Faculty of Health Sciences **Research Ethics Committee**

Standard Operating Procedure: Rapid Review and Approvals

1. Purpose

The purpose of the SOP is to define the circumstances and the conditions that apply for rapid review and approval of a research study or amendment, and the procedures by which approval is given for these. An rapid review is alternatively called an emergency review. This SOP should be distinguished from the SOP for expedited review and expedited approvals. This SOP was approved by resolution of the Faculty of Health Sciences Research Ethics Committee on 27 September 2023 and replaces all previous SOPs in this regard. It should be reviewed within 3 years after this date of approval.

_____Date: 27 September 2023

Signed by the Chairperson

2. Scope

The SOP is intended to inform and guide all researchers, members of the Research Ethics Committee, the Executive Management Committee, the Preliminary Subcommittee of the REC, and the REC in its deliberations. It should be interpreted alongside the Ethics Guidelines of the Department of Health (2015), guidelines 4.4.1, 3.2.4, 3.2.4.3, and 3.2.4.4. This SOP should also be interpreted with reference to the Terms of Reference of the REC and other SOPs that may be relevant.

Rapid review and approval apply only to emergency research or an emergency amendment to previously approved research. It applies thus to new research applications and amendments, and includes interventional and non-interventional research. An rapid review should be at least as thorough as would pertain ordinarily even though performed much quicker. It may be applicable to

studies in all risk categories. The benefit-risk-ratio should be high in cases of emergency submissions. A rapid review of an amendment is warranted in case participants' safety may be compromised if an rapid review and approval process are not followed.

3. Definitions and criteria

3.1 *Rapid research or study*: Rather than referring to an emergency setting or an emergency department, emergency research comprises research that should be conducted as a matter of urgency appropriate to an emergency.

3.2 *An emergency*: For purposes of this SOP, an emergency is a situation that poses an immediate risk to the health or lives of people, and for which urgent research is required to prevent a worsening of the situation, or reduce its negative impact. Examples are the emergence of an epidemic, or pandemic, or a natural disaster.

3.3 *Rapid amendment*: For the purposes of this SOP, an rapid amendment comprises an amendment that should be made to previously-approved research as a matter of urgency appropriate to an emergency, or when a delay in doing so may put research participants at risk of harm.

4. Responsibilities

Whether a study or amendment is suitable for rapid review is at the discretion of the chairperson and Executive Management Committee of the REC, guided by this SOP. Researchers are responsible for applying for an rapid review of an amendment in case participant safety may be compromised if review and approval are not done as an emergency as defined above.

5. Procedures

Applications will be submitted and reviewed in the usual manner unless an emergency as defined above pertains. In case of the latter, an ad hoc process will be initiated by the chairperson or a deputy chairperson and resulting rapid approval will be granted only after a quorate number of members voted for its approval. This voting may be at an quorate meeting or through e0mail correspondence.

The procedures are as follows:

1) The researcher will submit an application on the PeopleSoft e-platform and attach all documents related to the study.
2) The researcher will request by e-mail to the chairperson of the REC that a specific study be processed as rapid research.
3) Once an application is accepted for rapid review, the submission will be fast-tracked by the chairperson or a deputy-chairperson, assigning the study to REC members who are suitable for the review, with an option to obtain a review from or consult with an expert in the field who is not a member of the REC.

4) Reviews will be returned by reviewers in no more, and ideally less than four work days of requesting them to do the reviews.
5) Reviewer comments will be collated within 72 hours of receiving all reviewer comments and at the discretion of the Executive Management Committee, these may be sent to the researcher for responses and modifications.
6) The Executive Management Committee will consider the researcher's responses to the reviewers' comments within 72 hours of receiving these, and consult further with the reviewers should it consider this essential.
7) In deliberating about rapid applications, the Executive Management Committee may use any suitable media in their deliberations, including face-to-face meetings, e-mails, and e-conferencing. Written records should be maintained of the process and decisions.
8) Once comments by reviewers have been addressed satisfactorily in the view of the Executive Management Committee, voting by members of the REC will be obtained and collected during no less than a 24-hour period.
9) If a majority of votes from a quorate number of members support approval, the Executive Management Committee will issue an rapid approval certificate.
10) The study will be considered at the next quorate meeting of the REC for imposing further requirements or instructions upon the study.

The Executive Management Committee of the REC may approve a study as a rapid approval when all of the following criteria are met:

1) The study has been reviewed by four or more members of the REC;
2) The researcher has addressed all the comments raised by the REC members and the Executive Management Committee satisfactorily as judged by the Executive Management Committee; and
3) A majority of votes from a quorate number of REC members supports its approval.