


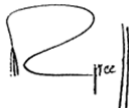







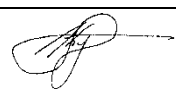

**Faculty of Health Sciences**

<b>ETHICS OFFICE</b>		<b>Standard Operating Procedure</b>	
<b>Title</b>	SOP for complaints management		
<b>SOP no</b>	2.2.4_SOP_Ethics_1.5	<b>Version no</b>	2
<b>Date of approval</b>	6 June 2018	<b>Revision date</b>	June 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>	Page 1 to 8

**1 COMPILATION AND AUTHORISATION**

<b>Action</b>	<b>Designated person</b>	<b>Signature</b>	<b>Date</b>
Compiled by:	Prof Minrie Greeff		30 Aug 2016 6 June 2018
Checked by:	HREC		8 Sept 2016
	AnimCare		8 Sept 2016
	Ethics Office		8 Sept 2016
	Faculty Board		9 Nov 2016
Authorised by:	Prof Minrie Greeff as Head of the Ethics Office		9 Nov 2016 6 June 2018

## 2 DISTRIBUTION

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

## 3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2015	1	Formulated the SOP
6 June 2018		Change in university structure

## 4 PURPOSE OF THE SOP

This SOP provides guidelines for the management of three types of complaints:

1. Complaints from researchers about a member of the HREC/AnimCare or the HREC/AnimCare itself
2. Complaints from a member of the HREC/AnimCare or the HREC/AnimCare itself about a researcher
3. Complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher.

During any investigation of complaints, the Ethics Office and RECs will adhere to the following principles:

- *Fairness*
- *Confidentiality*
- *Integrity*
- *Prevention of detriment*

## 5 SCOPE

Notwithstanding this complaint procedure, processes will comply with National Regulations, including that the Chair of an Ethics Committee retains the right to immediately suspend or terminate any research study that violates National Regulations.

## 6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
HREC	Health Research Ethics Committee
AnimCare	The Ethics Committee on Animal Care, Health and Safety in Research
REC	Research Ethics Committee
NWU	North-West University
Complaint	Refers to any action of RECs, an REC member, researcher, co-researcher, research assistant, research participant, or interested community member about dissatisfaction with research-related activities which they wish to take forward in a formal manner.
FMC	Faculty Management Committee

## 7 RESPONSIBILITIES

This SOP provides guidelines for RECs, an REC member, researcher, co-researcher, research assistant, research participant, or interested community member on how to handle any dissatisfaction related to research-related activities.

## 8 PROCEDURE(S)

### 8.1 Procedure for complaints from researchers about a member of the HREC/AnimCare or the HREC/AnimCare itself

Should a researcher / postgraduate student experience a problem with a specific HREC/AnimCare member's behaviour or the HREC/AnimCare itself regarding meeting procedures, application management or reviewer report(s), they have the opportunity to lodge a complaint.

The complaint should be lodged in writing to the Head of the Ethics Office ([Minrie.Greeff@nwu.ac.za](mailto:Minrie.Greeff@nwu.ac.za)) as well as the chair of the applicable ethics committee (HREC ([Wayne.Towers@nwu.ac.za](mailto:Wayne.Towers@nwu.ac.za)) or AnimCare ([Tiaan.Brink@nwu.ac.za](mailto:Tiaan.Brink@nwu.ac.za))).

Such a written complaint will initiate the following process:

A meeting will immediately be constituted with the complainant, the Head of the Ethics Office, the Chair and the Vice-Chair of the applicable ethics committee and the member to discuss the complaint in an attempt to find an amicable solution. If the complainant is a postgraduate student, the supervisor will be included in this discussion. A written report of this meeting will be compiled by the Ethics Office. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

A meeting will be called as soon as possible with the complainant, the Deputy Dean Research and Innovation, the Head of the Ethics Office, the Chair and the Vice-Chair of the applicable ethics committee, the member and the Director of the applicable research entity to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by the Ethics Office. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

The complainant may approach the National Health Research Ethics Council (NHREC) to lodge the unresolved complaint, also providing proof that the aforementioned internal mediation process was followed unsuccessfully. The procedure is available on the webpage of the NHREC.

The complaint and its outcome will be reported during the following HREC/AnimCare meeting.

**Flow diagram 1: Procedure for complaints from researchers**



## 8.2 Complaints from a member of HREC/AnimCare or HREC/AnimCare about a researcher

Should a member of the HREC or AnimCare or the HREC/AnimCare itself experience a problem with a specific researcher's behaviour or research actions, they have the opportunity to lodge a complaint.

