Contact the Research Ethics Office: REB@bruyere.org
Visit the REB Website: https://www.bruyere.org/en/researchethicsboard

BRUYÈRE HEALTH RESEARCH ETHICS BOARD (REB)
TERMS OF REFERENCE

Date Established: January 1991

Revision History:
October 8, 2015
November 16, 2018
May 15, 2023
Oct 24, 2024 (technical revision only)

1. MANDATE:

The REB shall act in accordance with these Terms of Reference, the REB Standard Operating Procedures, as revised from time to time (collectively, the "SOPs"), the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans, as revised from time to time (the "TCPS2"), accepted research ethics standards and applicable legal and regulatory requirements, notably Federal and Ontario privacy legislation.

The REB at Bruyère Health shall strive to:

a) Provide impartial, fair, informed, and balanced review of proposed research at Bruyère Health involving people in accordance with its Scope of Authority, below;

b) Protect the dignity of research participants by ensuring that their participation in research studies is the result of informed consent voluntarily given without coercion or undue influence;

c) Protect the safety of research participants by ensuring that the risks of research participation are appropriately minimized and are justified by potential benefits;

d) Protect and safeguard personal information about research participants and others;

e) Provide special protection for vulnerable research participants who may lack the capacity to give informed consent, or may be subject to undue influence, and may therefore be unable to give free and informed consent in accordance with their own fundamental values;

f) Ensure that research studies conducted at Bruyère Health are conducted in accordance with Bruyère Health's mission and values and the Catholic Health Ethics Guide including research studies that are reviewed by the REB or by any other research ethics board on behalf of, or on appeal from, the REB.

g) Promote the integrity of the scientific endeavor;

h) Promote the effective stewardship of research resources at Bruyère Health;

i) Ensure that post-approval monitoring of ongoing studies and requests for changes in previously approved research studies comply with the terms and spirit of the original study approval and evolving circumstances;

2. REB REPORTING AND OPERATIONAL RESPONSIBILITY:

a) The REB reports to the Board of Directors of Bruyère Health through the Board Quality Committee (BQC).

b) The REB reports administratively to the Bruyère Health Research Institute (Bruyère Health RI) CEO/Vice President, Research and Academic Affairs via the Senior Director of Operations of the Bruyère Health RI who is accountable for the financial and administrative operations of the REB.

3. INDEPENDENCE:

The REB operates independently in decision-making with respect to its mandate under the current TCPS2. All other entities and offices shall respect the independence, accountability and authority delegated to the REB and may not override a decision of an REB to reject or require changes to a research protocol, or to suspend or withdraw its approval, except in accordance with the appeals procedure described below.

4. LINK TO STRATEGIC GOALS:

#2: Engaged people.
#5: Accelerate learning, research and innovation.

5. SCOPE OF AUTHORITY:

The REB has authority with respect the following research studies:

a) Research carried out, as Principal Investigator or Co-Investigator, or by any member of the Bruyère Health Community. Members of the Bruyère Health Community include all employees and health care providers of Bruyère Health, Bruyère Health RI or any independent Services, Programs, or Centers affiliated with Bruyère Health.

b) Any research involving participants who are i) registered patients and residents at Bruyère Health; or ii) employees health care providers and volunteers of Bruyère Health, or iii) any independent Services, Programs, or Centers affiliated with Bruyère Health, that relates to their clinical or other patient-related duties.

c) Studies for which Bruyère Health staff will carry out or assist in the recruitment of prospective participants.

6. FUNCTIONS AND RESPONSIBILITIES:

Unless determined by the REB to be exempt under the TCPS2 or the SOPs, all proposals for research involving human participants within the REB Scope of Authority must be submitted for review and approved by the REB before any research activities may commence.

7. PROPORTIONATE REVIEW:

Ethics review shall be proportionate to the level of risk to participants and researchers. To the extent that risk is greater, review of research protocols shall be more detailed and subject to greater scrutiny.

