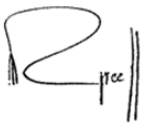
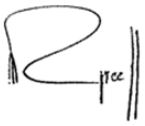
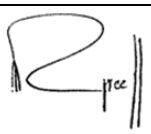
NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

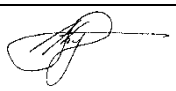
## Faculty of Health Sciences

| ETHICS OFFICE | | Standard Operating Procedure | |
|---|---|---|---|
| **Title** | SOP for the expedited review process | | |
| **SOP no** | SOP_Ethics_1.7 | **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 |  | 9 Sept 2016 |
| Checked by: | Ethics Office |  | 14 Sept 2016 |
| | HREC |  | 14 Sept 2016 |
| | AnimCare | | 14 Sept 2016 |
| | Faculty Board |  | 9 Nov 2016 |
| Authorised by: | Prof Minrie Greeff as Head of the Ethics Office |  | 9 Nov 2016 |

## 2 DISTRIBUTION

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

## 3 DOCUMENT HISTORY

| Date | Version no | Reason for revision |
|---|---|---|
| 9 Nov 2016 | 1 | Formulated the SOP |
| | | |
| | | |

## 4 PURPOSE OF THE SOP

The purpose of the SOP is to provide researchers, the Faculty of Health Sciences Ethics Office and RECs guidelines for the management of expedited reviews, as well as for the decision-making processes during this type of review.

## 5 SCOPE

5.1. The NHREC permits RECs to establish procedures for expedited reviews under *two circumstances*:

- only in certain research studies where research activities pose no more than *minimal risk* to human participants or category 0 studies for animals;
- during *major incidents* where planning of the research and ethics clearance processes must usually occur rapidly.

5.2. The *nature* of these reviews refers to:

- prospective collections of *only* biological specimens for research purposes by non-invasive means, e.g. hair or nail clippings, excreta and external secretions (including sweat), cannulated saliva, mucosal and skin cells collected by buccal scraping or swab, skin swab, mouth washing, or human sperm;
- *only* weighing or testing sensory acuity;
- amendment requests of limited extent;

- aspects of the study that can only be approved as the research progresses, e.g. instruments, interview schedules, etc. and that were set out as conditions during the approval;
- transfer of samples for analysis;
- systematic, rapid or critical reviews should they require ethics approval;
- major incidents where resources are constrained, so that responding urgently and appropriately is difficult and planning and ethics clearance must occur rapidly with the time for deliberation curtailed;
- collection and use of fresh or archived biological specimens of vertebrate or higher invertebrate animals already euthanized in a legally and ethically sound manner, or non-invasive behavioural (e.g. *in situ* observation) studies, or routine-care interventions on domestic and farm animals on home property, provided that a review by the full animal research ethics committee may be ordered if the former is unclear.

5.3. *Other types of studies* that normally do not need ethical clearance but where the researcher wants an ethics number for publication purposes:

- research that relies exclusively on publicly available information or that is accessible through legislation or regulation. This does not mean that ethical considerations are irrelevant to the research;
- research involving observation of people in public spaces and natural environments, provided:
    - the researcher does not interact directly with individual groups;
    - the researcher does not stage any intervention;
    - the individuals or groups do not have a reasonable expectation of privacy;
    - dissemination of research findings does not identify any individual or groups.
- research that relies exclusively on secondary use of anonymous (non-identifiable) human biological materials;
- quality assurance and quality improvement studies, programme evaluation activities and performance reviews not intended for publication. Should publication be envisaged, ethics approval should be obtained before the activity as RECs cannot grant retrospective ethics approval;
- research on lower invertebrate animals that requires notification to the animal research ethics committee.

## 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 |
| NWU | North-West University |
| Expedited review | An expedited review process consists of a faster review (two weeks) of a research-related request through the process of the chairperson of the REC allocating two REC members for this fast track review. The request is approved and only ratified during the next REC meeting. See 5 for a description of the scope. |
| Full review | A full review process consists of a more extensive, time consuming review done before a REC meeting by a minimum of two REC members allocated to this task by the chairperson of the REC, but deliberated on in a face-to-face manner during a full sitting of a REC meeting. REC members are encouraged to be independent, objective and informed during their assessment and to act without fear or favour in their scientific and ethical reviews. An engaging decision-making process about the application ensures that decisions move from aggregate, debate to consensus. Voting only takes place if it is impossible to reach consensus.<br>A review of this nature ensures:<br>• protection of participants from harm;<br>• protecting the safety and welfare of animals; |

| | |
|---|---|
| | • holding researchers accountable;<br>• promotion of important social and ethical values. |
| Minimal risk | Where the probability and magnitude of possible harms implied by participation are no greater than those posed by daily life in a stable society. |
| Major incident | Refers to major incidents were resources are so constrained, that responding urgently and appropriately is difficult, e.g. natural or man-made – such as floods, tornados, earthquakes, outbreak of deadly disease, deadly contamination of water resources, political violence and armed conflict with resultant injuries to humans. The planning of the research and ethics clearance processes must usually occur rapidly and the time for deliberation curtailed. |
| | |

# 7 RESPONSIBILITIES

## 7.1. Of researchers:

Researchers should ensure that they include the correct documentation and follow the correct processes as not to hold up the expedited process.