The complaint should be lodged in writing to the Head of the Ethics Office ([Minrie.Greeff@nwu.ac.za](mailto:Minrie.Greeff@nwu.ac.za)) as well as the chair of the applicable ethics committee (HREC ([Wayne.Towers@nwu.ac.za](mailto:Wayne.Towers@nwu.ac.za)) or AnimCare ([Tiaan.Brink@nwu.ac.za](mailto:Tiaan.Brink@nwu.ac.za)))

Such a written complaint will initiate the following process:

A meeting will immediately be called with the complainant, the researcher, the Head of the Ethics Office, as well as the Chair and the Vice-Chair of the applicable ethics committee to discuss the complaint about the researcher in an attempt to find an amicable solution, and to communicate the problem and consequences to the researcher in the most appropriate way. A written report of this meeting will be compiled by the Ethics Office and kept on file. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

A meeting will be called as soon as possible between the complainant, the Head of the Ethics Office, and the Chair and the Vice-Chair of the applicable ethics committee, and the researcher to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by

the Ethics Office which will be kept on file. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

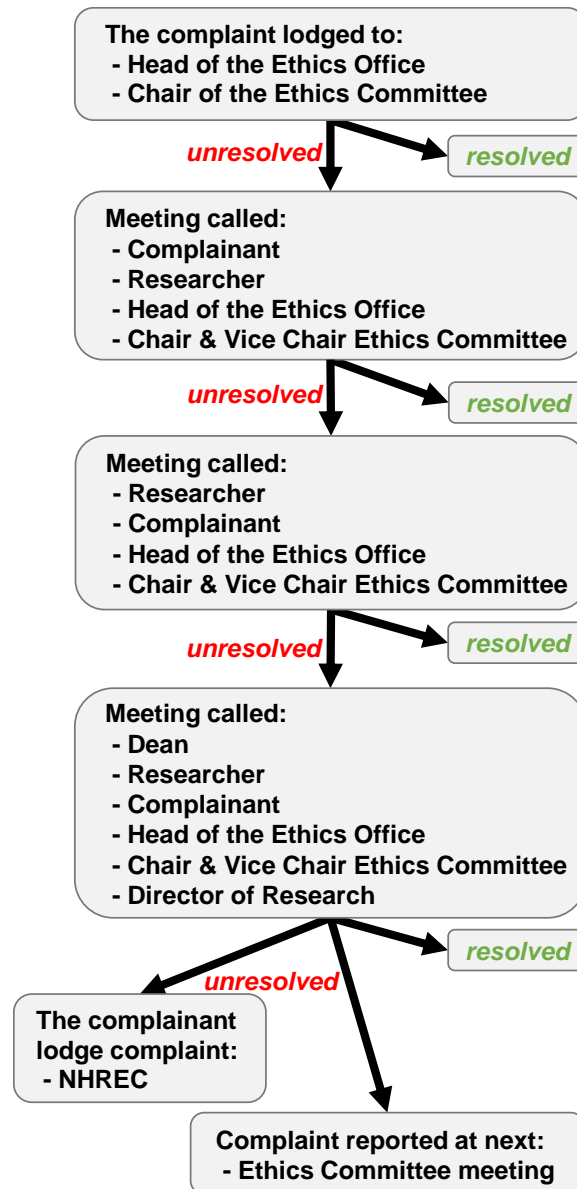
A meeting will be called as soon as possible with the researcher, the complainant, the Deputy Dean Research and Innovations, the Head of the Ethics Office, the Chair and the Vice-Chair of the applicable ethics committee, and the Director of the applicable research entity to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by the Ethics office which will be kept on file. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

The complainant may approach the NHREC to lodge the unresolved complaint, also providing proof that the aforementioned internal mediation process was followed and unsuccessful. The procedure is available on the webpage of the NHREC. Should the researcher feel unfairly treated he/she can follow the internal process and if unresolved also approach the NHREC.

The complaint and its outcome will be reported during the following HREC/AnimCare meeting.

**Flow diagram 2: Procedure for complaints from REC members**



**8.3 Procedure for complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher**

In the informed consent documentation, clear reference is made to either the researcher or the applicable HREC or AnimCare secretariat that should be contacted if a research participant has any queries or complaints regarding either the research conduct or the researcher.

Likewise, a complaint can be lodged by a co-researcher, research assistant, or interested community member about the research conducted itself and/or the researcher.

