Human Research Ethics Roles and Responsibilities Procedure

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<tr>
<th>Office of Administrative Responsibility:</th>
<th>Research Ethics Office</th>
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<td>Approver:</td>
<td>Vice-President (Research)</td>
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<td>Scope:</td>
<td>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.</td>
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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 roles and responsibilities of REBs, the Executive Director – Research Ethics Office, the Research Ethics Office and the Research Ethics Board Oversight Committee.

Purpose

- Describe the membership, roles and responsibilities of the Research Ethics Board.

- Describe the roles and responsibilities of the Executive Director – Research Ethics Office.

- Describe the roles and responsibilities of the Research Ethics Office.

- Describe the roles and responsibilities of the Research Ethics Board Oversight Committee.

1. RESEARCH ETHICS BOARD (REB) MEMBERSHIP, ROLES AND RESPONSIBILITIES

a) Membership of REBs

Potential REB members (who include REB Chairs) shall be recruited through nomination by the Executive Director – Research Ethics Office, REB chairs, current REB members, the Research Ethics Board Oversight Committee or researchers at the University of Alberta, and by other organizations and institutions participating in the University of Alberta ethics review process by special agreement. REB Chairs shall be appointed by the Vice-President (Research) following consultation with the Executive Director – Research Ethics Office. REB size and composition shall be determined by the Research Ethics Board Oversight Committee following receipt of recommendation of the Executive Director – Research Ethics Office following consultation with the REB Chairs and members. The term of appointment for each member shall be established at the time of such appointment to allow for continuity of the research ethics review. REB members, other than the Chair, shall be appointed by the Executive Director – Research Ethics Office. The guiding principle is to ensure that the membership is of adequate size and composition to manage effectively the REB’s workload and to ensure a reasonable pool of expertise to review applications within each REB, recognizing they may also draw on the specialized expertise including the Expert Resource Pool. The Research Ethics Board Oversight Committee shall review and either manage or make recommendations, as is appropriate, on the maintenance and adjustment of REB membership to ensure the same meets the needs of the REBs and the research community.

b) Roles and Responsibilities
REB members shall fully acquaint themselves with the Policy and its Procedures and any other relevant policies for ethics review, including in particular the Tri-Council Policy Statement. Members are expected to be fully engaged with, and to maintain high levels of participation in, REB meetings and discussions. Members who do not attend, or fail to actively participate in, three consecutive meetings shall be asked to reaffirm their commitment to the REB. Such members, other than the REB Chair may be removed at the discretion of the Chair following consultation with the Executive Director – Research Ethics Office, or, in the case of a member who is a REB Chair, by the Executive Director – Research Ethics Office. REB members must be aware of and declare when first aware of the same and when otherwise required by the Procedures any real or potential conflicts of interests relevant to the REB activities in general and to specific REB applications and applicants.

2. EXECUTIVE DIRECTOR – RESEARCH ETHICS OFFICE ROLES AND RESPONSIBILITIES

The Executive Director – Research Ethics Office shall oversee the institutional processes of research ethics review, the evaluation of REBs and their members, the provision and evaluation of REB education and training, and the provision of researcher education regarding ethical conduct of research. The Executive Director – Research Ethics Office shall send an annual letter to Department Chairs or Deans for consideration in annual evaluations, copied to the Vice-President (Research), detailing the nature of the duties and responsibilities of and commenting on the performance of a REB member on the REB.

The Executive Director – Research Ethics Office shall be responsible for the operationalization of the Procedures and shall advise the REBs on those Procedures and other processes and procedures implemented on behalf of the Research Ethics Board Oversight Committee. The Executive Director – Research Ethics Office and the Research Ethics Office are responsible for REB replenishment, education and training of REB members and researchers, and the securing of associated resources.

It is anticipated that the person appointed or designated as the Executive Director – Research Ethics Office pursuant to the Policy and its Procedures shall be appointed or designated as the Integrity Policy Officer pursuant to the Research and Scholarship Integrity Policy for the University of Alberta.

