

Approval Date: February 11, 2011 Effective Date: May 11, 2011

Parent Policy: [Human Research Ethics Policy](#)

Human Research Ethics Appeals Procedure

Office of Administrative Responsibility:	Research Ethics Office
Approver:	Vice-President (Research)
Scope:	Compliance with this procedure extends to all persons who conduct research involving humans within the jurisdiction or under the auspices of the University of Alberta.

Overview

A **researcher** has the right to request, and a **REB** has an obligation to provide, reconsideration of a decision by that REB to reject or provide conditional approval of a request for ethics approval of **research involving humans**. If the researcher and the REB cannot achieve agreement through such reconsideration, the researcher may appeal that disputed decision of the REB in accordance with this Appeals.

Purpose

To describe the basic procedure for the appeal of a disputed decision by a REB.

PROCEDURE

1. RIGHT TO AND INITIATION OF APPEAL

a. If after exhausting all reasonable informal attempts to resolve a disputed decision of a REB cooperatively, including deliberation, consultation or advice, and following reconsideration of that disputed decision, an **applicant** continues to dispute that REB decision, the applicant may appeal that decision.

b. An appeal of a disputed REB decision may be made by an applicant only in writing outlining the grounds for the appeal, including any alleged breaches to the established research ethics review process or any elements of the REB decision that are not supported by the **Policy**, and accompanied by supporting documentation. The written appeal and supporting documents must be submitted to the Administrative Director - Research Ethics Office within thirty (30) working days (days that the administrative offices of the University of Alberta are open for business) of receipt by the applicant of the written REB decision of such reconsideration. The disputed decision may be the subject of only a single appeal by the applicant.

c. The Administrative Director - Research Ethics Office shall acknowledge receipt of the appeal in writing to the applicant and shall forward a copy of the appeal and supporting documentation to the **Responding Chair**. The Responding Chair shall provide a written response to the appeal within ten (10) working days of receipt of the request.

d. The written response of the Responding Chair shall minimally include the following information:

- i. all documents available at the REB meetings related to the decision being appealed;
- ii. a response to the applicant's grounds for appeal; and
- iii. the steps taken to resolve the dispute.

The Administrative Director – Research Ethics Office shall ensure that each of the applicant and the Responding Chair receive copies of all materials provided by the other and a list of the **members of Research Ethics Board Oversight Committee**. The Administrative Director – Research Ethics Office shall provide each member of the Research Ethics Board Oversight Committee with a notice of the appeal.

e. Any timeline set forth in this Appeals Procedure, other than that set forth in paragraph 1 b., may be modified prior to its expiration by agreement between the applicant and the Responding Chair.

2. SELECTION OF APPEAL COMMITTEE

a. A member of the Research Ethics Board Oversight Committee must within five (5) days of receipt of the notice of appeal from the Administrative Director – Research Ethics Office disclose real or potential conflicts of interests to the Administrative Director – Research Ethics Office. If any such real or potential conflict of interests is disclosed, the member disclosing such conflict shall not be selected as a member of the Appeal Committee for that appeal. No member of the REB whose decision is under appeal shall serve on the Appeal Committee.

b. Each of the applicant and the Responding Chair has the right to challenge any member of the Research Ethics Board Oversight Committee regarding conflicts of interests. Challenges may only be made on the grounds that the member has a real or potential conflict of interests and must include written reasons to support the challenge. A Research Ethics Board Oversight Committee member who is challenged by either the applicant or the Responding Chair shall not be called on to serve on the Appeal Committee unless the challenge is, in accordance with the balance of this paragraph, determined to be not valid. If the Administrative Director – Research Ethics Office determines in relation to an appeal that the number of members of the Research Ethics Board Oversight Committee excluded through automatic acceptance of challenges would prevent the selection of the required number of qualified members to serve as an ad hoc Appeal Committee, the Administrative Director – Research Ethics Office shall consider each challenge and shall make the final decision as to whether or not each such challenges is valid.

c. The Administrative Director - Research Ethics Office shall select no fewer than five members of the Research Ethics Board Oversight Committee, not otherwise excluded by challenge or recusal, to serve as an hoc Appeal Committee and shall designate one of those members as the Chair of the Appeal Committee. The composition of the Appeal Committee must reflect a range of expertise and knowledge similar to that of the REB whose decision is under appeal.

d. The Appeal Committee may approve, reject or request modifications to the research proposal to which the disputed decision rates.