8. REB MEMBERSHIP AND COMPOSITION:

Composition:
The REB shall be multidisciplinary in nature and composed of individuals who have a demonstrated interest in research ethics. The majority of members shall be Canadian citizens or permanent residents of Canada. The membership of the REB shall, at a minimum, comply with the TCPS2 and the SOPs regarding numbers and composition.

a) **Chair:**
The Chair of the REB shall preside at REB meetings and generally supervise all ongoing activities of the REB, together with those duties described in the SOPs.

The Chair shall be appointed by the Bruyère Health Board of Directors with consultation from the Bruyère Health RI CEO/Vice President, Research and Academic Affairs via the Senior Director of Operations of the Bruyère Health RI to an initial fixed term, which shall be renewable.

b) **Vice-Chair:**
The Vice-Chair of the REB shall undertake the role and responsibilities of the Chair in their absence, and act as delegated decision-maker and signatory for the Chair as needed together with those duties described in the SOPs.

The Vice-Chair shall be appointed by the Bruyère Health RI CEO/Vice President, Research and Academic Affairs via the Senior Director of Operations of the Bruyère Health RI to an initial fixed term, which shall be renewable.

c) **Members:**
Excluding the Chair and the Vice-Chair, members shall be appointed by the Board Quality Committee and normally serve a two-year term which may be renewed at the discretion of the Board Quality Committee of the Board of Directors upon recommendation by the Chair.

d) **REB Sub-Committees:**
The REB may establish such permanent or ad hoc Sub-Committees as it considers necessary to undertake special or ongoing tasks relating to the review of proposed research at Bruyère Health, and any matters incidental to such review.

e) **Research Ethics Office:**
The Research Ethics Office shall serve as the administrator of the Board and shall support its work, and the work of the Board Chair, Vice-Chair and Sub-Committees as more fully described in the SOPs.

9. REB MEETINGS:

a) Frequency:
Meetings will be scheduled monthly at a set time and publicized in advance. At the discretion of the Chair, scheduled meetings may be cancelled if there is insufficient meeting business.

b) Quorum:
REB meeting quorum shall be not less than that required by the TCPS2 and shall, at a minimum, be greater than 50% of voting members (not counting alternate members if any).

c) Remote Participation using Virtual Technology:
Members and guests may join the meeting by teleconference, videoconference, or other technological means. Any member joining a meeting by such virtual means shall be provided with all meeting materials for prior review and be included in determining quorum for the meeting.

d) Confidentiality:
Study-related documents provided to REB members and the proceedings of REB meetings shall be confidential and generally not disclosed to others without the consent of the principal investigator of the study. Guests may be invited to attend a meeting of the REB if approved by the Chair but shall be subject to the same confidentiality of study information and meeting proceedings.

10. CATEGORIES OF REVIEW:

The REB may undertake the categories of review as more fully described in the SOPs, including but not limited to:

i) new study submissions of various categories of research;
ii) amendments to approved studies;
iii) continuing review of approved studies, and;
iv) renewals, closures and withdrawals of studies

Such categories of review, and requirements for their review, including the submission forms to be used, shall be as more fully described in the SOPs.

a) **Determination of Exemption from Board Review:**
The Chair may, consistent with the provisions of the TCPS2, determine that a proposed project is exempt from review. Such determinations may be delegated to the Vice-Chair, another REB member or members, a sub-committee of REB members, the Research Ethics Office, or otherwise as provided in the SOPs.

b) **Delegated Review:**
For each new study submitted for review, the Chair or Vice-Chair shall determine whether the study is eligible for delegated review, and in so doing shall be guided by the SOPs. Delegated review of research studies may be done by the Chair, Vice-Chair, another REB member, a Sub-Committee of REB members, or otherwise in accordance with the TCPS2 and the SOPs.

c) **Administrative Review:**
The Chair and/or the Research Ethics Office shall undertake an administrative review of new studies otherwise subject to the REB review in which the primary research site is an outside institution and the Study already has approval of such institution's REB or similar research ethics review committee.

d) **Full Board Review:**
All other submissions of new proposed studies shall be reviewed by the full REB at a properly constituted meeting in accordance with the procedures provided in the SOPs.

