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## **1) Reconsideration of REB Decision**

A Principal Investigator has the right to request the REB or Sub-REB to reconsider its opinion or decision regarding his/her ethics protocol submission. (TCPS Article 1.10) If a Principal Investigator asks for a reconsideration, the REB or Sub-REB will provide that Investigator with a reasonable opportunity to rebut the reasons given for the REB'S or Sub-REB's opinion or decision. The nature of the opportunity provided to the researcher will be at the discretion of the REB or Sub-REB. These opportunities may include, but are not limited to written submissions, attendance at the REB meeting or review by experts. The REB or Sub-REB will then reconsider the information provided and provide reasoned and written grounds for its reconsidered opinion or decision.

## **2) Appeals**

### **2.1 Terms of Reference**

Principal Investigators have the right to request an appeal of an REB decision to reject or require a substantial methodological modification of a protocol submission once the REB has issued a final decision. The scope of any appeal will be limited to jurisdictional and procedural issues. That is, the Appeal Committee will determine whether the REB acted outside its mandate and/or committed a breach of the process for ethics review as set out in the most recent version of the UWO HSREB or NMREB Guidelines and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The Appeal Committee has no jurisdiction to make a decision regarding the ethical acceptability of the research study involved in the process under appeal. It should be stressed that the appeals process is not a substitute for the REB and the researcher working closely together to ensure high quality research, nor is it a forum to merely seek a second opinion. It is expected that an appeal will be an exceptionally rare occurrence.

### **2.2 Process**

To request an appeal, the Principal Investigator should submit a letter to the Manager of the Office of Research Ethics within 30 days of receiving the Notification of Decision from the REB. An extension of the time to appeal may be granted at the discretion of the Chair of the appropriate REB. The Manager will confirm which committee should review the appeal (see below) and give the letter to the appropriate Chair or his/her designate for action. At a minimum, this letter should indicate the grounds for the appeal and provide a summary of the information and material supporting the grounds for appeal. Investigators and REBs may be asked for additional information to assist the Appeal Committee with its decision-making. The Office of Research Ethics will act as the Secretariat for any appeals process.

Upon receipt of the letter, the Chair of the Appeal Committee and one other member, selected by the Chair, will first decide, in their discretion, whether or not the appeal merits review by the full Appeal Committee. If it is decided that the appeal does not merit review, the appeal shall be dismissed with reasons provided to the PI in writing. If it is decided that the requested appeal merits review, the Chair of the Appeal Committee will convene a meeting of the Appeal Committee and invite the investigator(s) and responsible REB Chair (or designate) to attend and make submissions on the review process regarding the protocol in question. Additional resource persons or experts may also be invited to attend at the discretion of the Chair of the Appeal Committee.

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The Appeal Committee shall establish rules governing the process to be followed at the meeting.

Appeals will be heard within 60 days of receipt of the letter in the Office of Research Ethics. The Appeal Committee **shall**:

- a) dismiss the Appeal; or
- b) declare the original REB decision void and direct the responsible REB or Sub-REB to reconsider the application; or,
- c) in the case of protocols reviewed by Delegated, Faculty or Departmental Sub-REBs, direct the investigator to submit the protocol, as a new submission, for review by the Full Board of either the NMREB or the HSREB.

A decision and comments supporting the decision will be provided in writing to the Principal Investigator and responsible REB/Sub-REB Chair within 30 days of the termination of the hearing. *Decisions of the Appeal Committee are final and not subject to further appeal within the University or affiliated institutions that utilize the UWO REBs.*

### **2.3 Appeal Committee regarding decisions made by the NMREB and the HSREB (Full Board)**

The University Council on Research Ethics (UCRE) will act as the Appeal Committee for Full Board decisions of the NMREB and the HSREB. The Chair of UCRE will act as the Chair of the Appeal Committee or designate an alternate Chair from the membership. The Chair and all members of UCRE (or their designated alternates) have voting privileges with regard to the appeal. A quorum of 5 voting members in attendance is required. Any member of UCRE who is in a perceived or actual conflict of interest will be excused from the Appeal proceedings.

### **2.4 Appeals regarding decisions made by Expedited review & Departmental or Faculty Sub-REBs**

- The HSREB will act as the Appeal Committee for decisions made by Delegated review for the HSREB.
- The NMREB will act as the Appeal Committee for decisions made by Delegated review or the Departmental or Faculty Sub-REBs that report to the NMREB.

The Chair of the appropriate REB will act as the Chair of the Appeal Committee or designate an alternate Chair from the membership. The Chair and all regular members (or their designated alternates) of the appropriate REB have voting privileges with regard to the appeal. A quorum of 5 voting members in attendance is required. Any member of the REB who is in a perceived or actual conflict of interest will be excused from the Appeal proceedings.