University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR EXPEDITED REVIEW PROCESS

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. PURPOSE OF THE SOP

To provide researchers, the Ethics Office and UFH HREC guidelines for managing expedited reviews and the decision-making processes for expedited reviews.

3. SCOPE

The NHREC permits the UFH HREC 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 the planning of the research and ethics clearance processes must usually occur rapidly.

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 was 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;

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 group.
- research that relies exclusively on the secondary use of anonymous (non-identifiable) human biological materials;
- quality assurance and quality improvement studies, programmes evaluation activities, and performance reviews not intended for publication. Should publication be envisaged, ethics approval should be obtained before the activity as UFH HREC cannot grant retrospective ethics approval.

4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/Definition	Description
REC	Research Ethics Committee
UFH HREC	University of Fort Hare Human Research Ethics Committee
NHREC	National Health Research Ethics Council
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 UFH HREC allocating two members for this fast-track review. The request is approved and only ratified during the next UFH HREC 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 UFH HREC meeting by a minimum of two UFH HREC members allocated to this task by the chairperson of the UFH HREC, but deliberated on in a face-to-face manner during a full sitting of a UFH HREC meeting. UFH HREC 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 a consensus. A review of this nature ensures the protection of participants from harm; holds researchers accountable; promoting 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, or earthquakes. Others include the outbreak of deadly disease, deadly contamination of water resources, political violence, and armed conflict resulting in injuries to humans. The planning of the research and ethics clearance processes must usually occur rapidly, and the time for deliberation is curtailed.

5. RESPONSIBILITIES

5.1 Researchers

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

5.2 UFH HREC

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

6. PROCEDURE(S)

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

- amendments (see UFH HREC SOP 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 UFH HREC SOP 4); or
- a full review in the case of major incident research (UFH HREC SOP 4).

6.1 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 fully convened UFH HREC meeting.

7. 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 UFH HREC. 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:
UFH HREC administration (Ethics-HRECApply@ufh.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 *five days*) to two independent reviewers who have *five working days* for review.

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

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

If corrections are needed, they are done by the applicant and sent back to either the UFH HREC administration for research involving humans (note that the corresponding person for UFH HREC now changes to Ethics-HRECProcess@ufh.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 UFH HREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (*five 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 UFH HREC administration for research involving humans (note that the corresponding person for the UFH HREC remains Ethics-HRECProcess@ufh.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher(s) by either:
the HREC administration for research involving humans(Ethics-HRECApply@ufh.ac.za).

Research can start or continue according to the approved application.

The decision is ratified during the next UFH HREC meeting.

8. EXPEDITED PROCESS FOR MAJOR INCIDENTS

In this context, planning of the research and ethics clearance processes must usually occur rapidly, and expedited approval sought. When the research is dependent on the context of a major incident, the proposal should be approached cautiously. Major incident research should take place concerning matters that are unlikely to occur in "ordinary" contexts. UFH HREC should consider carefully whether sufficient justification is presented for expedited processing.

Informed consent usually has to be obtained rapidly and when the 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. UFH HREC may need to consider alternative ways such as proxy consent or delayed consent in particular circumstances.

Note: All actions and documentation as explained in UFH HREC SOP 4 must be followed.

However, the review process will be shortened, as discussed in UFH HREC SOP 4.

9. REFERENCE DOCUMENTS

The UFH HREC adopts as its guiding reference the following documents:

- The National Health Act, No. 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The Declaration of Helsinki, 2013.
- The Belmont Report, 1979.
- The Singapore Statement on Research Integrity, 2010.
- The Code of Federal Regulations of the USA (Title 45 Part 46).
- The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP), 1997.
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- The Rules for the Management of Research Ethics at the University of South Africa, 2016.
- The Rules for the Management of Research Ethics at the University of Cape Town, 2015.