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## Ethical Conduct for Research Involving Humans Policy

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<b>Policy Sponsor:</b>	Office of the Provost and Vice President, Academic
<b>Policy Contact:</b>	Research Ethics Officer, Research Centre
<b>Policy Number:</b>	N/A
<b>Effective Date:</b>	March 23, 2016
<b>Approval Group:</b>	Executive Group
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<b>Review Date:</b>	Biennially
<b>Procedure:</b>	<a href="#">Ethical Conduct for Research Involving Humans Procedure</a>

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### **Purpose**

To delineate principles to guide the design, ethical conduct, and ethics review process for research involving humans at Athabasca University (the University). Inherent in these principles are respect for persons, concern for their welfare, and justice.

Athabasca University adopts the articles of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2014 and as amended from time to time) and shall be guided by the application sections of these articles in the implementation of this policy and related procedures.

### **Definitions**

Anonymous Information	Information that never had identifiers associated with it; the risk of identification of individuals is low or very low.
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).
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.
Justice	A core ethical principle that refers to the obligation to treat people fairly and equitably with equal respect and concern and to the obligation to distribute the benefits and burdens of research participation so that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge gained from it.
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 the University to provide financial or other support for research.
Respect for Persons	A core ethical principle that recognizes the intrinsic value of human beings and the respect and consideration that they are due. The principle incorporates a moral obligation to respect autonomy and protect those with developing, impaired, or diminished autonomy.
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.
Secondary Use	The use in research of information or Human Biological Materials originally collected for a purpose other than the original research purpose.

## **Policy Statements**

University affiliated research involving humans shall be designed and conducted in strict accordance with the standards and principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2014 and as amended from time to time), hereafter referred to as the TCPS2, as well as all applicable legal and regulatory requirements with respect to informed consent and the protection of privacy of Participants.



Research funds shall not be released to Researchers conducting Research involving humans until such time as the Research Ethics Board has approved the Research unless the activities involving Human Participants will take place only in the future, in which case a part of the funds may be released to cover only expenses to be incurred before involving Human Participants.

### **Scope of Research Ethics Review**

Research Ethics Board review and approval is required for Research involving:

- a) Living human Participants (and their data), or
- b) Human Biological Materials derived from living or deceased individuals where:
  - Research is conducted by members of the University community or in collaboration with those members;
  - Research is conducted using University resources (e.g., research space, material, equipment, human resources, research funds); or
  - Research is conducted at or under the auspices of the University by external researchers.

Research involving humans that is exempt from REB review includes Research that:

- a) relies exclusively on publically available information that is legally accessible to the public and appropriately protected by law or that is publically accessible where there is no reasonable expectation of privacy;
- b) involves the observation of people in public places and does not involve any intervention staged by the researcher or direct interaction with the individuals or groups, and those individuals or groups targeted for observation have no reasonable expectation of privacy; and dissemination of research results does not allow identification of specific individuals; or
- c) relies exclusively on secondary use of anonymous information or anonymous Human Biological Materials, so long as the process of data linkage, recording, or dissemination of results does not generate identifiable information.

### **Research Ethics Board**

The University President (or designate) shall establish a Research Ethics Board to independently review, on behalf of the institution, the ethical acceptability of all Research involving humans conducted by University faculty, staff, or students (regardless of where the Research is conducted) and by Researchers external to Athabasca University where that Research is proposed to be conducted within the jurisdiction of the University.

The REB shall consist of at least five members, including both men and women, of whom

- a) at least two members have expertise in relevant Research disciplines, fields, and methodologies covered by the REB;
- b) at least one member is knowledgeable in ethics;
- c) At least one member is knowledgeable in the relevant law (but who is not the University's legal counsel or risk manager); and
- d) at least one community member not affiliated with the University.



To ensure the independence of its decision-making, senior university administrators shall not serve on the REB.

The REB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions.

The REB is accountable to the President (or designate) for the integrity of the ethics review process.

