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

Human Research Ethics Board Structure, Application and Review 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

The University of Alberta serves the community by the dissemination of knowledge through teaching and the discovery of knowledge through **research**. The University of Alberta is committed to excellence in research based on the highest national and international standards which resulted in the adoption by the University of Alberta of the **Policy** and requires a statement of the structure of **REBs**, the decision making and review requirements of REBs and the application and review process.

Purpose

- Define the structure of REBs at the University of Alberta.
- Define the decision making and review requirements for ethics review of research involving humans.
- Describe the basic **procedures** for application and ethics review of research involving humans.

PROCEDURE

1. STRUCTURE OF REBs and GENERAL CONSIDERATIONS

- a. The University of Alberta through the **Vice-President (Research)** shall establish such number of REBs as determined appropriate from time to time by the Vice-President (Research) which REBs shall be organized around specific ethics concerns.
- b. It is the joint responsibility of the **researcher** and the REB to ensure the ethical conduct of research involving humans.
- c. The REBs shall apply the core principles and ethical principles adopted pursuant to the Policy in review of an application, in order to consider the implications of the research proposal in the application at various levels: the individual, institutional, organizational, community, cultural and societal. The REB and its **members** should not base their approval on epistemological, ontological, methodological or theoretical preferences, but should be aware of, and be willing to consider and suggest, a range of approaches to promote the ethical conduct of research involving humans.
- d. The REBs shall adopt a proportionate approach to research ethics review. The more potentially harmful the proposed research is to **participants**, the greater shall be the level of scrutiny that it receives. Ethics review shall be based upon fully detailed ethics applications submitted for review through the HERO system. HERO records shall be the official records of the initial assessment and ongoing review of human research. Approval by only one REB is necessary and no ethics application shall require approval from more than one REB. An **applicant** may not submit the same application to more than one REB.

e. The REBs shall function impartially, provide a fair review to a researcher with respect to an application and provide reasoned and appropriately documented opinions and decisions. The REBs should make their decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate all approvals and refusals to researchers in writing, in print or by electronic means.

2. DECISION MAKING AND REVIEW REQUIREMENTS

a. The REB Chair (or designate) shall make a preliminary determination whether proposed research involving humans in an application for **approval** involves more than **minimal risk**.

b. If the determination of the REB Chair (or designate) is that such proposed research involving humans does not involve more than minimal risk the application may be referred by the REB Chair (or designate) for Delegated Review.

c. While the disposition of any individual review rests solely and exclusively with either the REB or, in the event of an appeal, with the appeal committee composed of members from the **Research Ethics Board Oversight Committee**, the REBs are accountable to the University of Alberta for their processes and procedures. In the event of a disagreement as to the interpretation or application of processes or procedures, other than the **Procedures**, the Chair of the Research Ethics Board Oversight Committee shall have final authority.

d. An approval, in the absence of a renewal, is valid for twelve (12) months from the date of issuance or for such shorter period of time specified in the approval. Where research involving humans requires ongoing REB approval pursuant to the Policy in excess of the period for which an approval applies, it is the responsibility of the applicant to ensure that an application for renewal of the approval, including reporting of any changes to the study protocol or staff (including any adverse events in the research) is made in sufficient time prior to the expiry date of the approval to permit prior review of that application for renewal. A REB Chair may require a researcher to submit a fully detailed updated version of the original application by way of an application for a renewal of an approval or when otherwise deemed appropriate by such REB Chair.

e. Prior to implementing any substantive change to research involving humans to approved research, except where necessary to eliminate an immediate risk to the participants, the applicant must submit, and receive REB approval for, a request for amendment to the REB that issued the approval. Where a substantive change necessary to eliminate an immediate risk to participants is made without the applicant submitting a request for amendment, such request shall be submitted as soon as reasonably possible following implementation of that change. In case of doubt as to whether a change is substantive the applicant should discuss the change with the **REBA** and may rely on the decision of the REBA as to whether such change is substantive. Any request for an amendment shall be considered according to the proportionate approach to review regarding the risk associated with the change proposed as well as the degree of departure from the original proposal.

f. Requests for exceptions to review procedures stated in this Procedure to apply “typically” shall be considered by the REB Chair on a case-by-case basis. An applicant must justify the need for the exception, appealing to particular obligations to meet particular criteria as set out by specific research contexts, agreements or international requirements. REBs shall endeavor to review these exceptions as quickly as possible once all necessary information has been provided by the applicant.

3. APPLICATION AND REVIEW PROCESSES

General Requirements

All applications for human ethics review at the U of A shall be routed through *Human Ethics Research Online* (HERO), an online application, distribution, and data management system. Applicants shall choose one REB to review their application. The receiving REB may redirect any application that would be more suitably reviewed by another REB and notify the applicant as necessary. Upon completion and submission, applications for REB review shall be received by a REBA or a REB Chair following which the REB Chair (or designate) shall make assessment referred to in Section 2 a. above. Where special cases of research, for instance stem cell research or research funded by the US Department of Health and Human Services, require unique ethics review processes, the requirements shall be met through modification to regular Full Board Review processes.

