

Faculty of Health Sciences

ETHICS OFFICE		Standard Operating Procedure		
Title	SOP for whistleblowing pertaining to research			
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1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		14 Oct 2016
		n ce	6 June 2018
Checked by:			10.0 10010
	Dr Wayne Towers		19 Oct 2016
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	Ethics office		19 Oct 2016
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	AnimCare	(BBm)	19 Oct 2016
	HREC		19 Oct 2016
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	Faculty Board	AD-	9 Nov 2016
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Authorised by:	Prof Minrie Greeff as Head of the Ethics Office	\square	9 Nov 2016
		Mhee	6 June 2018

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof Minrie Greeff	hee	10 Nov 2016 6 June 2018
Chairperson on behalf of HREC	Dr Wayne Towers	Allan	10 Nov 2016 6 June 2018
Chairperson on behalf of AnimCare	Prof Tiaan Brink	BBme	10 Nov 2016 6 June 2018
Executive Dean of the Faculty of Health Sciences	Prof Awie Kotzé	A	10 Nov 2016 6 June 2018
Faculty of health Sciences	Ms Leanie van Ronge	ArrRonge	10 Nov 2016 6 June 2018

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2016	1	Formulated the SOP
6 June 2018	2	Change in university structure

4 PURPOSE OF THE SOP

This standard operating procedure (SOP) sets out the *procedure to follow when* a member of the Health Research Ethics Committee (HREC) or the Ethics Committee on Animal Care, Health and Safety in Research (AnimCare), a staff member or a student of the North-West University (NWU) wants to raise concerns with the Head of the Faculty of Health Sciences Ethics Office or a relevant Research Ethics Committee (REC) chairperson. The concerned individual must have reasonable grounds to believe that there is 1) research non-compliance, 2) violation of good research practice, 3) misconduct, 4) fraud, 4) maladministration, or 5) non-adherence to approved research procedures, guidelines or policies committed by a researcher (staff member and/or student) of the North-West University (NWU), in respect of research.

Members of the RECs, staff members or students of the NWU enjoy the full protection afforded by the Public Disclosure Act No. 26 of 2000 (PDA) and can blow the whistle on the four mentioned aspects without fear of disclosure.

This SOP ensures confidentiality to all members of the RECs, staff members or students of the NWU, and furthermore ensures that nobody would be exposed for disclosing in good faith information that would assist the Head of the Faculty of Health Sciences Ethics Office or the Chairpersons of the RECs in meeting their obligation in terms of the guiding principles and regulations as set out in the various documents in section 9.

5 SCOPE

This SOP deals only with alleged actions committed by *researchers* (staff and/or students of the NWU) within the ambit of research with respect to human participants, animals or environmental impact. The SOP deals primarily with, but is not limited to, misconduct, fraud, maladministration and non-adherence to approved research procedures, guidelines or policies as defined in the definition section below, only to the extent that they may relate to the principles and regulations as set out in the various documents mentioned under section 9.

Concerns are raised with respect to matters relating to:

- 1) Research non-compliance
- 2) Violation of good research practice

- 3) Misconduct.
 - a. Fabrication (making up research data or results and recording or reporting the fabricated material).
 - b. Falsification (manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research records).
 - c. Plagiarism (the appropriation of another person's research ideas, processes, results, or words without giving appropriate credit).
- 4) Fraud.
- 5) Maladministration.
- 6) Non-adherence to approved research procedures, guidelines or policies.

It is not the objective of this SOP to replace any other policies or procedures of the NWU. Should the reported concern/irregularity not lie within the ambit of research, the person must be referred to the Director Internal Audit (Internal Box 473) and follow the procedure as set out in *the Policy on the Report of Maladministration and Irregularities and the Protection of Disclosure (Ref no 2P/2.9.6) of the NWU, 2009.* The provision is that the disclosure is made in good faith, in the reasonable belief of the individual making the disclosure that it shows irregularities in research practices, and the disclosure is made to the appropriate person(s).

Personal grievances must be dealt with in terms of existing labour procedures at the institution. This SOP should not be used to reconsider any matter which has already been addressed under harassment, complaint, disciplinary or other procedures.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/ definition	Description	
REC	Research Ethics Committee	
HREC	Health Research Ethics Committee	
AnimCare	The Ethics Committee on Animal Care, Health and Safety in Research	
NWU	North-West University	
PDA	Public Disclosure Act, 2000 (Act No. 26 of 2000)	
Whistleblowing	The act of informing someone in authority (Head of the Faculty of Health Sciences Ethics Office, or Chairperson of one of the RECs) about alleged research misconduct (fabrication, falsification or plagiarism), fraud, maladministration and non-adherence to approved research procedures, guidelines or policies occurring at the North-West University. In relation to the context of this document, the alleged acts have to be <i>related or incidental to the execution of research</i> .	
Ethics	The term "ethics" refers to standards of research conduct, which indicate how a person should behave based on moral duties and virtues arising from the principles of right and wrong. Ethics therefore involves two aspects:	
	 The ability to distinguish right from wrong; and The commitment to do what is right as articulated in various pieces of legislation and guidelines regulating the execution of research. 	
Values	Refers to the beliefs of a person or social group in which they have an emotional investment either for or against something.	
Integrity	Refers to the quality or state of being of sound moral principle, uprightness, honesty and sincerity.	
Fraud	Involves actions or behaviour like dishonesty, deception or forgery by an individual, other person or entity that manipulate others or systems into providing a benefit that would not normally accrue to that person.	
Non-compliance	Any violation of any regulation governing human or animal research or any deviation from the REC-approved proposal/protocol. Non-compliance varies in nature, severity and frequency (adapted from UCT, 2013).	
Violation of good research practice	 Violations of good research practice that damage the integrity of the research process or of researchers. Examples include but are not limited to: 	

