

## **WOMEN'S COLLEGE HOSPITAL**

### **Research Ethics Board**

### **Terms of Reference**

#### **PURPOSE**

The Research Ethics Board (REB) is responsible to ensure that research involving humans conducted within or by members of Women's College Hospital (WCH) meets current scientific and ethical research standards for the protection of human research participants. The REB complies with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) requirements for activities that require review by an REB. These activities include:

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

#### **AUTHORITY AND ACCOUNTABILITY**

The WCH Board of Directors has delegated decision-making authority to the REB. In compliance with TCPS 2, the REB operates independently in its decision making. The REB shall report to the WCH Board of Directors through the Medical Advisory Committee (MAC). The Chair of the REB shall make annual reports to the MAC.

The Board of Directors, MAC, or other administrative bodies within WCH may not overturn a negative decision/dis-approval of the REB. However, WCH retains the authority to deny the implementation of REB-approved research protocols for reasons other than research ethics; such reasons may be administrative, programmatic, or resource-based in nature. The REB maintains an arm's-length relationship with WCH. As an entity that draws its authority and resources from Women's College Hospital, the REB remains accountable to the Hospital for the integrity of its processes.

#### **MANDATE AND RESPONSIBILITIES**

The REB has the mandate to independently approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants or human biological materials, which is conducted at or by members of WCH.

The REB is responsible for providing research ethics review and oversight to ensure the ethical acceptability of research prior to initiation and throughout the lifecycle of a research study. This is accomplished by the following tasks:

- Reviewing all proposed research from ethical and scientific perspectives before the research begins;
- Conducting continuing review of ongoing studies;
- Reviewing amendment requests before the amendments are implemented;
- Reviewing protocol deviation reports;
- Reviewing adverse event and unanticipated problem reports;
- Reviewing study closure reports;

The REB is also responsible for:

- Recommending policies and procedures governing ethical conduct of research at Women's College Hospital;
- Acting as a resource on matters of research ethics for Women's College Hospital.

Decisions made by the REB are based on the scientific and ethical acceptability of the research study, and are made independently of other interests of WCH. The REB is guided by the following core ethical principles in Article 1.1 of the TCPS 2:

- Respect for Persons;
- Concern for Welfare; and
- Justice

At a minimum, the REB shall comply with and apply the requirements of the 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)*, 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. The REB has adopted the N2/CAREB Standard Operating Procedures and WCH-specific Addenda. The REB is also guided by WCH institutional policies, and trends in research ethics that may impact the research study at WCH.

## **REB MEMBERSHIP COMPOSITION**

The REB will consist of members both affiliated and non-affiliated with WCH and 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 and will include a diverse representation of lived and living experience. The REB will consist of at least 5 members, of whom:

- At least two members have expertise in relevant research disciplines, fields and scientific methodologies covered by the REB (for regulated

clinical trials, this will include at least one member who practices medicine or dentistry);

- At least one member is knowledgeable in ethics;
- At least one member is knowledgeable in Canadian laws relevant to the research being reviewed;
- At least one member is knowledgeable in considering privacy issues;
- At least one member is knowledgeable in complementary or alternative health care (where applicable)
- At least one community member who has no current affiliation with the sponsor, institution, and who is not part of the immediate family of a person who is affiliated with WCH
- at least one member whose primary area of expertise/interest is in a non-scientific discipline
- Any additional people with relevant expertise appointed by the Chair and/or as required by applicable legislation or guidelines.

A member may not fulfill more than two representative capacities during a Full Board meeting.

To ensure the independence of REB decision making, institutional senior administrators (Director level or above) shall not serve on the REB.

## **APPOINTMENT TO THE REB**

The Chair of the REB is an administrative position within WCH appointed by the hospital CEO in consultation with the Chair of the MAC of the Women's College Hospital Board of Directors. The Chair reports administratively to the hospital CEO or delegate and liaises with the University of Toronto on research ethics matters.

Chairs shall normally be appointed for a two (2) year term, subject to an annual review, and may be renewed at the discretion of the Women's College Hospital CEO or delegate in consultation with the Chair of the MAC.

The Chair must not occupy any administrative position or committee membership or other professional activity over the course of their term that may compromise the independence of the ethics review process at WCH.

The Members of the REB will normally serve for a term of two years. By mutual consent between Members and the Chair of the REB, members may be appointed for additional terms. Attempts will be made to stagger the terms of service to ensure continuity.

## **MEETINGS**

A schedule of REB review meetings will be regularly updated and communicated to Women's College Hospital researchers via the REB website so that Research can be planned in an orderly manner. Typically, these shall be monthly, though the Chair may call additional meetings if the need arises.

Attendance at REB meetings is crucial to the success of the review process. REB Members are expected to attend every REB meeting. Failure to attend a minimum of seventy five percent (75%) or 9 out of 12 scheduled meetings per year without explanation (i.e. sabbatical, maternity or parental leave) may result in a loss of membership to the REB. In the event that a REB member fails to meet these criteria, the appropriate Hospital leader will be notified by the Chair of the REB so that a replacement can be obtained.

The REB is entitled to invite researchers to a meeting to discuss a research study. Research team members shall not be present when the REB is deliberating.

The REB may permit observers to attend REB meetings at the discretion of the Chair. All observers must sign a confidentiality agreement.

### **QUORUM**

A quorum shall consist of at least 5 voting members of the REB representing the full range of membership and expertise as defined in the TCPS2 and as described above. For research which is subject to the US Code of Federal Regulations, quorum shall also include a majority (50% + 1) of the current voting members.

REB decisions will be made by a majority vote of REB members present at a convened REB meeting, and will not include those who have recused themselves due to a conflict of interest. Wherever possible, consensus will be sought.

### **APPEALS PROCESS**

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. The REB shall follow the TAHSN REB Appeals process.

### **CONFLICTS OF INTEREST**

Members of the REB must disclose any conflicts of interest regarding a proposal under review. Members may not be present for any REB discussion regarding a proposal in which they have any vested interest and may not participate in the decision process for such a proposal. The meeting minutes should reflect that a conflict of interest was declared and whether/when the REB member removed themselves from the deliberations.