
- 9.1.11 Reference documents
- 9.1.12 Addenda

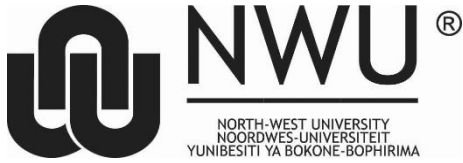
10 REFERENCE DOCUMENTS

None

11 ADDENDA

No	Document name
1	Template for the establishment of an SOP

Addendum 1: Template for the establishment of an SOP



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