Faculty of Health Sciences

ETHICS OFFICE		Standard Operating Procedure	
Title	SOP for research ethics complaints management		
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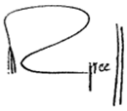
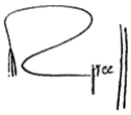
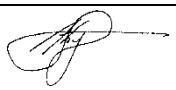
Date of approval	6 June 2018 Revised version November 2021	**Revision date**	Nov 2024
Web address	http://health-sciences.nwu.ac.za/healthethics	**Page no**	Page 1 to 9

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		30 Aug 2016 6 June 2018 5 November 2021
Checked by:	NWU-HREC		8 Sept 2016
	NWU-AnimCareREC		8 Sept 2016
	Ethics Office		8 Sept 2016
	Faculty Board		9 Nov 2016
Authorised by:	Prof Wayne Towers as Head of the Ethics Office		9 Nov 2016 6 June 2018 15 November 2021

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof Wayne Towers		10 Nov 2016 6 June 2018 15 Nov 2021
Faculty of Health Sciences	Ms Carolien van Zyl		10 Nov 2016 6 June 2018 15 Nov 2021

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2015	1	Formulated the SOP
6 June 2018	2	Change in university structure
5 Nov 2021	3	Changed Integrated Research Integrity Management System (IRIMS) for the Faculty of Health Sciences

4 PURPOSE OF THE SOP

This SOP provides guidelines for the management of two types of research ethics-related complaints:

1. Complaints from researchers about a member of the NWU-HREC/NWU-AnimCareREC or the NWU-HREC/NWU-AnimCareREC itself during the research ethics application or monitoring process.
2. Complaints from a member of the NWU-HREC/NWU-AnimCareREC or the NWU-HREC/NWU-AnimCareREC itself about a researcher related to research ethics during the ethics application or monitoring process.

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 and the IRIMS of the Faculty of Health Sciences. The Chair of an Ethics Committee in collaboration with the Deputy Dean: Research and Innovation (DD: R&I) and the Head of the Ethics office retains the right to immediately suspend or terminate any research study that violates National or Institutional Regulations.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-HREC	North-West University Health Research Ethics Committee
NWU-AnimCareREC	North-West University Animal Care, Health and Safety in Research Ethics Committee
REC	Research Ethics Committee
NWU	North-West University

DD: R&I	Deputy Dean: Research and innovation
RIO	Research Integrity Officer
IRIMS	Integrated Research Integrity Management System
FHS	Faculty of Health Sciences
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
Research Ethics	Research ethics is the set of rules that govern the norms and standards of conduct for researchers on how research is performed and how it is disseminated (Wallace & Sheldon, 2015:272, Greenwood, 2016:514).
Research Integrity	The active adherence to specific research integrity principles and responsibilities that becomes visible in Responsible Conduct of Research (RCR).
Responsible Conduct of Research (RCR)	The act of making research integrity visible and refers to the practice of scientific investigation with *responsibility and integrity* through an awareness and application of established *ethical principles, professional research norms and standards, research integrity principles and responsibilities* in the performance of all activities related to the research.
Breach in Research Integrity	The finding of a *formal intra-faculty research integrity assessment* (research non-compliance, and/or violation of good research practice) or *preliminary intra-faculty research integrity investigation* (fabrication, falsification, or plagiarism) that a researcher has transgressed/potentially transgressed in responsible conduct of research based on the mentioned acts.

7 RESPONSIBILITIES

This SOP provides guidelines for RECs, a REC member, and researcher on how to handle any dissatisfaction related to research ethics-related activities during the research ethics application or monitoring process.