	 Direct violation of good research practices set out in the Code of Conduct for researchers of the NWU or for members of the RECs and other regulatory requirements. Manipulating authorship or denigrating the role of other researchers in publications. Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original (self-plagiarism). Citing selectively to enhance own findings or to please editors, reviewers or colleagues. Withholding research results. Deliberate misrepresentations in publications. Improper conduct in peer review. Allowing funders/sponsors to jeopardise independence in the research process or reporting of results so as to introduce or promulgate bias. Expanding unnecessarily the bibliography of a study. Accusing a researcher of misconduct or other violations in a retaliating, intimidating and malicious way. Misrepresenting research achievements. Exaggerating the importance and practical applicability of findings. Delaying or inappropriately hampering the work of other researchers. Misusing seniority to encourage violations of research integrity. Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.
Misconduct	 Involves intentional deception during research conduct through <i>fabrication, falsification,</i> or <i>plagiarism</i> in proposing, performing, or reviewing research, or in reporting research results. 1) Fabrication (making up research data or results and recording or reporting the fabricated material). 2) Falsification (manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research records). 3) Plagiarism (the appropriation of another person's research ideas, processes, results, or words without giving appropriate credit). Misconduct furthermore relates to any infringement of the guiding principles of ethical research, obligations of researchers towards human participants or animals, regulations relating to consent, ministerial consent and the reviewing of proposals for research with human participants or animals as mentioned under section 9. Note: Honest errors / differences of opinion / disagreements are not research misconduct.
Conflicts of interest	Not classified as research misconduct. It could, however, undermine the integrity and trustworthiness of the research. Conflicts of interest should always be declared, as well as the precautionary measures that will be taken.

7 **RESPONSIBILITIES**

The NWU is committed to the highest standard of ethics and integrity in research.

Researchers of the institution are expected to behave in an honest and responsible way at all times.

Research activities will be carried out in an open and transparent manner and in accordance to the code of conduct for researchers of the NWU.

Any member of the RECs, staff member or student of the NWU who has a reasonable belief that any act of misconduct, fraud, maladministration, or non-adherence to approved research procedures, guidelines or policies has been committed, is obligated in terms of this SOP to report any such unethical research practices at the NWU using the correct procedure as described in section 8 of this SOP.

Any whistleblowing should be done in a bona fide and non-vindictive manner.

8 PROCEDURE(S)

- 8.1 A disclosure should be made in writing using the *official complaint/referral form* (see Addendum 1) and submitted to the either the Head of the Faculty of Health Sciences Ethics Office or one of the appropriate REC Chairpersons as soon as possible after the Head or the Chairpersons have become aware of the concerning practice of a researcher.
- 8.2 When a member of one of the RECs, a staff member or a student of the University makes a disclosure to the Head of the Ethics Office or one of the applicable REC Chairpersons, it must be done in a responsible and honest manner.
- 8.3 If the notification is made to one of the REC Chairpersons, they must as soon as possible acknowledge receipt of the disclosure directly to the whistleblower and immediately (within three days) notify the Head of the Faculty of Health Sciences Ethics Office by forwarding the disclosure.
- 8.4 The Head of the Ethics Office will immediately upon receipt of the disclosure set up an appointment with the whistleblower, the applicable chairperson and legal representative of the REC (investigating team) within 14 (fourteen) working days of the acknowledging of the disclosure.
- 8.5 The aim of this appointment is to allow the investigating team to conduct an initial investigation in order to establish whether there is a *prima facie* case to answer.
- 8.5.1 If the investigating team considers that there is no *prima facie* case to be answered and that no further action will be taken, this decision will be explained to the whistleblower.
- 8.5.2 If the investigating team considers that there is a *prima facie* case to be answered, the way forward is discussed to the satisfaction of all members.
- 8.5.3 If disciplinary measures are required, the research director will be notified and the appropriate University procedure followed.
- 8.6 Investigations will be dealt with sensitively, on an impartial basis and within a reasonable time frame.
- 8.7 Details of the allegation, the identity of the person making the allegation and against whom the allegation is made will remain confidential.
- 8.8 The Head, Chairperson and legal representative of the REC can request the assistance of an independent person. Those requested to assist in the investigation will be chosen on the basis of being independent from the issues/events from which the allegation has been initiated.
- 8.9 The Deputy Dean Research and Innovations of the Faculty of Health Sciences is notified of the reporting and the actions taken. If necessary the Deputy Dean Research and Innovations is included in the actions.
- 8.10 If the whistleblower is not satisfied with the outcome of the investigation they should raise their concerns with the Head of the Ethics Office to find another solution or to refer them to a higher authority.

9 REFERENCE DOCUMENTS

- Constitution of the Republic of South Africa.
- The National Health Act, No. 61 of 2003.
- Regulations relating to research with human participants (Government Gazette nr 38000, of 19 September 2014).
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).

- South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008).
- Public Disclosure Act, Act No. 26 of 2000.
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- Code of conduct for researchers of the NWU, 2016.
- Policy on the report of maladministration and irregularities and the protection of disclosure (Ref No. 2P/2.9.6) of the NWU, 2009.

10 ADDENDA

No	Document name	
1	Appendix 1: Form for the reporting of possible research misconduct, fraud, maladministration, or non-adherence to approved research procedures, guidelines or policies	

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