Terms of Reference (ToR)

Queen's University General Research Ethics Board (GREB)

1 Introduction

1.1 Overview

There are two research ethics boards for Queen's University:

- General Research Ethics Board (GREB)
- Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB)

GREB primarily conducts reviews in humanities, social sciences, science, engineering, and administrative research. HSREB primarily reviews health sciences research, including all research conducted at the affiliated teaching hospitals. This Terms of Reference (ToR) is specific for GREB and its review of all research protocols involving human participants (within its disciplinary oversight) that occur at Queen's University.

All individuals (i.e., faculty, staff, students) involved in human participant research conducted at Queen's University (including GREB members), must be trained in, and adhere to, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS 2) 2022 as the ethical guide for the conduct of research involving humans.

GREB was established to fulfill the ethical responsibilities concerning research involving human participants by the standards developed by the Tri-Council: Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), and Social Sciences and Humanities Research Council (SSHRC). All research, including that funded by the Tri-Council or industry, requires adherence with the TCPS 2.

The activities of GREB are built upon the guiding core ethical principles of the TCPS 2: respect for persons, concern for welfare, and justice. Applying these core principles is intended to balance the necessary protection of participants and the legitimate research requirements. Queen's University researchers and research teams will also uphold relevant institutional and regulatory policies concerning ethical conduct, research integrity, conflict of interest and commitment, including but not limited to: The Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use-Good Clinical Practice Guideline (ICH-GCP), and all relevant Queen's University policies.

This ToR and any amendment hereafter require the approval of the Vice-Principal Research (VPR).

1.2 Standard Operating Procedures

The operations, policies, and procedures will adhere to the Standard Operating Procedures (SOPs). The SOPs guide the processes of the Research Ethics Office, GREB and the GREB Chair/Vice-Chair. The SOPs align with the TCPS 2, allowing for a streamlined process and transparency of ethical research decisions involving human participants.

2 Mandate, authority, accountability, and independence

2.1 Mandate

The mandate of GREB is to review the ethical acceptability of human participant research conducted at Queen's University by faculty members, staff, and/or students by the TCPS 2.

In support of fulfilling this mandate, GREB will:

- Provide an impartial, informed, and balanced review using a proportionate approach outlined in the TCPS 2 and SOPs.
- Be the body to approve, reject, propose modifications to, suspend, or terminate any proposed or ongoing research involving human participants and human biological materials from living and deceased individuals, including human embryos, fetuses, fetal tissues, reproductive materials, and stem cells.
- Ensure further research submissions to the GREB are aligned with the originally approved project via amendments, renewals, or other post approval submissions.
- Serve the research community and stakeholders as a consultative body regarding ethical matters in research and compliance.

2.2 Authority

GREB shall review the ethical acceptability of all human participant research (both funded and unfunded) involving humans and/or their data/information as conducted within the university's jurisdiction and shall have authority concerning the following research studies:

- Research carried out by a Principal Investigator or Co-Investigator, or is facilitated by any Queen's University faculty member, staff member, post-doctoral fellow or student, regardless of where the research is conducted.

and

- Any research involving participants (or prospective participants) within Queen's University.

2.3 Accountability

GREB shall report to the highest governing authority at Queen's University, the Principal and Vice-Chancellor – in keeping with TCPS 2. The GREB Chair is responsible for ensuring that GREB upholds the requirements of TCPS 2.

The Research Ethics Office will oversee day-to-day administrative matters and report to the VPR**.**

2.4 Independence

Review and subsequent decisions by GREB regarding research are made independently of the University and are guided by the current TCPS 2. All offices and the University shall respect the independence, accountability, and authority of GREB. A decision made by GREB may not be overridden except under the reconsideration and appeal process. However, the University, through the VPR, does have the authority to refuse to allow research that GREB has approved.

3 Reconsideration and Appeal Process

A Principal Investigator may appeal against the decision of GREB by sending a written request to the GREB Chair. The written request will outline the reasons for asking for reconsideration or appeal of a decision. The subsequent review will follow the GREB procedures and SOPs.

4 REB Meetings, Membership and Quorum

4.1 Meeting schedule and notice

Full Board meetings allow every member of GREB to discuss studies that require a greater level of scrutiny or discussion. GREB will schedule Full Board meetings monthly, set in advance. Additional meetings will be held if appropriate. For example, if quorum is not met, an ad hoc meeting will be held with 7-10 days' notice.

4.2 Meeting decisions

Decisions of GREB will be held by a consensus vote declared by the Chair. In accordance with TCPS 2, if a minority of the GREB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort will be made to reach a consensus. Consultation with the Principal Investigator, researcher, ad hoc members, external advisors, peer review or further reflection by GREB may be required.

4.3 Quorum

Quorum is met when *both* of the following requirementsare satisfied:

- Minimum membership representation as required by the TCPS 2 2022:
    - 2 members with expertise in the relevant research discipline of the research proposal.
    - 1 member knowledgeable in ethics.
    - 1 community member (no affiliation with the University).
    - 1 member knowledgeable in the applicable law.

and

- A majority of members are present: 50% (+1).

