

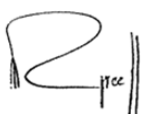











Faculty of Health Sciences Ethics Office

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|-------------------------|---|-------------------------------------|---------------|
| ETHICS OFFICE | | Standard Operating Procedure | |
| Title | SOP for the establishment of SOPs in the Faculty of Health Sciences Ethics Office | | |
| SOP no | SOP_Ethics_1.1 | Version no | 1 |
| Date of approval | 9 November 2016 | Revision date | November 2019 |
| 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 Minrie Greeff |  | 18 Aug 2016 |
| Checked by: | Dr Wayne Towers |  | 18 Aug 2016 |
| | Ethics office |  | 24 Aug 2016 |
| | AnimCare |  | 24 Aug 2016 |
| | HREC |  | 24 Aug 2016 |
| | ExCo FMC |  | 9 Nov 2016 |
| Authorised by: | Head of the Ethics Office |  | 9 Nov 2016 |

2 DISTRIBUTION

| Department/Unit | Name | Signature | Date |
|--|--------------------|---|-------------|
| Ethics Office | Prof Minrie Greeff |  | 10 Nov 2016 |
| HREC chairperson on behalf of HREC | Dr GW Towers |  | 10 Nov 2016 |
| AnimCare chairperson on behalf of AnimCare | Prof T Brink |  | 10 Nov 2016 |
| Executive Dean of the Faculty of Health Sciences | Prof Awie Kotzé |  | 10 Nov 2016 |
| Faculty of Health Sciences | Ms L van Ronge |  | 10 Nov 2016 |

3 DOCUMENT HISTORY

| Date | Version no | Reason for revision |
|------------|------------|---------------------|
| 9 Nov 2016 | 1 | First document |
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4 PURPOSE OF THE SOP

The purpose of this SOP is to provide a framework for the establishment of all SOPs within the Ethics Office of the Faculty of Health Sciences relating to ethics matters, as well as for the Health Research Ethics Committee (HREC) and the Animal Care, Health and Safety in Research Ethics Committee (AnimCare) further referred to as Research Ethics Committees (RECs) in all associated documents. Important procedures and processes should be documented to ensure standard and uniform practices so that activities can be reproduced.

5 SCOPE

The scope of this document covers the establishment of all new SOPs for the Ethics Office and RECs. 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 |
|-------------------------|---|
| SOP | Standard Operating Procedure |
| HREC | Health Research Ethics Committee |
| AnimCare | Animal Care, Health and Safety in Research Ethics Committee |
| REC | Research Ethics Committee |

7 RESPONSIBILITIES

All staff members of the Ethics Office and the REC members should be aware of the procedure to follow for the establishment of a SOP for research ethics 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.
- 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 to **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 for the Ethics Office – **2.2.4_SOP_Ethics_1.xvy**
 - 8.5.2 For SOPs for the Ethics Office administration – **2.2.4_SOP_EthicsAdmin_4.xyz**
 - 8.5.3 For SOPs for the HREC – **2.2.4_SOP_HREC_2.xvy**
 - 8.5.4 For SOPs for AnimCare – **2.2.4_SOP_AnimCare_3.xvy**
- 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.
 - 8.6.3 In the case of SOPs for the Ethics Office, it is first discussed with the Head and Academic Advisor of the Ethics Office and then tabled at the next personnel meeting of the office where it can be approved.
 - 8.6.4 If the SOP has greater relevance to the Faculty of Health Sciences as a whole, it is first discussed with the Head and Academic Advisor of the Ethics Office, then discussed during a personnel meeting, then at the appropriate REC meeting(s), and then taken to the Executive Committee (ExCo) of the Faculty of Health Sciences. During the ExCo a decision can be taken of whether the SOP should go to the Research Committee and/or the Faculty Management Committee for approval.
 - 8.6.5 In the case of an SOP for one of the RECs, it is first 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 ExCo where a decision can be taken of whether the SOP should go to the Research Committee and/or the Faculty Management Committee for approval.
- 8.7 Any changes will be sent to the Head of the Ethics Office to implement with the requestor.
- 8.8 The SOP is finalised, approved and signed by all parties.
- 8.9 The SOPs for general use and for the RECs are placed on the Faculty of Health Sciences, Health Research Ethics Webpage and a notice is sent to all in the Faculty via the intranet.
- 8.10 After approval, the SOP will be placed on the Webpage of the Ethics Office.
- 8.11 A database of all SOPs is kept in the Ethics Office.
- 8.12 A record of all SOPs is kept in the Ethics Office.
- 8.13 SOPs are revised as indicated on the specific SOP, following the same process that was followed during its development.
- 8.14 SOPs must be adhered to stringently.
- 8.15 When a SOP becomes redundant it should be withdrawn from the Webpage and widely communicated.

9 ESSENTIAL ELEMENTS TO BE INCLUDED

- SOP identification:
 - Title
 - SOP no
 - Version no
 - Date of approval
 - Revision date
 - Web address
 - Page no
- Compilation and authorisation
- Distribution
- Document history
- Purpose of the SOP
- Scope
- Abbreviations and/or definitions
- Responsibilities
- Procedure(s) to be followed
- Reference documents
- Addenda
- Any other elements essential to the specific SOP

10 REFERENCE DOCUMENTS

None

11 ADDENDA

| No | Document name |
|----|---|
| 1 | Template for the establishment of a SOP |
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Addendum 1: Template for the establishment of a SOP



NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

Faculty of Health Sciences

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8 PROCEDURE(S)

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10 REFERENCE DOCUMENTS

11 ADDENDA

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|----|---------------|
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