Terms of Reference (ToR)

Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB)

1 Introduction

1.1 Overview

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

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

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. The affiliation agreement of the Joint Liaison Committee (JLC) lists all affiliated hospitals.

This Terms of Reference (ToR) is specific for HSREB's review of all research protocols involving human participants (within its disciplinary oversight) that occur at Queen's University and its affiliated hospitals.

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

HSREB was established to fulfill 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). HSREB also ensures that research involving human participants abide by Good Clinical Practice (GCP). All research, including that funded by the Tri-Councils or industry, requires adherence with the TCPS2 and GCP.

HSREB'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 Council for Harmonization of Technical Requirements for 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.

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, HSREB and the HSREB 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 the HSREB is to review the ethical acceptability of human participant conducted at Queen's University and its affiliated hospitals by faculty members, staff, and/or students by the TCPS 2.

In support of fulfilling this mandate, the HSREB 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 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.

2.2 Authority

HSREB 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 and affiliated hospital's jurisdiction and shall have approval/decision-making authority concerning the following research studies:

- Research carried out by a Principal Investigator or Co-Investigator, who is conducting health sciences related research, has an affiliation through Queen's University and/or its affiliated hospitals.

and

- Research involving participants (or prospective participants) regarding health sciences related research within Queen's University and affiliated hospitals.

2.3 Accountability

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

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

2.4 Independence

Review and subsequent decisions by HSREB regarding research involving participants are made independently of the University and its affiliated hospitals and are under the current TCPS 2. All units/departments of Queen's University and affiliated hospitals shall respect the independence and authority of the HSREB. A decision made by the HSREB may not be overridden except under the reconsideration and appeal process. However, an affiliated hospital does have the authority to refuse to allow research that the REB has approved to be undertaken.

3 Reconsideration and appeal process

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

4 REB meetings, membership, and quorum

4.1 Meeting schedule and notice

Full Board meetings allow every member of HSREB to meet and discuss studies that require a greater level of scrutiny or discussion. HSREB 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 the HSREB will be held by a consensus vote declared by the Chair. In accordance with TCPS 2, if a minority of the HSREB 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 the HSREB may be required.

4.3 Quorum

Quorum is met when *both* requirements listed below are 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 or affiliated hospitals).
    - 1 member knowledgeable in the applicable law.

and

- Having a majority of members present: 50% (+1).

Discussions of protocols/submissions (and review of HSREB policies/guidance) requiring full review can occur without quorum. However, HSREB 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. However, the decision of HSREB 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 HSREB 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 the HSREB and the Research Ethics Office staff 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. HSREB 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 new members at the request of HSREB and the Research Ethics Office. Term renewal is based upon review by the HSREB Chair, with consultation with the Vice-Chair and Research Ethics Leadership Team. VPR will receive quarterly updates on the Board composition.

4.7 HSREB Chair

The HSREB Chair is appointed by the VPR for a term of approximately 5 years, renewable for further terms at the discretion of VPR. The Chair ensures that the HSREB reviews uphold the TCPS 2, and other ethical requirements listed above. In addition, the Chair will monitor the HSREB'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 outlined in the SOPs.

4.8 Vice-Chair

The Vice-Chair of HSREB will be appointed by the HSREB Chair for 3 years, renewable for a further 3-year term at the discretion of the HSREB Chair, with consultation with the Research Ethics Manager. The HSREB Vice-Chair also holds responsibility for ensuring that the HSREB reviews uphold 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

Board members are expected to attend the HSREB meetings monthly. If a member is absent for more than half (50% or more) of 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 HSREB 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 risk level of review, this will be discussed with the chair of HSREB.

5.1 Ongoing/continuing reviews and study closures

Once a protocol has been reviewed and granted HSREB 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. HSREB must maintain ethical oversight for the duration of the study. HSREB 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 HSREB Chair and HSREB 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, HSREB agenda items, HSREB agendas, attendance at board meetings, meeting minutes.
- Perform other functions as described within the SOPs.

Approved By: Dr. Steven Smith, PhD, Deputy Vice-Principal Research
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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