## 7.2. Of RECs:

RECs must have effective procedures in place and facilitate a rapid decision-making process that reflects the nature of an expedited process.

# 8 PROCEDURE(S)

The procedures will vary depending on *what* is being requested to be expedited.

It could be:

- amendments (see SOP_Ethics_1.4 8.4);
- seeking approval for aspects as the study progress (an explanatory cover letter and the needed document);
- transfer of samples (an explanatory cover letter and the needed transfer agreements and permits);
- a systematic review (see SOP_Ethics_1.4 8.3); or
- a full review in the case of major incident research (see SOP_Ethics_1.4 8.1).

Specific requirements:

- The standard of informed consent applies regardless of the type of review.
- An expedited review may not lead to outright disapproval/rejection of the proposal. It may only be disapproved after being referred to a full convened REC meeting.

## 8.1. Expedited processes for minimal risk studies

***Process:***

Decide what it is that you want to request to be expedited.

Develop the necessary documentation as required by the request.

Formulate a clear and systematic cover letter guiding the REC.

Clearly indicate:

- the title of the research
- the researcher(s)

- what it is that is being requested
- if changes were made the nature thereof and where it was made
- which documents are attached to the application, and
- add any explanation to clarify your application

Submit the application either to the:

- AnimCare administration for research involving animals (Ethics-AnimCare@nwu.ac.za) or
- HREC administration for research involving humans (Ethics-HRECApply@nwu.ac.za).

Attach all the required documents separately to the e-mail.

The chairperson allocates the review to a minimum of two reviewers and notifies the administrator.

The application is sent by administration (within *two days*) to two or three independent reviewers who have *three working days* for review.

As soon as the reviewer reports are received, the chairperson of the REC makes a consolidated response and forwards it to the administrator.

A formal letter of decision of the REC with feedback is sent to the applicant (always the supervisor or PI) as soon as possible (approximately *three working days*) after the decision.

If corrections are needed, they are done by the applicant and sent back to either:

- the AnimCare administration for research involving animals (Ethics-AnimCare@nwu.ac.za) or
- the HREC administration for research involving humans (note that the corresponding person for HREC now changes to Ethics-HRECProcess@nwu.ac.za).

A rebuttal letter should be included indicating *what*, *how* and *where* in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well).

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (*three working days*).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicants to either:

- the AnimCare administration for research involving animals (Ethics-AnimCare@nwu.ac.za) or
- the HREC administration for research involving humans (note that the corresponding person for the HREC remains Ethics-HRECProcess@nwu.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher(s) by either:

- the AnimCare administration for research involving animals (Ethics-AnimCare@nwu.ac.za) or
- the HREC administration for research involving humans (Ethics-HRECApply@nwu.ac.za).

Research can start or continue according to the approved application.

The decision is ratified during the next REC meeting.

### 8.2. Expedited process for major incidents

In order to carry out research in this context, planning of the research and ethics clearance processes must usually occur rapidly and expedited approval sought.

When the research is actually dependent on the context of a major incident, the proposal should be approached cautiously. Major incident research should take place with regard to matters that are unlikely to occur in “ordinary” contexts.

RECs should consider carefully whether sufficient justification is presented for expedited processing.

Informed consent usually has to be obtained rapidly and in a time when vulnerability of participants is likely to be extreme. Participants may be incapacitated, e.g. unconscious or on a ventilator, which points to difficulties with the usual approach to informed consent. RECs may need to consider alternative approaches such as proxy consent or delayed consent in particular circumstances.

Note: All actions and documentation as explained in SOP_Ethics_1.4 8.1 must be followed. However, the process of review will be shortened as discussed in 8.1 of this SOP.

## 9 REFERENCE DOCUMENTS

- Regulations Relating to Research with Human Participants, 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).
- The Rules for the Management of Research Ethics at the North-West University, 2016.

## 10 ADDENDA

| No | Document name |
|---|---|
| 1 | SOP_Ethics_1.9 |
| 2 | SOP_Ethics_1.4 |
| | |