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## Ethical Conduct for Research Involving Humans Procedures

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<b>Policy Sponsor:</b>	Office of the Provost and Vice President, Academic
<b>Name of Parent Policy:</b>	<a href="#">Ethical Conduct for Research Involving Humans Policy</a>
<b>Policy Contact:</b>	Research Ethics Officer, Research Centre
<b>Procedure Contact:</b>	Research Ethics Officer, Research Centre
<b>Effective Date of Procedures:</b>	March 23, 2016
<b>Review Date:</b>	Annually

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### Purpose

To outline the procedures for application and ethics review of research involving humans.

### Definitions

Concern for Welfare	A core ethical principle that requires researchers and research ethics boards to aim to protect the welfare of participants (i.e., the quality of a person's experience of life in all its aspects and the impact on individuals of factors such as their physical, mental, and spiritual health, as well as their physical, economic, and social circumstances).
Conflict of Interest	The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research such that one cannot be fulfilled without compromising another. A conflict of interest may arise in research when activities or situations place an individual in a real, potential, or perceived conflict between the duties and responsibilities related to the research interests, and personal, institutional, or other interests (including, but not limited to, business, commercial, or financial interests).



Delegated Reviewers	Appointed members of the Research Ethics Board of Athabasca University or faculty members of University graduate programs appointed by the Research Ethics Board to review minimal-risk graduate student applications for ethical approval.
Harm	Anything that has a negative effect on a Participant's welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical, or economic.
Human (Participant)	An individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to in other policies/guidance as "subject" or "research subject."
Human Biological Materials	Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. This term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues, and human reproductive materials.
Institution	Universities, hospitals, colleges, research institutes, centres, and other organizations eligible to receive and manage Tri-Agency grant funds on behalf of grant holders and the Agencies.
Minimal Risk Research	Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by Participants in the aspects of their everyday life that relate to the research.
Proportionate Approach (to research ethics review)	The assessment of foreseeable Risk to determine the level of scrutiny a research proposal will receive (i.e., delegated review for Minimal Risk Research or full Research Ethics Board review for research above minimal risk), as well as the consideration of foreseeable Risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.
Publicly Declared Emergency	An emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official (in accordance with legislation and/or public policy).
REB	Research Ethics Board at Athabasca University
REAC	Research Ethics Appeal Committee at Athabasca University
REO	Research Ethics Officer at Athabasca University



Research	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation, or both.
Researcher	Anyone who conducts research activities, including, but not limited to, faculty, undergraduate and graduate students, post-doctoral fellows, and other personnel involved directly or indirectly in research, including, but not limited to research assistants/associates, technical staff, adjunct professors, visiting professors, and institutional administrators.
Research Sponsor	An external entity that enters into a formal agreement with AU to provide financial or other support for research.
Risk	The possibility of the occurrence of harm; the level of foreseeable Risk posed to Participants by their involvement in research assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to Participants or third parties.

## **Procedure**

It is the joint responsibility of the researcher and the Research Ethics Board (REB) to ensure the ethical conduct of research involving humans.

### **Application and Review Processes**

All applications for ethics review of research involving humans shall be made through the University Research Portal. Subsequent mandatory reporting (annual renewal reports, project completion reports, unanticipated event reports, and modification requests) shall also be submitted through the University Research Portal.

All applications are received by the Research Ethics Officer (REO), after which the Chair (or designate) shall determine whether the application requires a delegated or full REB review. In keeping with a Proportionate Approach to research ethics review, the level of foreseeable Risk to participants shall be used to determine if the proposal warrants a higher (i.e., full REB review) or lower (i.e., delegated) level of scrutiny.

A research proposal may be submitted to a funding agency or sponsor prior to REB review, however the research cannot commence until REB approval has been obtained. Researchers shall submit their research proposal for REB review and obtain written approval of ethical acceptability prior to recruiting participants, accessing data, or collecting human biological materials.

REB approval pertains only to the ethical acceptability of the research and does not, in itself, constitute authorization for the research to proceed. Researchers are responsible for determining if additional requirements must be met in the setting(s) in which the research is to be conducted.

Decisions about the ethical acceptability of the Research, including approvals and refusals, shall be made and communicated to the Researcher(s), in writing, in an efficient and timely manner.



Requests for modifications or amendments to the originally approved Research shall be dealt with in a similar manner.

If a project spans more than 12 months, Researchers shall submit an ethics renewal request annually (through the University Research Portal) to renew ethical approval for a further period up to 12 months. Researchers shall submit a project completion report when the Research project is concluded.

