

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

## Human Research Ethics Policy

<b>Office of Accountability:</b>	Vice-President (Research)
<b>Office of Administrative Responsibility:</b>	Research Ethics Office
<b>Approver:</b>	Board of Governors
<b>Scope:</b>	Compliance with this policy extends to all persons who conduct <b>research involving humans</b> 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.

### Purpose

To adopt core principles and ethical principles for the conduct of research involving humans.

To identify the relationship between this **Policy** and the **Tri-Council Policy Statement** and the **Tri-Council MOU**.

To provide that research involving humans may not be commenced by a **researcher** unless first approved in accordance with this Policy and its **Procedures** and if approved may only be undertaken in accordance with any such **approval** and any requirements or conditions contained in or imposed in accordance with this Policy and its Procedures.

To establish the jurisdiction and mandate of the **REBs** and to define the key elements in the structure and implementation of this Policy and its Procedures.

To authorize an REB to accept the review of decisions of an external research ethics board.

### POLICY

#### 1. CORE PRINCIPLES AND ETHICAL PRINCIPLES

Researchers contribute to human welfare by acquiring knowledge and applying it to human problems. In the design and conduct of research involving humans, they are obliged to:

- a) pursue research involving humans as capably as their knowledge permits; and
- b) respect human dignity which requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration they are due.

The following core principles, together with the following ethical principles which are incorporated within those core principles, are adopted by the University of Alberta as foundational core principles and ethical principles to be applied in the implementation of this Policy and its Procedures:

#### Core Principles

- Respect for persons – a recognition of the intrinsic value of human beings and the respect and consideration they are due
- Concern for welfare – a holistic concept that refers to how a person or group is faring
- Justice – refers to the obligation to treat people fairly and equitably

#### Ethical Principles

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits
- Minimizing harm
- Maximizing benefits

These core principles and ethical principles shall be interpreted having regard to any interpretation or commentary on the same contained in the most recent Tri-Council Policy Statement containing such core principles or ethical principles as the case may be

If any change to the Tri-Council Policy Statement results in its inclusion of a core principle or ethical principle that has not been adopted by the University of Alberta through this Policy the **Vice-President (Research)** may make a written determination adopting such core principle or ethical principle as a part of this Policy.

## 2. RELATIONSHIP TO TRI-COUNCIL POLICY STATEMENT AND TRI-COUNCIL MOU

The University of Alberta adopts as a part of this Policy the articles of the Tri-Council Policy Statement to apply in the implementation of this Policy and its Procedures and shall be guided by the application sections of the articles.

In the event of any conflict between any adopted article of the Tri-Council Policy Statement and any other provision of this Policy or its Procedures, the adopted article shall apply and take precedence.

If additional requirements to the adopted articles are imposed pursuant to this Policy or its Procedures or are dictated by provincial, territorial, federal, international or other requirements, those additional requirements shall not be considered to be in conflict with any adopted article of the Tri-Council Policy and shall also be applied in the implementation of this Policy and its Procedures.

This Policy and its Procedures conforms to the requirements of the Tri-Council MOU.

## 3. RESEARCH REQUIRING ETHICS REVIEW

Research Involving Humans may not be commenced by a Researcher, including through contact with, or recruitment of, potential **participants**, until ethics approval has been requested and an approval has been granted pursuant to this Policy and its Procedures unless otherwise specifically permitted in this Policy and its Procedures. An approval must subsist for the duration of the participation of humans in the research, or for the duration of the funding of the

research, whichever is greater. An approval is initially issued only for a maximum of twelve months and it is the responsibility of the researcher to apply for any required renewal of the approval in accordance with the Procedures.

#### 4. JURISDICTION AND MANDATE OF THE RESEARCH ETHICS BOARDS

The University of Alberta establishes such number of REBs organized around specific ethics concerns as determined appropriate from time to time by the Vice-President (Research). The University of Alberta will provide sufficient financial and administrative resources to support the REBs in the fulfillment of their duties. The REBs shall be independent in their decision-making on individual ethics applications, and are accountable to the Vice-President (Research) for their ethics review processes.

