

**CAMH Research Ethics Board
Terms of Reference
Version: April 1, 2019**

The Centre for Addiction and Mental Health (CAMH) recognizes that research is an essential component in the provision and enhancement of care for patients with mental illness. CAMH also recognizes that special conditions exist when conducting research involving vulnerable individuals or groups. The CAMH Research Ethics Board (REB) ensures that only research that meets the highest ethical and scientific standards is conducted 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 Federalwide Assurance (FWA) with the federal government of the United States of America.

The CAMH REB will provide initial review and ongoing oversight of research projects to ensure they meet ethical principles and that they comply with applicable regulations and guidelines pertaining to human participant protection. At a minimum, the REB shall comply with and apply the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)* to all research projects. In addition, as applicable to the research, the REB shall comply with and apply the requirements of the *Food and Drugs Act* and applicable *Regulations*, *Personal Health Information Protection Act (PHIPA 2004)*, and *International Council for Harmonisation (ICH) Good Clinical Practice (GCP)* guidelines. When applicable to the research, the REB shall comply with and apply the requirements of the *US Code of Federal Regulations* to the extent that they vary from the requirements of applicable Canadian regulations and guidelines.

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 twice.

The REB Chair appoints the Vice-Chair and members of the REB for a term of three years, renewable twice. The Research Committee of the CAMH Board of Trustees is notified of new member appointments on a routine basis. Membership terms are staggered in such a manner as to safeguard the continuity of the REB.

Functions and Responsibilities of the REB

The CAMH REB assesses and oversees the ethical acceptability of research involving human participants (including their biological specimens and/or data). The REB defines research as an undertaking to extend knowledge through a disciplined inquiry and/or systematic investigation. “Disciplined inquiry” refers to

an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

The CAMH REB has the authority to ensure that all research it reviews is designed and conducted in an ethically acceptable manner. Specifically, the REB has the authority to:

- Provide research ethics oversight to ensure the ethical acceptability of research prior to initiation and throughout the life of a research project;
- Approve, require changes to, or disapprove research projects or proposed changes to approved research projects, and monitor, suspend or terminate any ongoing research;
- Ensure that the Project Lead (Principal Investigator) has policies in place to protect the rights, safety and welfare of participants as a condition of approval and ongoing conduct;
- Place restrictions on the research project;
- Request, receive and share any 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 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. Such activities include:

- 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 same standards of review will apply to all research endeavors whether or not they represent funded research, research by students, potential publications or pilot work.

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The REB does not normally review quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes.

REB Composition

The REB consists of members both affiliated and not affiliated with CAMH. The REB will have a majority of members who are Canadian citizens or permanent residents of Canada. The REB will not be comprised of members of a single gender. Having regard to the multicultural community which CAMH serves, the REB selection committee will appoint a fair representation of diverse members, taking into consideration gender, culture, race, ethnicity, disability, and sexual orientation.

Although the membership may reach 20 individuals, at a minimum, it will include at least five members represented by the following categories:

- At least two members who have expertise in relevant research disciplines, fields and methodologies covered by the REB (as the REB reviews regulated clinical trials, this will include at least one member who is from a medical discipline in accordance with the research reviewed);
- At least one member whose primary experience and expertise are in a non-scientific discipline;
- one member knowledgeable in ethics;
- one member knowledgeable in the relevant laws;
- one member knowledgeable in considering privacy issues;
- At least one external community member who has no current affiliation with the institution or the sponsor; and
- Other membership as required by the applicable regulations and policies, if applicable.

A senior administrator cannot be a member of the REB.

The REB may appoint alternate members with the appropriate knowledge, expertise and training to contribute to the research ethics review process. Alternate members be attend an REB meeting to establish quorum (i.e., in absence of the regular member) or to provide specific expertise.

The REB may seek input from individuals with expertise and competence in areas not represented by the REB membership (ad hoc advisors); these individuals are not REB members and do not alter the composition of the REB.

Quorum

At minimum, the REB will follow the quorum requirements of the TCPS 2 and will apply additional quorum requirements as necessary based on the applicable regulations and guidelines for the application under review.

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.

For REB members, the standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare and safety of the participants. If there is any doubt concerning conflict of interest, the member is expected to discuss the matter with the REB Chair.

If a member has a conflict with an application under review, they will be absent for the review and vote (i.e., they will not vote) on the application and this will be noted in the minutes.

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 in each case, subject to approval by the CAMH REB and Board of Trustees. The designated REB acting as the Board of Record carries out the mandate of the designating institution's REB provided it meets and maintains acceptable research ethics review qualification or accreditation standards.

REB Decisions

Decisions made by the REB are based on scientific and ethical merits of the research study, and are made independently of other interests of CAMH. The REB is guided by the following core principles as defined 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

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A Principal Investigator (PI) may appeal the decision of the REB if the disagreement between the PI and the REB cannot be resolved through the reconsideration process. A final decision after reconsideration must be issued by the CAMH REB before an appeal can be initiated.

The same authority that established the REB shall appoint an appeal committee that reflects a range of expertise and knowledge similar to that of the REB. The appeal committee will meet the REB quorum requirements as applicable to the study under review. Members of the REB whose decision is under appeal shall not serve on that appeal committee.

The appeal committee shall have the authority to review negative decisions made by the REB and in doing so it may approve, disapprove or request revisions to the research proposal. The decision of the appeal committee on behalf of CAMH is final.

Research Ethics Office

Research Ethics Office (REO) personnel provide support to the REB Chair and for the work of the REB. In addition to other duties, REO personnel act as a liaison for the REB, advise researchers on their applications for ethics review, and assist with the review process. The REO is responsible for the storage and maintenance of REB documents in accordance with the applicable regulations, policies and guidelines.

Reporting

The REO will provide weekly reports of approved initial or amended Research Project applications to the CAMH Senior Director, Research Strategy and Operations. 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 reports to the Director, Research Operations. 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), the Toronto Academic Health Science Network Research Ethics Committee (TREC) and Clinical Trials Ontario (CTO)).