

APPENDIX I

Appeals

Process

1. Researchers and REBs should make every effort to resolve disagreements they may have through deliberation, consultation or advice. Disagreement between the researcher and the REB over a decision that cannot be resolved through discussion and reconsideration can be resolved through the normal appeal process.
2. A Researcher may appeal a decision of a University constituted REB on procedural or substantive grounds to the Human Research Ethics Appeals Committee (HREAC).
3. A Notice of Appeal of an REB decision shall be sent to the Director, Office of Human Research Ethics and Compliance in writing which shall include:
 - (a) The grounds of the appeal, and
 - (b) Supporting documentation which may include a copy of the protocol submission, the decision of the REB, relevant correspondence between the Researcher and the REB, and any other pertinent information to assist HREAC in making its decision.

The onus is on the Researcher to demonstrate breaches in the review process or aspects of the REB decision not supported by the TCPS2.

4. Upon receiving the Notice of Appeal, the Director will acknowledge receipt and forward a copy of the Notice of Appeal to the Associate Vice-President (Research) (AVPR) and Chair of the REB making the original decision.
5. Within 10 working days of receipt of the Notice of Appeal, the REB Chair may provide a response to the Director and AVPR, clarifying the REB's decision.
6. Upon receipt of the Notice of Appeal, the AVPR will appoint members, on an ad hoc basis, to HREAC, paying attention to diversity considerations.

Human Research Ethics Appeals Committee

7. HREAC shall be comprised of:
 - (a) Two members with expertise in the discipline(s), fields, and methodologies being proposed by the Appellant,
 - (b) One member knowledgeable in ethics,
 - (c) One community member with no affiliation with the University, and
 - (d) Ad hoc experts if required.

The AVPR will appoint a member of HERC to chair HREAC in a non-voting capacity.

No members of the REB involved in making the original decision can serve on HREAC. Potential members must be free of all conflicts of interest before being appointed.

8. HREAC must hear the appeal within 45 working days of receipt of the Notice of Appeal by the AVPR. Logistics for the hearing will be supported by Office of Human Research Ethics.
9. HREAC:
 - (a) May seek additional information and/or documentation prior to hearing the appeal,
 - (b) Shall invite the Researcher and/or an REB representative to speak to the matters raised in the Notice of Appeal at the hearing,
 - (c) Approve, not approve, or request modifications to the submitted protocol.The decision of HREAC is final.
10. HREAC shall send its written decision to the AVPR within 10 working days of its decision.
11. Upon receipt, the AVPR shall forward the decision to the Researcher, the REB Chair, and Director forthwith.
12. The REB Chair, in conjunction with the Researcher, will be responsible for any implementation and follow-up as required.