

	<b>RESEARCH ETHICS BOARD</b>	
	<b>STANDARD OPERATING PROCEDURES</b>	
	<b>SOP Number</b>	408
	<b>Reconsideration and Appeals</b>	
	<b>Date of Issue</b>	2008 04 29
	<b>Date of Revision</b>	2012 01 14
		2017 06 09
		2018 03 30
		2022 07 13
<p><b>Purpose:</b> The purpose of this standard operating procedure (SOP) is to describe to process by which as Researcher may seek reconsideration of an REB decision, and ultimately, appeal the REB decision.</p> <p><b>Directive:</b> Fraser Health Policy “The Ethical Conduct of Research and Other Studies Involving Human Participants”</p> <p><b>Responsibility:</b> The VP responsible for Research, REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.</p>		

## Procedure

The REB is guided by the principles of respect for persons, concern for welfare and justice in its decision-making. In fulfilling its mandate, the REB functions impartially, provides a fair hearing to researchers involved, and provides reasoned and appropriately documented opinions and decisions.

### 1.0 Reconsideration

- 1.1 A Researcher may request, and the REB has an obligation to provide, prompt reconsideration of the REB’s decision. Initial consideration may be by way of informal discussions between the Researcher and the REB Chair;
- 1.2 If the matter is resolved through this informal process, the resolution will be documented in the study file and study materials as appropriate;
- 1.3 If informal discussions do not result in a resolution of the issues, the Researcher may request formal reconsideration. In order to receive formal reconsideration, the Researcher shall submit a written request to the relevant REB;
- 1.4 Reconsideration will take place at the next regularly scheduled Full Board Meeting;

- 1.5 The onus is on the Researcher to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by the Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS 2), the Fraser Health Policy on Ethical Conduct of Research and Other Studies Involving Human Participants, or the Fraser Health REB standard operating procedures;
- 1.6 The Researcher may provide additional information for the Board's consideration, and may also attend the Full Board Meeting; however, the Researcher shall not be present during the REB's deliberations;
- 1.7 The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full Board meeting;
- 1.8 The Researcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeal.

## **2.0 Notice of Appeal**

- 2.1 If, after the completion of the relevant REB's reconsideration, a Researcher is still not satisfied with the decision made by a REB, the Researcher may seek an appeal of that decision by sending a written Notice of Appeal to the REB Office;
- 2.2 The written Notice of Appeal must be filed with the REB Office within thirty (30) working days of the final decision being received by the Researcher;
- 2.3 The appeal process is NOT a forum to merely seek a second opinion of the REB's decision. Instead, the Notice of Appeal must clearly state the grounds on which the appeal is being made and should be accompanied by supporting documentation. Such supporting documentation may include (but is not limited to):
  - The original REB application,
  - The original REB decision,
  - All subsequent written communications between the REB and the Researcher,
  - Documents and records, including a copy of the funding proposal (if appropriate),
  - Relevant references or copies of pertinent guidelines, internal and external policies, and legislation;
- 2.4 An appeal may be based on procedural grounds (e.g. alleged noncompliance with the REB's procedures) or substantive grounds (e.g. alleged noncompliance with a specific article of the TCPS 2 or a relevant regulation or guideline);
- 2.5 The REB Office will acknowledge receipt of the Notice of Appeal in writing and issue a waiver to the Researcher, which must be signed by the Researcher prior to initiation of the appeal procedures;

### **3.0 Composition of the Research Ethics Appeal Committee**

- 3.1 The Island Health REB serves as the appeal committee for Fraser Health. The composition of the appeal committee is set by the Island Health REB's respective SOPs;
- 3.2 For studies submitted for harmonized review via the Provincial Research Ethics Platform, the appeal committee will be appointed by the board of record in accordance with the board of record's respective REB SOPs;
- 3.3 Where Fraser Health is appointed as the appeal committee, the Chair of the REB, in conjunction with the Manager of Research Ethics & Compliance, shall appoint members to the Research Ethics Appeal Committee (REAC) for the purpose of hearing the appeal;
- 3.4 The composition of the REAC must reflect the range of expertise and knowledge similar to that of the REB whose decision is being appealed, and must also meet the procedural requirements of the TCPS 2.
- 3.5 Specifically, the REAC shall consist of at least five (5) members, including both men and women, of whom:
  - at least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB,
  - at least one member shall be knowledgeable in ethics,
  - at least one member shall be knowledgeable in law, and
  - at least one member shall have no affiliation with Fraser Health, but shall be recruited from the community served by the Health Authority;
- 3.6 The REAC may appoint ad hoc experts as required;
- 3.7 Members of the REAC must all be free of conflicts of interest in relation to the study under appeal. In addition, no member of the Appeal Committee may be a member of the REB whose decision is under appeal, or can have been a member of the REB when the decision being appealed was made;
- 3.8 The REAC will be appointed on an ad hoc basis;
- 3.9 The REAC will appoint one of its members to serve as Committee Chair.

### **4.0 The Appeal**

- 4.1 The onus is on the Researcher who filed the Notice of Appeal to justify the grounds of the appeal, and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS 2, the Fraser Health Policy on Ethical Conduct of Research and Other Studies Involving Human Participants, or the Fraser Health REB standard operating procedures;

- 4.2 The REAC shall have the authority to review negative decisions made by the REB. In doing so, it may approve, reject, or request modifications to the research proposal. Its decision on behalf of the institution shall be final;
- 4.3 The REB Office will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the REAC for review, with a copy to the REB Chair whose decision is under review and the Researcher;
- 4.4 A meeting of the REAC, with provision for presentations by both the Researcher and REB Chair or designee will be organized by the REB Office and held within thirty (30) days of receipt of the Notice of Appeal by the REB Office;
- 4.5 Both the Researcher and the REB representative have the right to speak to any issues raised in the Notice of Appeal and supporting documentation, and the REAC may ask questions throughout the process. Neither party shall be present when the REAC deliberates and makes a decision;
- 4.6 The majority decision of the REAC will be final and binding and will normally be communicated within ten (10) days of the meeting;
- 4.7 The Chair of the REAC will communicate the decision of the REAC in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision of the Researcher, the REB Chair, the REAC and the REB Office Personnel;
- 4.8 The REB Chair will be responsible for any implementation and follow-up required through the REB.