All REBs shall be responsible for and capable of considering the full range of core principles and ethical principles of this Policy. Each REB shall have a specific area of focused expertise and must also be capable of considering a broad range of potential research methods, contexts, populations and risk. The REBs are mandated to approve, reject, propose modifications to, or terminate the approval of any proposed or ongoing research that is subject to review under this Policy. Researchers should choose the REB most suitable to the specific research project for which approval is sought and need not restrict themselves to only one REB for all projects they undertake.

The University of Alberta establishes a **Research Ethics Board Oversight Committee** reporting to the Vice-President (Research) to oversee the governance and performance of REBs; to ensure compliance of individual REBs with this Policy and its Procedures; to periodically review and when deemed appropriate recommend to the Vice-President (Research) changes to this Policy and its Procedures; to hear appeals of REB decisions as necessary; and to develop additional processes or procedures necessary or useful for the operations of the REBs.

In the case of applications for approval of research which will be funded in whole or in part with funds emanating from the Canadian federal government, the Procedures shall enable an applicant to submit an application for an approval in either the English language or the French language.

#### 5. RECOGNITION OF DECISION OF EXTERNAL REB

Where an approval for research involving humans is required from an REB pursuant to this Policy and ethics approval is also required from a research ethics board of one or more other institutions pursuant to the human research ethics policy of that other institution(s) - sometimes referred to as multi-jurisdiction reviews - the REB may accept the review of the research ethics board of one of those other institutions if permitted by, and in accordance with the requirements of, the Tri-Council Policy Statement and if approved by, and in accordance with the requirements of, the Vice-President (Research).

### **DEFINITIONS**

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

<b>Research Involving Humans</b>	<p>Research involving participants.</p> <p>Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.</p> <p>Research involving <b>secondary use of data</b>.</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"> <li>- 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</li> </ul>
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	<p>third party;</p> <ul style="list-style-type: none"> <li>- 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.</li> </ul>
<b>Research</b>	<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"> <li>- 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</li> <li>- Normal practice of a profession including medicine, law and engineering</li> <li>- 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.</li> </ul>
<b>Policy</b>	The University of Alberta Human Research Ethics Policy.
<b>Tri-Council Policy Statement</b>	<p>Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, <i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i>. 1998 (with 2000, 2002 and 2005 amendments), an evolving policy, as further amended or replaced from time to time.</p> <p>These Agencies will consider funding (or continued funding) only to individuals and institutions that certify that they comply with this Policy regarding research involving human subjects.</p>
<b>Tri-Council MOU</b>	Tri-Council Memorandum of Understanding: Roles and Responsibilities in the Management of Federal Grants and Awards.
<b>Researcher</b>	<p>A person who:</p> <ul style="list-style-type: none"> <li>- is a <b>member</b> who conducts or advances research either: <ul style="list-style-type: none"> <li>(i) in that capacity;</li> <li>(ii) as Supplementary Professional Activity as defined in the University of Alberta Faculty Agreement; or</li> <li>(iii) otherwise under the auspices of the University of Alberta;</li> </ul> </li> <li>- is a member who accesses University of Alberta students or staff as participants;</li> <li>- is not a member but conducts research within the jurisdiction of the University of Alberta.</li> </ul>
<b>Procedures</b>	The Procedures, from time to time, in force with respect to the Policy.

<b>Approval</b>	An ethics approval granted in accordance with the Policy and its Procedures by an REB for proposed research involving humans.
<b>REB</b>	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.
<b>Vice-President (Research)</b>	Vice-President (Research) of the University of Alberta
<b>Participant</b>	<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"> <li>- whose body is the human remains or cadaver;</li> <li>- from whose body was obtained human remains, tissue, biological fluid, embryo or foetus;</li> </ul> <p>which is the subject of research involving humans.</p>
<b>Research Ethics Board Oversight Committee</b>	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.
<b>Secondary Use of Data</b>	<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>
<b>Member</b>	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.

## **RELATED LINKS**

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

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

[Research and Scholarship Integrity Policy](#) (UAPPOL)

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

## **PUBLISHED PROCEDURES OF THIS POLICY**

[Human Research Ethics Appeals Procedure](#)

[Human Research Ethics Board Structure, Application and Review Procedure](#)

[Human Research Ethics Roles and Responsibilities Procedure](#)