Standard Operating Procedure: Expedited Review and Approvals

1. Purpose

The purpose of the SOP is to define the circumstances, the conditions and the procedures that apply for expedited review and approval of a research study, an amendment, annual renewals, and progress reports. 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 Preliminary Subcommittee of the REC, and the REC in its deliberations. It gives effect to the Ethics Guidelines of the Department of Health (2015), section 4.3.1, 4.5, and specifically section 4.5.1.5.1. This SOP should be interpreted within the Terms of Reference of the REC and other SOPs that may be relevant.

Expedited review and approval may apply to new research application, amendments, annual renewals, and progress reports. For new research and amendments, expedited review applies only when no more than

minimal risk is incurred by the study or the amendment. Expedited review shall not apply to any substantive submissions in relation to clinical trials or NIH funded research.

3. Definitions

3.1 Minimal risk research: the probability and magnitude of harm or discomfort anticipated in the research, is not greater, in and of itself, than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

4. Responsibilities

Whether a study or amendment is suitable for expedited review is at the discretion of the chairperson, a deputy chairperson or the Executive Management Subcommittee of the REC, guided by this SOP.

The FHS REC delegated to its Preliminary Subcommittee decision-making responsibility and authority to approve suitable research and amendments that qualify for expedited review and approval.

5. Procedures

Applications will be submitted and reviewed in the usual manner. Reviewer comments will be considered at the Preliminary Subcommittee meeting.

The Preliminary Subcommittee of the REC may approve **a study** as an expedited approval when all of the following criteria are met:

1) The study poses no more than minimal risk;
2) The study will use *only* pre-existing data, pre-existing specimens or biomaterials, commercial cell lines, or involve no more than *in vitro* procedures (e.g., retrospective chart reviews; secondary data research; bone collection research) or is an animal based study that has already received approval from the Animal Ethics Committee; or is a case study/series, and
3) No substantive issue has been raised by reviewers

The Preliminary Subcommittee of the REC may approve an **amendment** to a study as an expedited approval when all of the following criteria are met:

1) The amendment poses no more than minimal risk; and
2) No substantive issue has been raised by reviewers
3) The amendment does not relate to a clinical trial or NIH-funded research.

The Preliminary Subcommittee of the REC may approve an **annual renewal or progress report** of a study as an expedited approval when all of the following criteria are met:

1) The annual renewal or progress report brings about no substantive additional risk;
2) No substantive issue has been raised by reviewers
3) The annual renewal or progress report does not relate to a clinical trial or NIH-funded research.

When a substantive issue has been raised for any of the above, this will be considered by the FSH REC at its next quorate meeting.