

## REB Procedure: Brock University's Research Ethics Appeal Board

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The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018), better known as the TCPS2, requires Institutions to have established mechanisms and procedures in place for promptly handling Appeal from researchers when, after reconsideration, the REB has refused ethics approval of research.

In accordance with <u>Brock Faculty Handbook (FHB) Section III C: 2.2.5</u>, the REB follows its own established guidelines and procedures to propose candidate names for members of the REB Appeal Board, to the Research and Scholarship Policy Committee of Senate. The Research and Scholarship Policy Committee then recommends members of the Appeal Board to Senate.

# Brock University's REB Appeal Board

Per the <u>TCPS2</u> (Article 6.4), the membership of the REB must meet the following composition requirements:

Five members, including both men and women, of whom:

- a. at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- b. b. at least one member is knowledgeable in [research] ethics;
- c. c. at least one member is knowledgeable in the relevant law (but not the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research (please see supplementary document on page 5 and/or <a href="TCPS2">TCPS2</a> [Article 6.4] for additional information on the role of this non-faculty member); and
- d. d. at least one member is from the community and no affiliation with the institution (please see supplementary document on page 5 and/or <u>TCPS2 [Article 6.4)]</u> for additional information on the role of this non-faculty member).
- e. For a more fulsome rationale for the composition of the REB Appeal Board please refer to TCPS2 (Article 6.4).

#### **Conflict of Interest Policy**

Brock University's conflict of interest policy (<u>FHB Section III</u>, 2.2.8) will apply to the REB Appeal Board. Members of the Appeal Board must not have any interest or involvement in the case before them.

Normally, members currently sitting on either of Brock's two REBs will not be eligible for appointment to the REB Appeal Board. Exceptions to this rule are members knowledgeable in the relevant law and community members. These members will be appointed by the Manager, Research Ethics, on a case-to-case basis, according to need and relevance, and will be drawn from:

- current REB community members provided that they are not members of the REB whose decision is under appeal and they do not have an interest in, nor have they been involved in the research in question.
- past REB community members
- the community

## Term of Appointment

REB Appeal Board members will serve a term of two years with the option to renew.

## **Brock University REB Appeal Procedure**

As per TCPS2 Article 6.18-20: Where researchers do not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. Efforts will first be made to resolve a disagreement between the researcher and the REB through deliberation, consultation or advice. If that is not successful, researchers may appeal using the established appeal mechanism in accordance with Brock University REB procedures. The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before a researcher initiates an appeal. A decision of a REB to disallow research on ethical grounds, unless reversed on reconsideration by that REB, may only be reversed through the REB appeal process.

The appeal process is not a substitute for REBs and researchers working closely together to ensure high-quality ethical research, nor is it a forum to merely seek a second opinion. An appeal may only be launched for procedural or substantive reasons. The onus is on the researcher to justify the grounds on which they request an appeal and to indicate any breaches to the established research ethics review process or any elements of the REB decision that are not supported by the TCPS2.

- Requests for reconsideration and Appeal should be made in writing, to the Manager, Research Ethics, normally within 20 working days of the REB's final decision and include all relevant documentation detailing the grounds for reconsideration or appeal, including the desired remedy.
- Normally within 20 working days of receiving a request for an appeal, the Manager of Research Ethics will convene a meeting of the Research Ethics Appeal Board and provide the committee with the researcher's written appeal. The Manager will not participate in the appeal proceedings unless called upon by the Research Ethics Appeal Board Chair to represent the REB decision in question.
- The Research Ethics Appeal Board will review the request and determine whether there is sufficient basis for the case to be heard. This decision will be based on whether the researcher's request sufficiently outlines procedural or substantive reasons to justify grounds for an appeal, i.e. breaches to the established research ethics review process or elements of the REB decision that are not supported by the TCPS2. The decision of the Research Ethics Appeal Board as to whether or not the researcher has sufficient grounds to appeal shall be final and not subject to appeal itself.
- If the Research Ethics Appeal Board determines that the researcher's request sufficiently outlines procedural or substantive reasons to justify grounds for an appeal, they will select a Chair from amongst their members to preside over the case.
- The committee deliberations will consist of a review of the process by which the REB reached its decision and all relevant policy.
- Both the researcher and a representative of the REB shall be granted the opportunity to
  address the Research Ethics Appeal Board in person at a meeting(s) scheduled within 20
  working days of the Board convening. Neither the researcher nor the REB representative shall
  be present when Board deliberates and makes a decision.
- Should the Chair feel it necessary, the committee may call on ad hoc advisors for specific expertise, provided those individuals have not been involved in the initial REB decision or in the research. Ad hoc advisors will not be present when Board deliberates and makes a decision; they will have no vote on appeal decisions

- The committee shall function impartially to reach a decision in a timely manner.
- The Research Ethics Appeal Board has the authority to approve or reject a contested decision of the REB and may request modifications to a research proposal. Research Ethics Appeal Board decisions made on behalf of the institution shall be final.
- The Research Ethics Appeal Board shall provide both the researcher and the REB whose decision was appealed, with reasoned and appropriately documented opinions and decisions, in writing (in print or by electronic means) within seven working days of a decision.
- In the case of conflict of interest, or where a situation arises where either the Appeal Board or the researcher can demonstrate that the feasibility or integrity of the Appeal process is compromised, the Manager of Research Ethics may seek the cooperation of an external appeal board as laid out in the TCPS2 (Article 6.19).

## **Supplementary Document**

For additional context, please find an elaboration on the two non-faculty members positions below:

## Member Knowledgeable in the Relevant Law

- TCPS2 (Article 6.4) states that an understanding of relevant legal issues and contexts is advisable for all REBs (and by extension REB Appeal Boards as per Article 6.19), although for non-biomedical research legal insights may be sought from an ad hoc advisor consulted only for specific research projects.
- The role of the member knowledgeable in the law (<u>Article 6.4[c]</u>) is to alert the REB Appeal Board to legal issues pertaining to proposed research and their implications (e.g., privacy issues), not to provide formal legal opinions or to serve as legal counsel for the REB Appeal Board.
- The TCPS2 stipulates that the institution's legal counsel or risk manager should not be a member of the REB or its Appeal Board as their presence could undermine independence and credibility. In-house legal counsel may be seen to identify too closely with the institution's financial interest in having research go forward or, conversely, may be unduly concerned with protecting the institution from potential liability. Any external legal counsel hired on a case-by-case basis by the institution should not serve as a member of that institution's REBs while working for the institution. If legal issues are identified by the REB and/or Appeal Board they may necessitate further scrutiny and even formal legal advice by the legal counsel to the institution; however, legal liability is a separate issue for institutions to handle through mechanisms other than the REB.

## Community Member

- The participation of a community member is a TCPS2 requirement essential to help broaden the perspective and value base of the REB Appeal Board. The community member must not be affiliated with the institution. In addition to a broad-based representation from the community, it is highly desirable that institutions seek to appoint former research participants. Their experience as participants provides the REB with a vital perspective and an important contribution to the research ethics review process. It is advisable that members are not currently engaged in research or legal work as their principal activities.
- The role of community members on the REB Appeal Board during the ethics review process is unique and at arm's length from the institution. Their primary role is to reflect the perspective of the participants. This is particularly important when participants are vulnerable and/or risks to participants are high.

For a more fulsome rationale for the composition of the REB Appeal Board please refer to TCPS2 (Article 6.4).