

There are two research ethics boards for Queen's University: General Research Ethics Board (GREB) and Health Sciences and Af liated 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 af liated teaching hospitals. This Terms of Reference (ToR) is specific for GREB's review of all research protocols involving human participants (within its disciplinary oversight) that occur at Queen's University.

All individuals (i.e., faculty, staf, 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 fulf II the ethical responsibilities concerning research involving human participants by the standards developed by the Tri-Councils: Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), and Social Sciences and Humanities Research Council (SSHRC). Funding by the Tri-Councils to researchers and institutions depends on compliance with the TCPS 2.

GREB's activities 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 Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use-Good Clinical Practice Guideline (ICH-GCP), and all Queen's University policies.

This ToR and any amendment hereafter require the approval of the VPR.

The operations, policies, and procedures will adhere to the Standard Operating Procedures (SOPs). The SOPs guide the processes of the Research Ethics Of ce, 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.

The mandate of GREB is to review the ethical acceptability of research that falls under its authority involving humans conducted at Queen's University by faculty members, staf, and/or students by the TCPS 2.

In support of fulf lling this mandate, GREB will:

Provide an impartial, informed, balanced review using a proportionate approach outlined in the TCPS 2 and SOPs.

Be the authority to approve, reject, propose modif cations 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 REB 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.

GREB shall review the ethical acceptability of all research within its disciplinary authority (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.

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 the GREB process conforms to the requirements of TCPS 2.

The Research Ethics Of ce will oversee day-to-day administrative matters and report to the VPR.

Review and subsequent decisions by GREB regarding research are made independently of the University and are guided by the current TCPS 2. All of ces



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. Through the Vice-Principal research, the institution does, however, have the authority to refuse to allow research that the REB has approved.

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Appointments to the Board are made by the VPR and are for a three-year renewable term. GREB determines the composition of Board members bi-annually. For example, recruitment ef orts 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. In addition, GREB may consult with faculty deans, department heads, or their delegates to obtain appropriate GREB membership or participate in actively recruiting members using social media or other forms of advertising. Term renewal is based upon review by the GREB Chair, with consultation with the Vice-chair and Research Ethics Manager, with f nal approval by the VPR.

The GREB Chair is appointed by the VPR for a period of approximately 5, renewable for further terms at the discretion of VPR. The Chair ensures that GREB's review process conforms to the TCPS 2, and other ethical requirements listed above. In addition, the Chair should 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.



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

The Research Ethics Of ce, chair and vice-chair will determine whether a study will be reviewed via a delegated review method or a full board review method. The review should be proportionate to the level of risk to the participants and