The university shall respect the authority of the REB and may not override a decision of the REB to reject a research proposal. Any appeal of a decision to reject a research proposal shall be adjudicated through established appeal processes.

The REB shall elect one of its members to act as Chair. The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2014, and as amended from time to time). The REB shall meet on a regular basis and may do so by meeting face-to-face or by electronic means provided that sufficient discussion occurs for effective REB decision-making on proposals and the collective education of REB members.

The REB shall be provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties.

### **REB Review and Approval**

Researchers must submit their research proposals for REB review and obtain ethics approval prior to recruiting Participants, accessing data, or collecting Human Biological Materials. Research ethics approval must be maintained throughout the life of the research project. REB approval is issued for a maximum of 12 months, at which time it must be renewed if a project is ongoing. It is the responsibility of the Researcher to apply for required ethics approval renewal in accordance with the procedures and to submit the required project completion report at the conclusion of the project.

Researchers must submit any requests for modifications or amendments to their originally approved Research, as well as any reports of unanticipated issues or events, in a timely manner.

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.

The REB shall adopt a Proportionate Approach to research ethics review by tailoring the level of scrutiny to the level of Risk presented by the Research (i.e., the greater the magnitude and probability of harms posed by the Research, the higher the level of scrutiny of the Research).

As part of research ethics review, the REB shall review the ethical implications of the methods and design of the Research.



The REB may consult ad hoc advisors in the event that it lacks the specific expertise to knowledgeably review the ethical acceptability of a research proposal.

Researchers have a right to request, and the REB has an obligation to provide, prompt reconsideration of decisions affecting a research proposal. If, after reconsideration, the REB denies ethical approval of the Research, the Researcher may appeal that decision.

### **Conflict of Interest**

Researchers are obliged to identify and disclose to the Research Ethics Board (REB) any real, potential, or perceived Conflicts of Interest in Research that cannot be avoided or prevented and that may jeopardize the integrity of the Research or the protection offered to Participants.

REB members must disclose any Conflicts of Interest when reviewing research proposals and shall refrain from participation in a decision on an application for ethical approval where they have a Conflict of Interest.

The Athabasca University Conflict of Interest in Research Policy and related Procedures shall govern the management of Conflicts of Interest in Research involving University Researchers.

### **Appeals of a Decision of the Research Ethics Board (REB)**

A Researcher may appeal a negative decision (denial of approval) of the REB, in writing to the Research Ethics Officer, within 30 days of receiving notice of such decision. When an appeal of a negative decision by the REB is advanced, the President (or delegate) shall appoint a Research Ethics Appeal Committee (REAC) to review the appeal on behalf of the University.

A Research Ethics Appeal Committee shall consist of at least three members, of whom:

- a) At least two are knowledgeable in ethics; and
- b) at least one has expertise in the research discipline, field, and methodology of the matter under appeal;
- c) additional members may be added, in the event that the committee lacks the specific expertise to review the appeal.

A member of the REB whose decision is under appeal shall not serve on that appeal committee.

Decisions of a REAC are final and shall be communicated in writing to the Researcher and the REB.

### **Research Ethics Review During a Publicly Declared Emergency**

During a Publicly Declared Emergency, the REB may follow modified processes and practices as outlined in the procedures. Normal practices shall resume as soon as is feasible following the end of the Publicly Declared Emergency.

The review of proposed Research during an emergency should take into account:

- a) whether the Research is 'essential' during the emergency;



- b) the impact of the emergency on potential Participants and the heightened vulnerability that may exist due to the emergency situation; and
- c) the timeliness of review during an emergency.

### **Applicable Legislation and Regulations**

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

Other relevant laws and regulations of the Province of Alberta and of Canada.

### **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 Procedures](#)

Athabasca University [Conflict of Interest in Research Policy](#) and [Procedures](#)

Athabasca University [Research Integrity Policy](#)

### **History**

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