3. APPEAL

a. The Administrative Director – Research Ethics Office shall convene a meeting of the Appeal Committee within thirty (30) working days of receipt of the appeal. That meeting shall include provision for presentations by the applicant and the Responding Chair.

b. The Appeal Committee may request additional material from either the applicant or the Responding Chair, may seek advice from an expert witness and may have a resource person or persons attend any or all portion of its hearings.

c. The Appeal Committee shall, as part of the appeal process, determine whether all reasonable attempts to resolve the disputed decision cooperatively have been exhausted. If it determines such reasonable attempts have not been exhausted, it may require the applicant and the REB whose decision is being appealed to continue those reasonable attempts prior to completing the hearing of the appeal.

d. The applicant shall be given the opportunity to present the grounds for the appeal and speak to the issues. The Responding Chair shall be given the opportunity to present the reasons for the decision of the REB and speak to the issues. The applicant, the Responding Chair and the Appeal Committee may call witnesses and question the parties.

e. The Appeal Committee, having heard the oral presentations of both parties and having reviewed the written presentation and supporting documentation, shall following *in camera* deliberations, reach a decision by majority vote.

f. The Appeal Committee may approve, reject or request modification to the research proposal to which the disputed decision relates.

g. The Appeal Committee shall, within ten (10) days of the appeal hearing, provide a written decision to the Administrative Director - Research Ethics Office. The Administrative Director - Research Ethics Office shall transmit the decision to the applicant and, through the Responding Chair to the REB, whose decision was appealed, the latter for implementation and follow-up as required. The Administrative Director – Research Ethics Office shall also transmit the decision to such other parties as deemed appropriate by the Appeal Committee.

h. All decisions made by the Appeal Committee are final and binding.

DEFINITIONS

Any definitions listed in the following table apply to this document only with no implied or intended institution-wide use. [▲Top](#)

Research	<p>An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.</p> <p>The following activities, in the absence of a specific element of research, do not generally fall within this definition:</p> <ul style="list-style-type: none"> - Procedures and practices exclusively used for pedagogic purposes including classroom discussion, practicum observation, student-teacher interviews and consultations, interviews and consultations with experts for teaching and learning purposes, testing within normal educational requirements and teaching evaluations - Normal practice of a profession including medicine, law and engineering - Quality assurance studies and performance reviews of an organization or its employees or students within the mandate of the organization or according to the terms and condition of employment or training.
Research Involving Humans	<p>Research involving participants.</p> <p>Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.</p> <p>Research involving secondary use of data.</p> <p>Research involving participants does not include the following research which is deemed excluded from such term:</p> <ul style="list-style-type: none"> - Research about a living individual based on published or publicly available information, documents, records, works, performances or archival materials which involves no interaction with that individual or a third party; - Research about a living individual based on observation of participation by that individual in public events where that individual is seeking public visibility which involves no interaction with that individual or a third party.

Researcher	<p>A person who:</p> <ul style="list-style-type: none"> - is a member who conducts or advances research either: <ul style="list-style-type: none"> (i) in that capacity; (ii) as Supplementary Professional Activity as defined in the University of Alberta Faculty Agreement; or (iii) otherwise under the auspices of the University of Alberta; - is a member who accesses University of Alberta students or staff as participants; - is not a member but conducts research within the jurisdiction of the University of Alberta.
REB	Research Ethics Board authorized by the Vice-President (Research) to review and approve, propose modifications to, reject or terminate research involving humans using the considerations set out in this Policy.
Applicant	A person that submits an application for an approval to a REB.
Policy	The University of Alberta Human Research Ethics Policy.
Responding Chair	The Chair of a REB the decision of which is the subject of an appeal pursuant to the Procedures or the designate of that Chair.
Member	Person who is a member of the faculty, the emeritus faculty or the staff of the University of Alberta or who is a sessional instructor, administrator, student, post-doctoral fellow, visiting or adjunct scholar, fellow, chair, paid or unpaid research associate or assistant of or at the University of Alberta and any person in a like position.
Research Ethics Board Oversight Committee	Body established by the Vice-President (Research) to oversee the relevant function and performance of REBs and to develop and review procedures to ensure compliance of the REBs with this Policy and its Procedures.
Procedures	The Procedures, from time to time, in force with respect to the Policy.
Participant	<p>A living individual who is the subject or one of the subjects of research involving humans.</p> <p>An identifiable individual, living or deceased:</p> <ul style="list-style-type: none"> - whose body is the human remains or cadaver; - from whose body was obtained human remains, tissue, biological fluid, embryo or foetus; <p>which is the subject of research involving humans.</p>
Secondary Use of Data	<p>Refers to the use in research of data contained in records collected for a purpose other than the proposed research itself. Common examples are patient or school records or biological specimens, originally obtained or produced for therapeutic, educational or other research purposes, but subsequently are proposed for use in research involving humans.</p> <p>Also refers to instances in which data is obtained for one REB approved project, but subsequently are proposed for use in new research involving</p>

	humans.
Vice-President (Research)	Vice-President (Research) of the University of Alberta.

FORMS

There are no forms for this Procedure. [▲ Top](#)

RELATED LINKS

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[Human Ethics Research Online \(HERO\)](#) (University of Alberta)

[Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#) (Government of Canada)