

FACULTY OF HUMANITIES




Standard Operating Procedure: SOP_HSSREC_2.6

SOP for the expedited review process


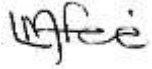

Faculty of Humanities

Standard Operating Procedure			
Title	SOP for the expedited review process		
SOP No	SOP_HSSREC_2.6	Version No	2
Date of approval		Next Revision date	April 2023
Web address		Page No	

1. COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Revised by:	Prof. C. van Eeden		7 April 2021
Checked by:	Prof. J. Rothmann		22 April 2021
Authorised by:	Prof. M. Nel		28 Sep. 21

2. DISTRIBUTION

Department/Unit	Name	Signature	Date
HSSREC	Prof. M. Heyns		27/4/21
Faculty of Humanities: Faculty Board	Prof. LM Fourie		29 Sept 2021
Committee for Research, Innovation and Higher Degrees	Prof. M. Nel		28 Sep. 21

3. DOCUMENT HISTORY

Date	Version No	Reason for revision
12 March 2018	1	Revision of 2015 SOP in line with NHREC audit of 30 November 2017. Based on the SOP of the NWU: HREC.
27 April 2021	2	Revision of 2018 SOP in line with NHREC requirements. Based on the SOP of the NWU: HSSREC: 2018.
29 October 2021	3	Final approval of HSSREC SOP documentation by Faculty Board and Deputy Dean Research and Innovation, Faculty of Humanities.

4. PURPOSE OF THE SOP

The purpose of the SOP is to provide researchers, the Faculty of Humanities and the Human Social

Sciences Research Ethics Committee 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 conditions*:

- 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. questionnaires, interview schedules, etc. and that were set out as conditions during the approval;
- transfer of data for analysis;
- systematic, rapid or critical reviews should these require ethics approval;
- major incidents where resources are constrained, i.e. necessitating rapid, yet appropriate planning and ethics clearance of said study with the time for deliberation curtailed;
- collection and use of new/additional data.

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) data;
- 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 HSSREC cannot grant retrospective ethics approval.

6. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
REC	Research Ethics Committee
HSSREC	Human Social Sciences Research Ethics Committee

NWU	North-West University
SCRE	Senate Committee for Research Ethics
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 HSSREC allocating two HSSREC members for this fast track review. The request is approved and only ratified during the next HSSREC 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 the HSSREC meeting, by a minimum of two HSSREC members allocated to this task by the chairperson of the HSSREC, but deliberated on in a face-to-face manner during a full sitting of the HSSREC meeting. HSSREC members are encouraged to be independent, objective and informed during their assessment and to act without fear of favour in their scientific and ethical reviews. An engaging decision-making process about the application ensures that the decisions move from aggregate, debate to consensus. A review of this nature ensures: <ul style="list-style-type: none"> ○ Protection of participants from harm; ○ Protection of the researcher. ○ Holding researchers accountable ○ Promotion of important social and ethical values.
Minimal risk	Where the probability and magnitude of possible harm implied by participation are no greater than those posted 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 in 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 the HSSREC:

The HSSREC 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_HSSREC_2.4; 8.4);
 - seeking approval for aspects as the study progress (an explanatory cover letter and the needed document);
 - transfer of data (an explanatory cover letter and the needed transfer agreements and

permits).

- a systematic review (see SOP_HSSREC_2.4; 8.3); or
- a full review in the case of major incident research (see SOP_HSSREC_2.4; 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 HSSREC.

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 to the HSSREC administration.

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 HSSREC makes a consolidated

response and forwards it to the administrator.



A formal letter of decision of the HSSREC 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 the HSSREC administration.

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 HSSREC administration.



If approved, a letter of approval is sent to the researcher(s) by the HSSREC administration.



Research can start or continue according to the approved application.



The decision is ratified during the next HSSREC 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.

The HSSREC 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, which points to difficulties with the usual approach to informed consent. The HSSREC 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_HSSREC_2.4; 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).
- Research Ethics Policy and Terms of Reference for the Management of Research Ethics at the North-West University (2018).
- Standard Operating Procedures of the HREC: NWU.

10 ADDENDA

No	Document name
None.	None.