These complaints should be received in the form of a written letter, e-mail or phone call. It should be clear on the nature of the complaint and providing the necessary facts. When such a complaint is received, the Head of the Ethics Office should be contacted immediately and a plan of action devised in agreement with the Chair of the HREC or AnimCare.

The minimum plan of action should include:

1. Immediately making contact with the complainant via telephone (preferred if available) plus e-mail if available (to have key deliberations on record).
2. If possible, an immediate meeting should be set up with the complainant.
3. The researcher is contacted immediately and requested to supply the Head of the Ethics Office and the Chair with a written report.

A separate meeting is set up between the Head of the Ethics Office, the Chair of the applicable Ethics Committee and the researcher.

The outcome of the two meetings (one with the complainant and one with the researcher) will inform the necessity of a further meeting as soon as possible where the researcher, the complainant, the Head of the Ethics Office and the Chair of the applicable ethics committee will finalise the complaint.

Should this not be achievable, a final meeting between all parties mentioned previously, as well as the Deputy Dean Research and Innovations and the Director of the applicable research entity, will be called as soon as possible in an attempt to find an amicable solution.

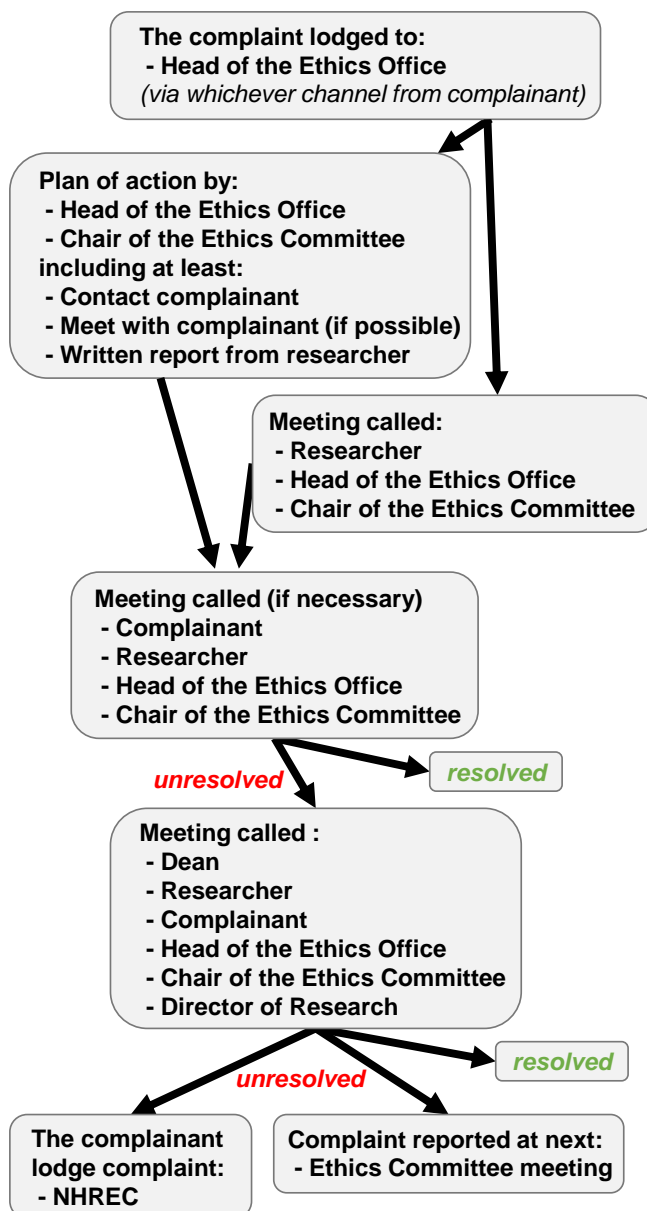
A detailed written report of the aforementioned processes and outcomes will be compiled by the involved persons (head of the Ethics Office or chairperson of the applicable REC) and circulated for correctness and fairness. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

The complainant shall be advised about his/her right to contact the NHREC. The procedure is available on the webpage of the NHREC and all necessary contact information shall be provided to the complainant.

The complaint and outcome will be reported during the following HREC/AnimCare meeting.

**Flow diagram 3: Procedure for complaints about research conduct**



## 9 REFERENCE DOCUMENTS

Guideline for the Management of Complaints, Complaints and Advisory Disciplinary Committee (CADC), NHREC, February 2015.

## 10 ADDENDA

No	Document name
	None

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