







NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).



North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Office (NWU-EMELTEN-REO)		Standard Operating Procedure	
Title	SOP for the expedited review process		
SOP no	SOP_EMELTEN_Ethics_1.7	Version no	3
Date of approval	22 September 2017	Revision date	22 September 2021
Email address	Ethics-EMELTEN@nwu.ac.za	Page no	Page 1 to 6

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by: Prof Minrie Greeff and amended by Prof Lukas Meyer	Prof Lukas Meyer		6 December 2016
Revised and Checked by:	NWU-EMELTEN-REO: Prof Lukas Meyer		1 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		9 March 2020
	Faculty Board: Faculty of Education Chair: Prof Lloyd Conley		15 April 2020
	SCRE Chair:		27 August 2020
Authorised by:	Chair of NWU-EMELTEN-REC: Prof Lukas Meyer		28 August 2020

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2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		28 August 2020
Deputy Dean: Research and Innovation			
NWU-EMELTEN-REC Administrator	Mrs Villera le Roux		31 August 2020

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 November 2016	1	Formulated the SOP
7 May 2018	2	Changing old NWU Logo to new NWU Logo
1 December 2018	3	Changing committee's name EMHS-REC to NWU-EMELTEN-REC
4 September 2019	4	Revision of document

4 PURPOSE OF THE SOP

The purpose of the SOP is to provide researchers, the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee Office (NWU-EMELTEN-REC) and the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) with 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;
- 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:

- 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;
- 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;

- 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.
 - 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;

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Research Ethics Office
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 NWU-EMELTEN-REC allocating two NWU-EMELTEN-REC members for this fast track review. The request is approved and only ratified during the next NWU-EMELTEN-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 an NWU-EMELTEN-REC meeting by a minimum of two NWU-EMELTEN-REC members allocated to this task by the chairperson of the NWU-EMELTEN-REC, but deliberated on in a face-to-face manner during a full sitting of a NWU-EMELTEN-REC meeting. NWU-EMELTEN-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. A review of this nature ensures: <ul style="list-style-type: none"> • protection of participants from harm; • protecting the safety and welfare of human; • holding researchers accountable; • 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 where 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 NWU-EMELTEN-REC:

NWU-EMELTEN-REC 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); 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 NWU-EMELTEN-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 NWU-EMELTEN-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:

- NWU-EMELTEN-REC administration for research involving humans (Ethics-EMELTEN-apply@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 NWU-EMELTEN-REC makes a consolidated response and forwards it to the administrator.



A formal letter of decision of the NWU-EMELTEN-REC with feedback is sent to the applicant (always the study-leader 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 NWU-EMELTEN-REC administration for research involving humans (note that the corresponding person for NWU-EMELTEN-REC now changes to Ethics-EMELTEN-process@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:

- The NWU-EMELTEN-REC administration for research involving humans (note that the corresponding person for the NWU-EMELTEN-REC remains Ethics-EMELTEN-process@nwu.ac.za during this reviewing process).



If approved a letter of approval is sent to the researcher/s by:

- the NWU-EMELTEN-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za).



Research can start or continue according to the approved application.



The decision is ratified during the next NWU-EMELTEN-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 likely to or do not occur in “ordinary” contexts.

NWU-EMELTEN-REC 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. Note: All actions and documentation as explained in SOP_EMELTEN-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).
- The Rules for the Management of Research Ethics at the North-West University, 2018.

10 ADDENDA

No	Document name