3. RESEARCH ETHICS OFFICE ROLES AND RESPONSIBILITIES

The Research Ethics Office (REO) shall be responsible for providing administrative support for the activities of the REBs and the Executive Director – Research Ethics Office. Such support shall include recruitment, supervision, training and management of REBAs, business management of the Human Ethics Research Online (HERO) system, liaison with internal and external offices on ethics administration issues, (e.g., Research Services Office), support for educational and training activities and the like.

The Research Ethics Office shall be responsible for providing opportunities and resources for the education of REB members. REB members shall be required to participate in the appropriate education and training opportunities provided. The Executive Director – Research Ethics Office shall ensure that the education and training offered is current, relevant, elucidates the University of Alberta’s ethics policies and is available widely across the University of Alberta.

To augment the expertise of the REBs, the Research Ethics Office shall maintain a pool of individuals 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. Members of this expert resource pool shall be ‘on-call’ to the REB chairs and may attend REB meetings and provide reports as requested, but shall not vote on any motion before any REB.

4. THE RESEARCH ETHICS BOARD OVERSIGHT COMMITTEE ROLES AND RESPONSIBILITIES

The Research Ethics Board Oversight Committee shall be responsible for developing, implementing and monitoring University of Alberta policy concerning human research ethics. It shall be responsible for ensuring the consistent interpretation and application of relevant policy by the REBs, as well as monitoring the consistency and equity of procedures, record keeping, decision-making, and performance standards across the REBs. The Research Ethics Board Oversight Committee shall be the body from which members of any appeal committee pursuant to the Appeals Procedure of the Policy is constituted.
The Research Ethics Board Oversight Committee is responsible for reviewing relevant policies and procedures, from time to time, to ensure their currency and relevance to national and other policies. These policies and procedures can be revised, subject to normal University of Alberta approval procedures in order to maintain compliance with relevant policies and procedures inside and outside the University. The Research Ethics Board Oversight Committee shall provide bi-annual reports to the Vice-President (Research). The Research Ethics Board Oversight Committee shall be made up of 50% of members drawn from the University of Alberta and the other communities the REBs serve, who are independent of the REBs and the Research Ethics Office (REO), and 50% of members drawn the REBs and REO. The overall composition of the Research Ethics Board Oversight Committee shall be as diverse as is reasonable within the scope of human participant research activity within the University of Alberta research community and should comprise a minimum of ten (10) and a maximum of twenty (20) members.

DEFINITIONS

Any definitions listed in the following table apply to this document only with no implied or intended institution-wide use. ▲ TOP

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<th>Research Involving Humans</th>
<th>Research involving participants.</th>
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<tr>
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<td>Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.</td>
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<td>Research involving secondary use of data.</td>
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<td>Research involving participants does not include the following research which is deemed excluded from such term:</td>
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<td>- 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;</td>
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<td></td>
<td>- 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.</td>
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<tr>
<th>Research</th>
<th>An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.</th>
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<td>The following activities, in the absence of a specific element of research, do not generally fall within this definition:</td>
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<td>- 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</td>
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<td></td>
<td>- Normal practice of a profession including medicine, law and engineering</td>
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<td>- 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.</td>
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| 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.

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 the Policy and its Procedures.

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

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.

Procedures | The Procedures, from time to time, in force with respect to the Policy.

REBA | Research Ethics Board Administrator

Participant | A living individual who is the subject or one of the subjects of research involving humans.

An identifiable individual, living or deceased:

- whose body is the human remains or cadaver;

- from whose body was obtained human remains, tissue, biological fluid, embryo or fetus;

which is the subject of research involving humans.

Secondary Use of Data | 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.

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.

RELATED LINKS

Should a link fail, please contact uappol@ualberta.ca. [▲ TOP]

Alberta Research Information Services (ARISE) (University of Alberta)
Research and Scholarship Integrity Policy (University of Alberta)

PUBLISHED PROCEDURES OF THE PARENT POLICY

- Human Research Ethics Appeals Procedure
- Human Research Ethics Board Structure, Application and Review Procedure
- Human Research Ethics Roles and Responsibilities Procedure