8 PROCEDURE(S)

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

Should a researcher / postgraduate student experience a problem with a specific NWU-HREC/NWU-AnimCareREC member's behaviour or the NWU-HREC/NWU-AnimCareREC itself regarding meeting procedures, application management, monitoring 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 (Wayne.Towers@nwu.ac.za) well as the chair of the applicable ethics committee (NWU-HREC (Petra.Bester@nwu.ac.za) or NWU-AnimCareREC (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:

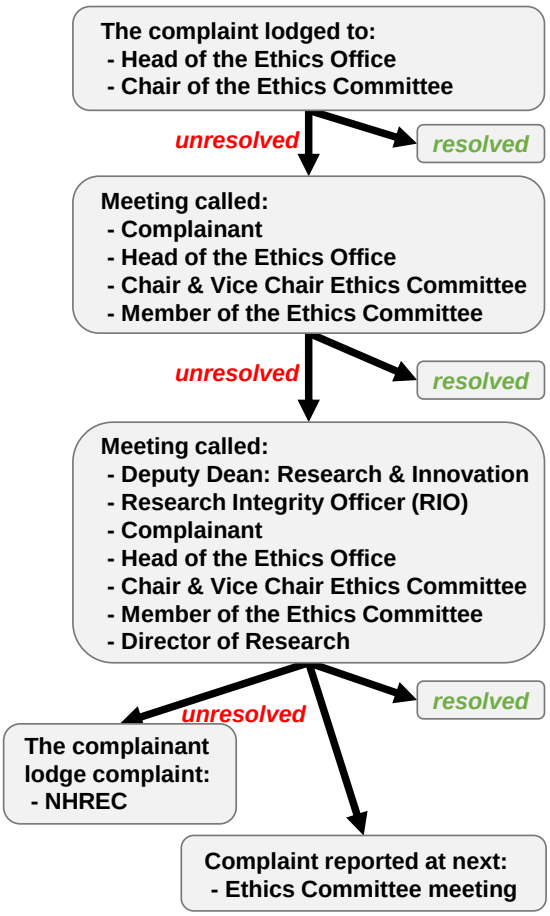
A meeting will be called as soon as possible with the complainant, the DD: R&I, the Research Integrity Officer (RIO), the Head of the Ethics Office, the Chair and the Vice-Chair of the applicable ethics committee, the member and the Director of the applicable research entity to discuss the complaint 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 NWU-HREC/NWU-AnimCareREC meeting.

Flow diagram 1: Procedure for complaints from researchers



8.2 Complaints from a member of NWU-HREC/NWU-AnimCareREC or NWU-HREC/NWU-AnimCareREC about a researcher

Should a member of the NWU-HREC or NWU-AnimCareREC or the NWU-HREC/NWU-AnimCareREC itself experience a problem with a specific researcher's behaviour or research actions related to research ethics during the research ethics application or monitoring process, they have the opportunity to lodge a complaint.

The complaint should be lodged in writing to the Head of the Ethics Office (Wayne.Towers@nwu.ac.za) as well as the chair of the applicable ethics committee (NWU-HREC (Petra.Bester@nwu.ac.za) or NWU-AnimCareREC (Tiaan.Brink@nwu.ac.za)).

Such a written complaint will initiate the following process:

A meeting will immediately be called with the complainant, 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 researcher, the Head of the Ethics Office, and the Chair and the Vice-Chair of the applicable ethics committee 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 DD: R&I, RIO, 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 NWU-HREC/NWU-AnimCareREC 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 ethics conduct and/or the researcher

Complaints received from a research participant, co-researcher, or research assistant about research ethics-related conduct and/or the researcher should be channelled through the IRIMS. Care should be taken not to handle any IRIMS matters that relate to a potential breach in research integrity through the acts of 1) research non-compliance, and/or 2) violation of good research practice, or 3) research misconduct, via the aforementioned process.

In the informed consent documentation, clear reference is made to either the researcher or the applicable NWU-HREC or NWU-AnimCareREC secretariat that should be contacted if a research participant has any queries or complaints regarding either the research ethics conduct or the researcher. Should the Head of the Ethics office receive such a complaint it should be channelled through the IRIMS of the FHS.

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 facilitated with the DD: R&I and RIO and the complainant and processed within the IRIMS.

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 should all internal processes fail. 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 NWU-HREC/NWU-AnimCareREC meeting as the final point of closure.

9 REFERENCE DOCUMENTS

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

Guidelines for the Integrated research Integrity Management System of the Faculty of Health Sciences, February 2021.

10 ADDENDA

No	Document name
	None

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