

RESEARCH ETHICS PROTOCOL APPEAL PROCESS

Extracted from Dalhousie University *Policy on Ethical Conduct for Research Involving Humans*, approved by: Senate, May 12, 2008 (amended May 12, 2012), as part of the revised 2024 Policy (approved by Senate April 8, 2024).

Mandate of the Human Research Ethics Appeal Board

The University research ethics appeal board is convened to review appeals from University researchers when the University research ethics board has refused ethics approval of the research. Appeals follow the process and guidance as outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The appeal board may approve, reject or request modifications to the research proposal. Its decision on behalf of the University is final. The appeal board chair and members are appointed by the Vice President Research and Innovation and may not include any members from the research ethics board whose decision is under appeal. Likewise, administrative support is provided by the Office of the Vice President Research and Innovation rather than the research ethics office.

Membership

The Appeal Board will include at least five members, including both men and women, of whom:

- at least two members have broad expertise in human participant research
- at least one member is knowledgeable in ethics
- at least one member is knowledgeable in law
- at least one member has no affiliation with the institution but is recruited from the community served by the institution

In addition:

- Appeal Board members shall not be selected from among the current Chairs or members of the University REBs to avoid potential conflict of interest
- Quorum is 5 members, and must include the ethics specialist, the community member and the legal specialist
- Terms of membership are 3 years. Members may be reappointed with due consideration to the evolving requirements of the Appeal Board. Terms of members may be staggered to allow for continuity within the Appeal Board over time
- Administrative support to the Board is provided through Research Services, but should not include members Research Ethics.

Grounds for an Appeal

If a researcher has requested and received a reconsideration of a REB decision and is not satisfied with the decision of a University REB to reject his/her/their protocol, the researcher has the right to appeal a University REB's decision. The Appeal Board will review negative

REB decisions launched for procedural or substantive reasons (breaches of the review process or any elements of the REB decision that are not supported by the TCPS) (per Article 6.20).

Appeal Procedures

1. A Researcher requesting an appeal of a protocol rejection (the appellant) will do so in writing to the Chair of the University Research Ethics Appeal Board.
2. The appellant will be provided with a copy of all the documentation upon which the REB based its original decision to reject the protocol, including any external reviews that may have been solicited by the REB in the evaluation of the project, along with a copy of the main Research Ethics file.
3. The Appellant will then provide a written submission to the Chair describing the basis for the appeal.
4. The Chair will determine whether the allegation raises an appropriate ground for an appeal. The decision of the Chair regarding the eligibility for appeal is final.
5. If, in the opinion of the Chair, the allegation raises an appropriate ground for an appeal, the Chair will forward a copy of the appellant's written submission to the Director, Research Ethics for response, and will convene the Appeal Board.
6. Copies of all documentation considered by the REB relating to the review process will be provided to members of the Appeal Board including, but not limited to, any external reviews that might have been solicited in the evaluation of the project, along with a copy of the main Research Ethics file associated with the project. In addition a copy of the written submission of the Appellant and the Director, Research Ethics' response to this submission will be provided to the Appeal Board members.
7. The Appeal Board will meet with the appellant, the Director, Research Ethics and other persons deemed relevant to the discussion. Following the meeting, the Appeal Board will deliberate in camera. If external opinions are sought and received by the Appeal Board a copy will be provided to the Appellant and the Director, Research Ethics for comment. If necessary, more than one such meeting may be held, prior to the Appeal Board rendering a decision.
8. The Appeal Board has the authority to make the following determinations:
 - 1) was a substantive error made by the REB in applying the ethical principles supported by the TCPS made with respect to the original review and rejection of the protocol?
 - or
 - 2) was there a substantial failure in the REB review process?

If not, the original finding of the REB is upheld.

If so, the Appeal Board must make a further determination, namely, does the protocol

meet the requisite ethical standards of the TCPS and the Institution such that it may receive ethics approval?

If so, the Appeal Board may grant ethics approval of the protocol.
If not, the Appeal Board must reject the protocol.

9. The Appeal Board will undertake its deliberations in a timely fashion and communicate its decision in writing to the REB that originally rejected the project, the Principal Investigator of the project that was rejected, and Research Ethics. In doing so it must provide reasons for either overturning or upholding the REB's original decision.
10. After reaching a decision, the Appeal Board will submit a written report to the Vice President Research, copied to the Chair of the REB and the Principal Investigator. This report will address the Appeal Boards' findings both with respect to the REB's conduct of the original review and with respect to final ethical approval of the protocol.

Authority

Decisions of the Appeal Board are final.