

<b>TITLE</b>	<b>401: Delegated Review</b>
<b>SCOPE</b>	All research submitted to the Human Research Ethics Board operating under the direct authority of Trinity Western University
<b>RESPONSIBILITIES</b>	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
<b>APPROVAL AUTHORITY</b>	The Vice-Provost, Research & Graduate Studies
<b>EFFECTIVE DATE</b>	November 14, 2019
<b>Supersedes documents dated</b>	N/A

### **1.0 PURPOSE**

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

### **2.0 RESPONSIBILITIES**

The HREB Chair or designee is responsible for determining if research is eligible for delegated review. In some circumstances, the HREB Chair or designee may delegate this task to qualified HREB Office Personnel; however, the responsibility for oversight remains with the HREB Chair or designee.

The HREB Chair or designee or qualified HREB member(s) is responsible for conducting the delegated review.

### **3.0 DEFINITIONS**

See Glossary of Terms.

### **4.0 PROCEDURE**

HREBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full Board review by an HREB should be the default requirement for all research involving human participants unless the HREB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the HREB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of HREB review for different research projects. The two levels typical used by HREBs are Full Board review or delegated review by one or more experienced HREB members, as determined by the HREB Chair or designee. A third level of review, where projects carried out within formal course requirements are reviewed by the relevant department, may be initiated as needed and at the discretion of the HREB.

#### 4.1 Determination of Qualification for Delegated Review

- 4.1.1 Full Board review is the default for most new research projects submitted to the HREB; however, some research may be eligible for delegated review;
- 4.1.2 Submissions that meet the following criteria may be eligible for delegated review:
  - Research projects that involve no more than minimal risk, where the researchers clearly distinguish between the risks that are attributable to the research, and the risks to which participants would normally be exposed,
  - Minor or minimal risk changes to approved research,
  - Continuing review of approved minimal risk research,
  - Continuing review of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,
  - Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full HREB; if permissible under all applicable governing Regulations,
  - The submission by the Researcher in response to the HREB review as a condition of approval, as authorized by the Board,
  - Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
  - Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);

- 4.1.3 The HREB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following:
- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
  - Authorized translations of English versions of documents previously-approved by the HREB;
- 4.1.4 The HREB Chair or designee may be authorized by the full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;
- 4.1.5 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the HREB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.
- 4.1.6 The extent of scholarly review for biomedical research that does not involve more than minimal risk shall depend on the expertise of the HREB reviewers in the discipline involved. Peer reviews conducted by granting agencies shall be considered acceptable forms of external peer review.
- 4.2 Delegated Review Process
- 4.2.1 Qualified HREB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the HREB may be forwarded for delegated review. For all other submissions, the HREB Chair or designee will make the determination of whether the submission meets the criteria for delegated review;
- 4.2.2 For research that meets the criteria, delegated review may be conducted by the HREB Chair, or by one or more qualified HREB members as designated by the HREB Chair or designee;
- 4.2.3 Normally research that does not involve more than minimal risk shall not be required to undergo discipline-specific peer review of research design;
- 4.2.4 The HREB Chair or designee reviewing research under delegated review must not have a conflict of interest in the research;
- 4.2.5 In reviewing the research under delegated procedures, the HREB Chair or designee may exercise all of the authorities of the HREB, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the HREB at a Full Board meeting;

- 4.2.6 HREB member(s) conducting a delegated review will contact the HREB Chair or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;
  - 4.2.7 If the HREB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review;
  - 4.2.8 The HREB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring FB or delegated review) and the outcome of the review. The responsible HREB Office Personnel may issue the review or decision letter.
- 4.3 Delegated Review of Class Projects Conducted as Course Requirements
- 4.3.1 At the discretion of the HREB and in cooperation with individual departments, the review of research conducted by students as a course requirement may be performed by departmental review.
  - 4.3.2 Instructors may apply for a three-year ethics approval for projects to be carried out by students in their classes as a course requirement.
  - 4.3.3 These projects are grouped in three broad categories:
    - Research where the research participants are not students in the instructor's course;
    - Research where the project is conducted by interview only, regardless of the participant population;
    - Research where the research participants are students in the instructor's course.
  - 4.3.4 Applications for class projects must include the supporting documentation as outlined on the application form.
  - 4.3.5 Where individual students or groups of students are required to (or wish to) carry out their own research projects involving human participants, they must submit the Request for Ethical Review – Class Project form and follow the standard protocols for ethics review.
- 4.4 Notification of the HREB
- 4.4.1 At its next Full Board meeting the HREB will be informed of research that was reviewed and approved using delegated review procedures.
- 4.5 Documentation
- 4.5.1 The type of HREB review conducted (i.e., Full Board or delegated) is documented in the HREB records and noted in the decision letter issued to the Researcher, where appropriate;
  - 4.5.2 The HREB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous HREB meeting was issued.

**5.0 REFERENCES**

See References.

**6.0 REVISION HISTORY**

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
SOP 401	November 14, 2019	Original version