Delegated Review

In the case of a Delegated Review, the REBA on instructions of the REB Chair (or designate) shall send the application to a single designated voting member of the REB who is delegated the authority to both review and approve the application. The following process applies to Delegated review.

- a. The delegated reviewer shall either confirm or reject the preliminary determination of the Chair (or designate) referred to in Section 2 a. of this Procedure that the application is no more than minimal risk and therefore suitable for Delegated Review.
- b. If the delegated reviewer rejects the preliminary determination that the proposed research involving humans in an application for approval is no more than minimal risk the application shall be referred for Full Board Review.
- c. If the delegated reviewer confirms the preliminary determination that the proposed research involving humans in an application for approval is no more than minimal risk, then the single designated reviewer shall proceed with an assessment of the application.
- d. The delegated reviewer may call on other reviewers who are members of the REB for assistance in the delegated reviewer's assessment of the application. If the delegated reviewer determines additional expertise, beyond that which can be provided by other reviewers who are members of the REB, is necessary for appropriate review, the delegated reviewer shall seek the assistance of a member of the **Expert Resource Pool** or other appropriate assistance.
- e. The delegated reviewer may refer the application for Full Board Review if the delegated reviewer deems the same appropriate.
- f. The delegated reviewer may in the assessment of the application request further information or clarifications from the applicant and the applicant shall provide the designated reviewer with such information or clarifications.
- g. If the delegated reviewer considers a negative decision resulting in the refusal of approval that potential negative decision shall be referred to the full REB for review and endorsement before the decision is communicated to the applicant.
- h. The delegated reviewer may in the assessment of the application request changes to the study protocol and supporting materials judged to be necessary to bring the proposed work into compliance with, or to permit the request for approval to be granted pursuant to, the Policy and its Procedures.
- i. This Delegated Review process is normally completed in writing, supported by the REBA.
- j. The applicant shall respond to the requests of the delegated reviewer and if the delegated reviewer is satisfied with such response the delegated reviewer shall issue the approval.
- k. The issuance of an approval through a Delegated Review shall be then reported to the Full Board at its next meeting for information.
- l. In the case of Delegated Review the decision of the delegated reviewer, on behalf of the REB, to issue an approval shall be final and shall be reported to the full REB for information only to permit the REB to maintain surveillance over its Delegated Review process.

Full Board Review

- a. In the case of a Full Board Review, the application shall be distributed to all members of the REB, but shall be specifically reviewed by two primary reviewers as well as the REB Chair or Associate Chair, and the community member(s) who is/are required to participate in all Full Board Reviews.

- b. If the REB Chair or one of the primary reviewers determines additional expertise, beyond that which can be provided by other members of the REB is necessary for appropriate review, the assistance of a member of the Expert Resource Pool or other appropriate assistance shall be sought.
- c. Typically the applicant (and if applicant is a trainee, that applicant's supervisor) shall attend the REB meeting at which the application of the applicant is being considered.
- d. The primary reviewers shall to the extent they deem it necessary discuss the application with the applicant to be satisfied that they understand the proposed research sufficiently to determine the ethical implications of the proposed research involving humans.
- e. The primary reviewers shall to the extent they deem it necessary also specifically discuss the relevant ethical implications of the proposed research involving humans with the applicant.
- f. All members of the REB shall be entitled to ask questions of the applicant and the community member shall comment on the application. These discussions typically take about fifteen (15) minutes per applicant.
- g. If the REB determines that an approval may be issued following satisfaction of requirements imposed by the REB with respect to such research involving humans, including the supporting material (such as an information letter or consent process) required in relation to such research involving humans, those requirements shall be communicated in writing to the applicant by the REBA. Upon the REB Chair confirming that the applicant has complied with those communicated requirements to the satisfaction of the REB Chair the approval shall be issued.

DEFINITIONS

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

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.
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

	<p>requirements and teaching evaluations</p> <ul style="list-style-type: none"> - 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.
Policy	The University of Alberta Human Research Ethics Policy.
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 the Policy.
Procedures	The Procedures, from time to time, in force with respect to the Policy.
Vice-President (Research)	Vice-President (Research) of the University of Alberta
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.
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.
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>
Applicant	A person that submits an application for an approval to a REB.
Approval	An ethics approval granted in accordance with the Policy and its Procedures by an REB for proposed research involving humans.
Minimal Risk	The level of risk where the probability and magnitude of possible harms and discomforts to participants from participation in research involving humans is no greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological

	examinations or tests.
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.
REBA	Research Ethics Board Administrator.
Expert Resource Pool	A pool of individuals, maintained by the Research Ethics Office, who may be called on as ad-hoc advisors to, and guest reviewers for, the REBs in order to ensure the best possible inclusion of specialized expertise in the review of ethics applications.
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 humans.</p>

FORMS

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

RELATED LINKS

Should a link fail, please contact uappol@ualberta.ca. [[▲Top](#)]

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

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