
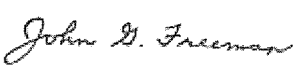



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| Section 400: | Review of Research |
| Title: | GREB Delegated Reviews |
| SOP Code: | 402.001 |
| Effective Date: | 2016MARCH07 |

Site Approvals

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1.0 PURPOSE

This SOP describes the decisions that the GREB may make during the Delegated review of proposed research for ethical acceptability.

2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen's University. The scope of GREB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants."

3.0 RESPONSIBILITIES

All GREB members and GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

The GREB Chair or designee is responsible for ensuring that: (1) each ethics application qualifies for delegated review based on criteria set out by the TCPS2 (2014) and this SOP; (2) GREB members act with due diligence in completing the review; (3) changes needed are communicated clearly to the researchers; (4) decisions are made in a timely manner; and (5) researchers are informed of their responsibilities for the duration of the application.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

As described in Article 6.12 of the TCPS2 (2014) guidelines, GREB uses 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 GREB should be the default requirement for all research involving human participants unless GREB decides to authorize delegated review based primarily on the risks or harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow GREB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research. This principle also applies to course-based research assignments.

In practice, proportionate review implies different levels of GREB review for different research projects. The two levels used by GREB are full board review or delegated review by one or more experienced GREB members, as determined by the GREB Chair

or designee. In the case of instructor course-based research assignments ethics applications, the GREB Chair or designee will conduct the reviews.

The GREB's primary duty is to protect the rights and welfare of human research participants. However, GREB's secondary role is to support the research enterprise by assisting researchers in fulfilling their obligations to research participants according to the TCPS2 (2014) guidelines and Queen's policies. In this capacity, GREB members endeavour to provide feedback in a positive and supportive manner, regardless of whether it is a delegated review or a full board review.

5.1 Determination of Qualification for Delegated Review:

5.1.1 Full board review is the default for new research projects submitted to the GREB (Article 6.12, TCPS2 [2014]);

5.1.2 Article 6.12 states: "In keeping with a proportionate approach to research ethics review, the selection of the level of (G)REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review)";

5.1.3 The Application Section 6.12 describes research that may be eligible for delegated review:

- Research project that is confidently expected to involve minimal risk,
- Minor or minimal risk amendments/changes to ethically cleared research,
- Annual renewals of approved minimal risk research,
- Annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal,
- Annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal;
- Annual renewals of more than minimal risk research in which there has been: i) no significant changes to the research, ii)

no increase in risk to (or other ethical implications for) the participants since the most recent review by the GREB, and iii) the GREB Chair has determined that the delegated review process is appropriate.

5.2 Delegated Review Procedures:

- 5.2.1 The GREB Chair or designee will examine all ethics applications to determine if there are more than minimal risks and decide whether or not the file should be assigned a full board review or a delegated review;
- 5.2.2 The GREB Chair may also base the decision regarding delegated to full board review on the recommendation of the UREB as well as an examination of the application and attachments to determine if there are other concerns related to the research methods, recruitment practices, participant population, rights, safety and well-being of research participants, confidentiality of data, and all regulatory and ethics guidance requirements as applicable;
- 5.2.3 Since most GREB ethics applications are of minimal or minor risk to participants, they are assigned to delegated review;
- 5.2.4 The Ethics Coordinator, with advice from the GREB Chair or designee, will assign one or two GREB members to each delegated review based on members' experience, expertise, and level of training;
- 5.2.5 The GREB Chair or GREB reviewers must not be in a conflict of interest situation with either the researchers or the research; if such a conflict occurs, the reviewer must report the conflict and a new GREB member will be assigned to the delegated review;
- 5.2.6 If GREB reviewers have concerns with their level of experience and expertise to review the application or if they believe it should be

reviewed by the full board, they can refer the application to the GREB Chair;

- 5.2.7 If an application is referred by reviewers, the GREB Chair will review the application or assign other GREB member(s) to the review team or, if appropriate, assign the application to a GREB full board review;
- 5.2.8 The GREB reviewers will either propose that the ethics application be cleared or ask for clarifications and/or modifications by the researchers;
- 5.2.9 Researchers will modify the ethics application and attachments to address the GREB reviewers' comments or may rebut the request for certain changes;
- 5.2.10 The responsibilities for additional review and the decision regarding ethics clearance conditions lies with the GREB reviewers. If, however, they have concerns with the application or their level of experience and expertise, they should refer the application to the GREB Chair;
- 5.2.11 Normally the reviews and corrections are completed within one or two exchanges with the researchers at which time the reviewers will either propose that the ethics application be cleared, or refer the application to the Chair for a full board review;
- 5.2.12 If the research cannot be granted ethics clearance after revisions are requested in the delegated review process, the research must be reviewed by the full board at GREB meeting.

5.3 Delegated Review of Course-Based Research Projects

- 5.3.1 The Applications Section of Article 6.12 states: "The REB should establish written procedures and set out criteria for determining which categories of research proposal may be eligible for different types of review, and specify who is responsible for implementing

and overseeing the approval mechanisms.” Based on this Article, GREB has established a system for student course-based research assignments;

- 5.3.2 Instructors are required to submit an Instructor Course-Based Research Assignment Ethics Application Form in TRAQ. This application form is streamlined for course assignments with instructors expected to submit their assignment outline and all materials that will be given to the students;
- 5.3.3 Some course-based ethics applications have been grandfathered into the TRAQ system if the application has already been submitted;
- 5.3.4 The Ethics Compliance Advisor or GREB Chair will normally review all instructors' course-based applications submitted in TRAQ. The procedures for the review follow 5.2 outlined above;
- 5.3.5 Undergraduate and graduate independent study courses and thesis courses do NOT qualify as course-based research. These applications will be reviewed through the regular delegated or full board review process;
- 5.3.6 The criteria for course-based research projects that may be assigned to the Instructor for adjudication and management are set out in guidelines, Student Course-Based Research Assignment Guidelines, available on the GREB webpage at <http://www.queensu.ca/urs/ethics/general-research-ethics-board-greb> . These guidelines include:
 - The research assignment is conducted solely for pedagogical and student assessment purposes,
 - Risks to both participants and student researchers must be minimal,
 - The number of participants (or time necessary) should be minimal,

- There is no reasonable expectation of privacy attached to the data collected,
 - The research data obtained and the final student research papers will not be disseminated outside of the classroom environment (or for online courses, outside of the online course's password protected domain),
 - The data obtained from student course-based research projects cannot later be used for research projects involving dissemination outside of the classroom environment as secondary use of data;
- 5.3.7 Course-based ethics applications that meet these criteria will be given clearance and the Instructor will be delegated the responsibility of reviewing and clearing student course-based assignments;
- 5.3.8 Course-based ethics applications that do NOT meet these criteria must use the regular ethics application form and will be reviewed and cleared by GREB as either a delegated or full board review.

5.4 Documentation:

- 5.4.1 Once cleared through the delegated review process, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;
- 5.4.2 The Ethics Coordinator will prepare, on the Chair's behalf, an Ethics Clearance Letter to be issued to the researchers with its date used to calculate the one-year expiry date of GREB ethics clearance. The Ethics Clearance Letter will contain a statement that any changes to protocol, consent, etc., must be submitted as an amendment and that the ethics clearance will expire on the Ethics Clearance Letter's anniversary date, at which time an Annual

Renewal Report will need to be submitted to keep the application open;

- 5.4.3 The GREB meeting agendas and minutes will include a list of submissions that were reviewed and ethically cleared using delegated review procedures from the time that the agenda for the previous GREB meeting was issued.

6.0 REFERENCES

TCPS2 (2014) Articles 2.9, 6.12, 6.14.

7.0 APPENDICES

Student Course-Based Research Assignment Guidelines

8.0 REVISION HISTORY

| SOP Title | Version | Updates |
|-----------------------|------------------------|--|
| GREB Review Decisions | v.402.001 2016MAR07 | Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2). |