Discussions of protocols/submissions (and review of GREB policies/guidance) requiring full review can occur without quorum. However, GREB decisions require quorum. For example, a discussion held at the Full Board meeting may proceed when the members in attendance have the specific expertise, relevant competence, and knowledge necessary, as determined by the Chair, to provide an adequate ethics review. The decision of GREB, however, will be determined by holding an ad hoc meeting as soon as possible.

Ad hoc advisors, observers, Research Ethics administration staff and observers (i.e., others attending GREB meetings) cannot be counted in the quorum or allowed to vote. Decisions made without quorum are not valid or binding.

4.4 Remote participation

Members of GREB and the Research Ethics Office may join the Full Board meeting via teleconference/videoconference. All members attending the meeting will be presented with a full package of meeting materials before the review date. Members joining virtually will be counted in quorum.

4.5 Minutes

Each Full Board meeting will have documented minutes of all relevant discussions, concerns, and comments.

4.6 Composition and appointment of members

Official appointments to the Board are made by the VPR. Appointments are made for a three-year renewable term. GREB and the Research Ethics Office will examine the composition of Board membership bi-annually. For example, recruitment efforts will be made if expertise (i.e., a research area) is absent from the Board. The VPR will assist in recruiting members at the request of GREB and

the Research Ethics Office. Term renewal is based upon review by the GREB Chair, with consultation with the Vice-chair and Research Ethics Manager. VPR will receive quarterly updates on the Board composition.

4.7 GREB Chair

The GREB Chair is appointed by the VPR for a period of approximately 5 years, renewable for further terms at the discretion of VPR. The Chair ensures that GREB reviews uphold the TCPS 2, and other ethical requirements listed above. In addition, the Chair will monitor GREB's decisions for consistency and ensure that decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible. The Chair's duties include but are not limited to those in the SOP.

4.8 Vice-Chair

The Vice-Chair of GREB will be appointed by the GREB Chair for approximately a 3-year term, renewable for a further 3-year term by the GREB Chair, with consultation with the Research Ethics Manager. The GREB Vice-Chair also holds responsibility for ensuring that GREB upholds the TCPS 2. In addition, the Vice-Chair will fulfil the role of the Chair when the Chair has a conflict of interest with a study or is unavailable. The duties of the Vice-Chair include but are not limited to, those listed in the SOPs.

4.9 Meeting attendance

Members are expected to attend the GREB monthly meetings. If a GREB member is absent for more than 50% of the meetings per calendar year, the Chair, Vice-Chair, and Research Ethics Manager will review whether that member should continue to serve on the REB.

4.10 Conflicts of interest

All GREB members must declare all conflicts of interest concerning any research project. Conflicts of interest should be declared before a review, and that member will be recused from the review process and the vote.

5 Levels and types of reviews and categories

The Research Ethics Office and the HSREB Chair together will determine the risk level of the study and the determination of a review via a delegated or a full board review method. The review should be proportionate to the level of risk to the participants and researchers (i.e., the greater the risk, the greater the level of scrutiny). Minimal risk is defined in the TCPS2 as follows: "Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research." There are two types of reviews:

- Delegated review for minimal risk studies (Delegated reviews will undergo review by the research ethics office and 1-2 reviewers of the Board).
- Full Board review for more than minimal risk studies. (Full Board reviews will undergo review by the research ethics office and every member of the Full Board.

If concerns are presented about the appropriate level of review, this will be discussed with the Chair of GREB.

5.1 Ongoing/continuing reviews/closure

Once a protocol has been reviewed and granted GREB approval, the protocol must be re-reviewed on an ongoing basis. Once the study activities have stopped, the protocol can then be 'closed' through the submission of a study closure. GREB must maintain ethical oversight for the duration of the study. GREB can suspend or withdraw the approval of any project that does not comply with the approved protocol or if major ethical concerns arise.

6 Research Ethics Office

The Research Ethics Office will:

- Provide administrative support to the GREB Chair and GREB members.
- Perform preliminary reviews on submissions to HSREB.
- Determine the HSREB and GREB submission criteria of applications and the appropriateness of submission to HSREB or GREB.
  Support stakeholders such Principal Investigators, Co-Investigators, students, postdoctoral fellows, other team members, and/or any person conducting research at the University and/or its affiliated hospitals with submission, application and ethical advice on studies.
- Prepare and maintain comprehensive records of reviews, GREB agenda items, GREB agendas, attendance at board meetings; meeting minutes.
- Perform other functions as described within the SOPs.

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Key Terminology

Abbreviations	Definitions
CIHR	Canadian Institutes of Health Research
GREB	General Research Ethics Board
HSREB	Health Sciences and Affiliated Teaching Hospitals Research Ethics Board
ICH-GCP	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice Guideline
KHSC	Kingston Health Sciences Centre
NSERC	Natural Sciences and Engineering Research Council
PCC	Providence Care Centre
REB	Research Ethics Board
SOP	Standard Operating Procedure
SSHRC	Social Sciences and Humanities Research Council
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
ToR	Terms of Reference
VPR	Vice-Principal Research