

Policy Title: Research Ethics Policy

Policy No: 5020 (formerly 5011)

Approval Date: November 9, 2011

Approval Body: Academic Council

Effective Date: September 12, 2012

Review Date: September, 2014

Policy Statement

University Canada West (UCW) endorses and complies with the principles, guidelines and processes for ethical research as set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2010).

In addition to the *Tri-Council Policy Statement*, UCW research must comply with the Personal Information Protection Act of British Columbia (PIPA) and the Personal Information and Protection and Electronic Documents Acts (PIPEDA) of Canada or the relevant legislation in the jurisdiction where participation in research takes place, regarding the collection, use and disclosure of personal information

Purpose

The purpose of the policy is to ensure that UCW members conduct research ethically and responsibly, and that research participants are treated with dignity and concern for their welfare in accordance with the *Tri-Council Policy Statement*. Participants must be fully informed of the purpose, requirements, and potential risks or harmful effects prior to giving their voluntary consent to participate. Researchers are accountable for minimizing the potential risks or harmful effects to participants and for protecting the privacy of individuals and the confidentiality of information provided to researchers.

Scope

The policy applies to research conducted by all members of the university community including faculty, students, and staff, external members working in collaboration with university members, and research involving university members as participants.

All researchers must obtain prior written approval from the *Research Committee* or the *Research Ethics Board* prior to conducting any research involving living human participants, with the following exceptions:

- Research based exclusively on publicly available information or research involving the writing of modern history, or literary or artistic criticism as outlined in the *Tri-Council Policy Statement*, or
- Quality assurance studies, program evaluations, performance reviews or testing within normal educational requirements.

The *Research Ethics Board* has the authority to review, approve, approve with conditions, and deny applications for research ethics approval and to ensure that researchers comply with the *Tri-Council Policy Statement* and the ethical principles expressed in the policy statement including:

- Respect for human dignity;
- