Faculty of Health Sciences

ETHICS OFFICE	Standard Operating Procedure		
Title	SOP for monitoring and amendment of approved research studies		
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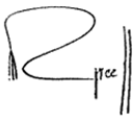
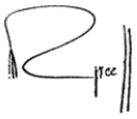
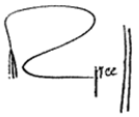
Web address	http://health-sciences.nwu.ac.za/healthethics	**Page no**	Page 1 to 6

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		6 Sept 2016 6 June 2018
Checked by:	Ethics Office		9 Sept 2016
	HREC		9 Sept 2016
	AnimCare		9 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
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
On behalf of the Ethics Office	Prof Minrie Greeff		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 2016	1	Formulated the SOP
6 June 2018	2	Change in university structure

4 PURPOSE OF THE SOP

The purpose of this SOP is to provide researchers, the Faculty of Health Sciences Ethics Office, and Research Ethics Committees (RECs) with guidelines on the monitoring of approved studies and amendments. RECs refer to the Health Research Ethics Committee (HREC) and the Ethics Committee on Animal Care, Health and Safety in Research (AnimCare).

5 SCOPE

5.1. Monitoring

RECs have the right to monitor the research they approve. The National Health Research Ethics Council (NHREC) sees this monitoring role of RECs as very important. The South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008) also makes specific reference to monitoring.

RECs may recommend and adopt any *additional appropriate mechanism* for monitoring, including:

- random (announced and unannounced) inspection of research sites;
- monitoring of data and signed informed consent documentation;
- monitoring of recorded individual interviews/focus groups;
- inspection to verify that experimenters adhere to SOPs and other approved experimental procedures;
- inspection of the scoring of welfare monitoring sheets (animals);
- ensuring that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals (SANS 10386:2008 section 5.2.7).

The frequency and type of monitoring should reflect the *degree* and the *extent* of risk of harm to participants or animals.

Researchers should provide comprehensive and appropriate information to the REC to facilitate the monitoring process.

Informed consent documentation should indicate to participants that such monitoring may take place during the research process.

5.2. Amendments

Researchers should inform and obtain approval of RECs for *any* amendment to a proposal, informed consent documentation or other documentation before implementation thereof.

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
NHREC	National Health Research Ethics Council
IRERC	Institutional Research Ethics Regulatory Committee
Monitoring	The process of ensuring that research conduct runs according to the REC-approved proposal by submitting and reviewing monitoring reports. It is also a system of granting researchers permission to continue with their research for a *further year*.
Passive monitoring	The submission of a monitoring report to the REC as set out as terms during the review process. *For HREC:* • Minimal risk studies – annual report. • Medium risk studies – six-monthly reports. • High risk studies – three-monthly reports. **or for children and adults incapable of giving consent:** • No more than minimal risk of harm – annual report. • Greater than minimal risk but provides the prospect of direct benefit/high probability of providing significant generalisable knowledge – six-monthly report. • At the end of a study. *For AnimCare:* • For category 0 to 5 studies as indicated or on a case-by-case basis. • At the end of a study. The review of this monitoring report by the REC followed by permission granted to continue the study for a further year.
Active monitoring	Any additional appropriate mechanism for monitoring during the research conduct that the REC deems necessary: • random inspection of research sites; • monitoring of data and signed informed consent documentation; • monitoring of recorded individual interviews/focus groups;

	• inspection to verify that experimenters adhere to SOPs and other approved experimental procedures; • inspection of the scoring of welfare monitoring sheets (animals).
Amendment	Any change to the proposal, informed consent documentation or other documents while the research is in progress. REC approval prior to implementation of such changes is essential. Changes could be minor or extensive in nature: • Minor changes refer to e.g. sample size, community entry etc. • Extensive changes refer to a change in the total methodology e.g. changing from individual interview to focus groups, from treadmill to captured swim test.

7 RESPONSIBILITIES

7.1. REC responsibilities

RECs should request regular, *at least annual*, reports from researchers on matters including but not limited to:

- progress to date, or outcome in the case of completed research;
- current enrolment numbers;
- whether participant follow-up is still active or completed;
- information concerning maintenance and security of records;
- evidence of compliance with the approved proposal;
- evidence of compliance with any conditions of approval;
- list of adverse events in the past 12 months;
- list of amendments made in the past 12 months;
- list of sub-studies (if applicable).

RECs should inform researchers *in writing* of concerns arising from such monitoring activities or request clarification if uncertainties arise (see monitoring feedback letter).

RECs should grant researchers *written permission* to continue with their studies for a further year (see monitoring feedback letter). The due date of the next monitoring report should be indicated clearly on the monitoring feedback letter.

7.2. Researcher's responsibilities

Researchers should provide RECs with detailed monitoring reports (comprehensive and appropriate information) for all studies approved by the REC on the dates indicated to researchers during the approval process.

Note: Monitoring reports should be provided for all REC approved studies of researchers and postgraduate students, which includes sub-studies.

Researchers should inform RECs of any *incidents/adverse events* that occur during the research process (2.2.4_SOP_Ethics_1.3).

Researchers should request *amendments* to the proposal, informed consent documentation or other documentation before changes are implemented (2.2.4_SOP_Ethics_1.4).

8 PROCEDURE(S)

8.1. Monitoring

The Faculty of Health Sciences Ethics Office keeps a database of all *active research studies* in the Faculty of Health Sciences, as well as other Faculties to whom they have granted ethics approval.

Note: Studies are granted a *one-year approval only*. This date is clearly indicated on the ethics approval letter.

Two months before a study's approval expires the administrator responsible for monitoring in the Faculty of Health Science Ethics Office sends a reminder to the researcher and attaches a copy of a monitoring report (see attached) to be completed within *one week* of receiving the reminder. The latter is to ensure that permission to continue can be processed within a six-week period as well as ratified during a REC meeting. If a study ends the researcher submits a final monitoring report to the Ethics Office.

The researcher completes the monitoring report and sends it to the administrator at: Ethics-HRECMonitoring@nwu.ac.za for HREC monitoring reports and Ethics-AnimMonitoring@nwu.ac.za for AnimCare monitoring reports

The administrator forwards the monitoring report to the chairperson for his/her decision, upon which two REC members will act as independent reviewers.

The chairperson sends the reviewer names to the administrator.

The administrator sends the completed monitoring reports to the allocated REC members for review. They then have three working days to review the report and return their comments to the administrator.

The administrator compiles an integrated report from the two reviews for the chairperson who then reviews the feedback and notifies the administrator of the final decision.

The administrator sends a monitoring feedback letter to the researcher indicating that the study:

- needs clarification on certain aspects;
- is suspended until certain aspects are clarified or corrected;
- is terminated on request of the researcher or the REC;
- is completed;
- can continue for a further year (indicating the date of when the next monitoring report is due).

If *clarification, suspension* or *termination* is the option chosen, this process is handled by the chairperson and the administrator:

- Clarification - the administrator sends a monitoring feedback letter to the researcher indicating which aspects need clarification. The researcher has to provide the administrator with the requested clarification for the chairperson's perusal. Once resolved the study can continue.
- Suspension (temporary stoppage) - the researcher is notified by the chairperson that the research is temporarily suspended. An urgent meeting is called with the Executive Committee of the REC and the researcher to discuss the concerns of the REC and to find immediate solutions. The REC can make recommendations or impose specific conditions. Once resolved the study can continue (see 8.2).
- Termination (permanent stoppage) - if the researcher requested the termination of the study the monitoring feedback letter will confirm this. If the REC terminates the study, this is done after due process has been followed (see 8.2).

The decisions are ratified during the next REC meeting.

8.2. Suspension or termination of studies

Where circumstances indicate that a project is non-compliant with the approved proposal and interest of the participants are at risk of harm or impact on animal wellbeing exceeds what has been approved or can be justified, the REC may withdraw approval, after due process has been followed (see 8.1).

A clear process should be followed that permits swift but proper investigation and decision-making to ensure protection of participants. This should include interaction with the researcher and other interested parties to ensure a fair and transparent process.

If a decision is to withdraw approval, the REC should inform the researcher and other interested parties, including the IRERC (see 8.1).

It should also recommend *remedial actions* where appropriate.

In the case of suspension, the researcher should comply with the recommendations and/or conditions imposed by the REC.

8.3. Amendments

RECs require that researchers immediately report anything that might warrant *reconsideration of ethical approval* of the proposal, informed consent documentation or other documentation including but not limited to:

- serious or unexpected adverse effects on participants (2.2.4_SOP_Ethics_1.3);
- proposed changes to the proposal (2.2.4_SOP_Ethics_1.4);
- proposed changes to the informed consent documentation;
- proposed changes to the monitoring sheets of animal wellbeing;
- unforeseen events that might affect continued ethical acceptability of the project.

Researchers must seek approval for the amendment (2.2.4_SOP_Ethics_1.4 – Amendment application process) at Ethics-HRECApply@nwu.ac.za (for studies with human participants) or Ethics-AnimCare@nwu.ac.za (for studies using animals) *before the change can be implemented* and the study continues.

Note: If the nature of the amendment is *extensive*, prior approval of the Scientific Committee must first be sought and proof provided to the REC during the application for the amendment process.

As soon as the REC receives a request for an amendment, the administrator sends the request through to the chairperson of the appropriate REC.

The chairperson handles it through the *expedited review process (unless amendments are significant and require full committee approval)* by allocating it to two reviewers who have three working days to give their feedback of the review.

The administrator sends the amendment request to the reviewers and on receipt sends their reviews to the chairperson who makes the final decision to approve the request.

The decision is ratified during the following REC meeting.

9 REFERENCE DOCUMENTS

- 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).
- The Rules for the Management of research ethics at the North-West University, 2016.

10 ADDENDA

No	Document name
1	Monitoring report
2	Monitoring feedback letter
3	2.2.4_SOP_Ethics_1.3
4	2.2.4_SOP_Ethics_1.4

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