Failure to renew ethical approval every 12 months (for ongoing projects) will result in a suspension of research funding until such time as required approval has been renewed.

If Researchers encounter any unanticipated issues or events that may increase the level of Risk to Participants or have other ethical implications that may affect Participants' welfare, they must report these to the REB as soon as possible.

Requests for modifications and amendments to an approved research project shall be submitted for review to the REB in a timely manner.

The REB shall maintain a record of all documentation related to Research submitted to the REB for review, attendance at all REB meetings, and accurate minutes of proceedings within the Office of Research Ethics.

### Delegated Review

Faculty and staff applications in which the Research is deemed by the REB Chair (or designate) to be Minimal Risk Research shall undergo review by two members of the REB. If, in the opinion of the Delegated Reviewers, the Research is of greater Risk than Minimal Risk Research, the application will proceed to a full REB review.

Graduate Student applications in which the Research is deemed by the REB Chair (or designate) to be Minimal Risk Research shall undergo review by Delegated Reviewers comprising two members of the department or faculty with which the student's program is affiliated.

Delegated Reviewers may:

- a) call on other members of the REB for assistance in conducting an assessment of an application as needed or consult other expert resources as needed to reach a decision regarding an ethics review application;
- b) request further information or clarifications from the Researcher and the Researcher shall provide such information or clarifications in writing; and
- c) request changes to the study protocol and support materials judged to be necessary to bring the proposed work into compliance with University Policy and permit the request for approval to be granted.



All decisions arising from Delegated Review shall be communicated in writing to the Researcher through the Research Portal by the Research Ethics Officer and reported (for information purposes only) to the REB at its next meeting.

If the Delegated Reviewers conclude that an application does not meet the ethics standards necessary for ethics approval and are considering a negative decision (denial of approval), that potential decision shall be referred to the full REB for review and endorsement before the decision is communicated to the researcher.

### Full Board Review

In the case of a full REB review, the application will be made available to all members of the REB who will participate in the review.

All decisions of the REB shall be communicated in writing to the Researcher through the Research Portal by the Research Ethics Officer. If the REB determines that an approval may be issued following satisfaction of conditions imposed by the REB, those requirements shall be communicated in writing to the researcher. The REB Chair (or designate) may issue a full approval of an application upon confirming that any required conditions have been met.

### Appeals of REB Decisions

In response to a request for an appeal of a negative decision (denial of ethical approval) by the REB, and upon appointment of the Research Ethics Appeal Committee (REAC) by the President (or delegate), the REAC shall commence their review within 30 days of receiving the notice of appeal.

The Chair of the REAC shall issue a written decision to the researcher and to the REB. A decision of the REAC is final.

### Research Ethics Review During a Publicly Declared Emergency

The REB shall use delegated review processes for all submissions made during a Publicly Declared Emergency (regardless of whether an application is deemed to be for Minimal Risk Research). A minimum of two reviewers shall assess applications during a Publicly Declared Emergency.

If duly appointed members of the REB are not available to review an application during a Publicly Declared Emergency, the REO will seek two reviewers from the wider University faculty membership to undertake such review, ensuring that members appointed have the appropriate expertise to review an application. Presidential (or delegate) appointment of non-REB members shall be sought as is reasonably possible.

All normal deadlines shall be suspended and applications for ethics review will be handled as expeditiously as possible.



All decisions made by Delegated Reviewers shall be communicated as soon as possible to the researcher(s) and to the REB.

### **Applicable Legislation and Regulations**

[Alberta Freedom of Information and Protection of Privacy Act, R.S.A. 2000, c. F-25](#)

### **Related References, Policies, Procedures and Forms**

Canadian Tri Council Policy Statement: *Ethical Conduct for Research Involving Humans* (2<sup>nd</sup> Edition 2014, and as amended from time to time)

<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

Agreement on the Administration of Agency Grants and Awards by Research Institutions (2011, and as amended from time to time): <http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/>

Athabasca University [Ethical Conduct for Research Involving Humans Policy](#)

AU REB Research Ethics Application Forms are accessible through the online Research Portal:

- a) AU REB Guidelines for Applicants
- b) AU REB Ethical Review Guidelines for Research Involving Students or Other Individuals Related to the Researcher as Research Participants
- c) AU Application for Ethical Review – Faculty & Staff
- d) AU Application for Ethical Review – All Students
- e) AU Application for Course-Based Research Activities (Blanket) Ethical Approval
- f) AU Application for Ethics Exemption
- g) AU Research Ethics Renewal Request, Modification Request and Final Report Forms

### **History**

The Governors of Athabasca University, March 23, 2016, Motion # 207-07 (associated policy approved)