CAMH Research Ethics Board
Terms of Reference
Version: April 28, 2023

Scientific research is an essential component of the provision and enhancement of patient care for patients with mental illness, and there are special ethical considerations in conducting research involving vulnerable individuals or groups with mental illness. The aim of the CAMH Research Ethics Board (REB) is to protect human subjects by ensuring that all research is conducted ethically at or under CAMH auspices.

Authority and Accountability

The REB is accountable to the CAMH Board of Trustees through the Research Committee of the CAMH Board of Trustees. CAMH maintains a Federal Wide Assurance (FWA) with the federal government of the United States of America.

The CAMH REB provides ethics review and oversees research to ensure compliance with applicable human participant protection regulations and guidelines. At a minimum, the REB complies with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)* Other relevant standards include the *Food and Drugs Act, the Personal Health Information Protection Act (PHIPA 2004)*, and *International Council for Harmonisation (ICH) Good Clinical Practice (GCP)* guidelines, and the *US Code of Federal Regulations* as applicable to specific research projects.

Appointment to the REB

The Research Committee of the CAMH Board of Trustees, upon recommendation by the CAMH Physician-in-Chief, appoints the Chair of the REB for a term of three years, renewable once.

The REB Chair appoints the Vice-Chair and members of the REB for a term of three years, renewable at the Chair's discretion. The Research Committee of the CAMH Board of Trustees is notified of new member appointments on a routine basis. Membership is staggered to maintain continuity.

Functions and Responsibilities of the REB

The CAMH REB evaluates and oversees the ethical conduct of research involving human participants, their biological specimens and data. The REB defines research as an undertaking to create new knowledge through scientific inquiry, using methods that can withstand review by scientific peers.

The CAMH REB has authority over the ethical conduct of research at or under the auspices of CAMH. Specific areas include:

- The initial review and approval of research at the outset of each project, and whenever any changes are proposed
- Oversight of all active research, with the authority to require modification, restriction, suspension or termination

- Full access to all information involving the research project that the REB considers necessary to fulfill its mandate while maintaining confidentiality and respecting privacy; and
- Take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety and well-being of participants in research.
- The REB will encourage education in research ethics for REB members and research personnel, and will participate in the development and ongoing improvement of policies and data related to research to adjudicate ethical questions

The REB will encourage education in research ethics for REB members and research personnel, and will participate in the development and ongoing improvement of policies and standard operating procedures related to research ethics

Activities Requiring Review by the REB

The CAMH REB follows the Tri-Council Policy Statement requirements for activities requiring review by the REB, including:

- Research involving living human participants;
- Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individual and includes secondary use of biological materials; and
- Research that relies exclusively on the secondary use of non-identifiable data or human biological materials.

Changes to approved research require ethics review and approval prior to initiation/implementation, except where necessary to eliminate apparent, immediate hazards to participants.

Data and biological specimens may only be used for research purposes for which REB approval was granted, or as amended and approved by the REB.

The REB does not review quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. This is reserved for the Quality Performance and Ethical Review (QPER) Department. Consultation with the REB is continuous to ensure all studies are reviewed by the appropriate Department.

REB Composition

The REB includes members affiliated with CAMH and external members. The REB will have a majority of members who are Canadian citizens or permanent residents of Canada. The REB selection committee will aim for a membership that reflects a diversity of gender, culture, race, ethnicity, disability, sexual orientation and opinions. There will be a minimum of five members, including:

- At least two members who have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- One member knowledgeable in ethics;
- One member knowledgeable in the relevant law, who is not a member of the institution's legal counsel or risk manager;
- One community member who has no affiliation with the institution;

A senior administrator cannot be a member of the REB.

The REB may appoint alternate members with the appropriate expertise to participate in research ethics review process (Article 6.4). Alternate members may substitute and be counted for quorum for a regular member at an REB meeting. *Ad hoc* advisors may also be recruited to supplement the expertise of the REB members.

Quorum

At minimum, the REB will follow the quorum requirements of the TCPS2 and will apply additional quorum requirements as necessary based on the applicable regulations and guidelines for the application under review (e.g.- US FDA 56.107).

Conflict of Interest

All REB members must adhere to the CAMH policies: AR 1.9 - Research Integrity, and AR 1.9.2 – Research Conflict of Interest.

The standard for determining conflict of Interest (COI) for REB members is the perception that a member has a personal or professional interest that would interfere with their ability to make ethical judgements about the conduct of research. Such COI would recuse that member from discussions of the relevant material.

Designated REB of Record Review

In certain circumstances (e.g. multi-centre research), the CAMH REB may be designated as another institution's Board of Record or conversely, another institution's research ethics board may be designated as the CAMH Board of Record.

REB Decisions

The REB evaluates whether research is conducted in an ethical manner, and this evaluation may also require a consideration of the scientific aspects of the proposed research. REB decisions are made independently of other CAMH interests. The REB is guided by the core principles in Article 1.1 of the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans": respect for persons, concern for welfare and justice.

CAMH ensures that the REB operates effectively and independently in their decision making. CAMH policies and procedures support and promote the independence of the REB in their decision making so that the REB may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest. CAMH will not approve a research project that has not been approved by a designated Board of Record.

Appeals

A Principal Investigator (PI) may appeal the decision of the REB if disagreements cannot be resolved through discussion. The appeals process will follow the TAHSN wide adopted Appeals Process (Version April 28, 2022).

Research Ethics Office

Research Ethics Office (REO) personnel provide support to the REB Chair and the REB, including as a liaison for the REB, advising researchers, assisting with review tasks delegated by the Chair. The REO is responsible for the storage and maintenance of REB documents in accordance with applicable regulations, policies and guidelines.

Reporting

The REO will provide weekly reports of approved initial or amended Research Project applications to the CAMH Director, Clinical Research. The CAMH REB will report to the Research Committee on a routine basis.

The REB Chair reports administratively to the Physician-in-Chief or delegate. The Manager, Research Ethics has a direct reporting line to the Director, Clinical Research and functional reporting line to the Chair, Research Ethics Board. . Additional REO personnel report to the Manager, Research Ethics.

Relationship with Stakeholders

The REB and/or REO personnel will liaise routinely with both internal stakeholders (e.g. Legal Services, Ethics Service, Information and Privacy Office, Industry Partnerships and Technology Transfer Office and Medical Advisory Committee) and external stakeholders (e.g. the University of Toronto (pursuant to the affiliation agreement between CAMH and the University of Toronto), and Clinical Trials Ontario (CTO)).

Terms of Reference Review Process

The REB and REO, in consultation with the REB Chair, will review the Terms of Reference every 3 years, or as identified by the Chair. The Terms of Reference will be approved by the Research Committee of the Board of Trustees.