e) **Amendments:**
Study Amendments shall be reviewed by delegated review by the Chair, the Vice-Chair, another REB member, a sub-committee of REB members, the Research Ethics Office, or otherwise as set forth in the SOPs. However, where an amendment materially affects the risks to participants or significantly alters participants' rights or welfare, such amendment shall be referred for review by the full REB.

f) **Ongoing/Continuing Review:**
After a research proposal has been approved by the REB, the REB shall maintain ethical oversight of the research through a continuing review process and shall require such ongoing reporting as set forth in the SOPs. The Chair of the REB is responsible to ensure that:

i) The REB regularly reviews all adverse events reported by research investigators;

ii) The REB shall withdraw or suspend its approval from any study that does not comply with the approved Protocol or that poses new or significant increases in the level of risk to research participants not identified in the approved REB application. When the REB withdraws or suspends its approval, the activities of the research study must cease immediately and the study investigators must take appropriate steps, approved or imposed by the REB, to correct the breach and to ensure that the interests of the study participants are not adversely affected because of such actions.

g) **Renewal/Closure:**
New studies and renewals may be approved for, at most, one year, and the status of each approved study is therefore subject to renewal annually or sooner as determined at the time of initial or renewed approval. Upon expiry of the study approval period, studies must be renewed, failing which the REB approval shall lapse.

Active studies shall be closed at the request of the Principal Investigator so long as all activities involving research participants have been fully completed, including compiling and analyzing study data.

h) **Effect of Delegated and Administrative Review:**
Decisions made by delegated and administrative review are valid decisions of the REB. Completed delegated and administrative reviews shall be reported to the next occurring meeting of the REB for information and comment.

11. REB DECISION-MAKING:

Although attempts shall be made to reach a consensus, a majority of votes for or against a motion shall be the REB decision provided there is a quorum of the voting membership. Written submission will be considered when a member

cannot attend, but written submissions will not be considered as a vote for or against a decision. When the vote of the membership present is evenly split, and there is a quorum present, the Chair shall vote to yield a majority decision.

12. HARMONIZING MULTI-CENTRE REVIEW:

On the advice of the REB, and consistent with the TCPS2, for greater than minimal risk studies, Bruyère Health may enter into Agreements with other research institutions having the effect of structuring the ethics review of proposed studies under the authority of both the REB and of other research ethics review committee(s). Such Agreements may assign some or all of the REB's review authority to another ethics review committee and/or may assign additional review responsibilities to the REB. Such Agreements may relate to the review of a single proposed study or may be ongoing to cover all or any studies having shared authority with such other institution or institutions.

13. REB MEMBERS' CONFLICT OF INTEREST:

Any REB member having a conflict of interest with respect to any protocol, or any other member believing that a member has such a conflict of interest, shall declare that conflict no later than the beginning of the meeting and the conflict shall be managed by the Chair, or a majority vote of the REB, in accordance with the SOPs.

14. APPEALS:

The Principal Investigator of a study reviewed by the REB may appeal a decision of the REB by sending a written request for reconsideration to the Chair of the REB. When reviewing the appeal received from a Principal Investigator, the REB will follow the procedures outlined in the SOPs. This approach includes:

a) The REB shall reconsider its decision in light of additional information provided by the Principal Investigator that was not available to the REB members at the time the decision of the REB was made;

b) In the event of a final decision by an REB to deny approval of a study, if the Principal Investigator believes there have been procedural irregularities or bias by the REB, or if the Principal Investigator believes that the conditions required by the REB compromise the feasibility or integrity of the proposed research the Principal Investigator may send a request for appeal to the Bruyère Health RI CEO/VP of Research and Academic Affairs via the Bruyère Health RI Senior Director of Operations of the Bruyère Health RI to have the REB's process reviewed. An independent REB located at another institution and duly constituted under the TCPS2, will undertake an appeal review according to TCPS2 standards and the SOPs and in accordance with a written agreement between the institutions. Such appeal review shall be undertaken in accordance with Bruyère Health's mission and values and the Catholic Health Ethics Guide.

15. CONFLICT WITH CORPORATION BY-LAWS:

In case of conflict between this document and the By-laws of the corporation, the provisions outlined in the By-laws shall prevail.

16. EVAULATION:

Every 3 years.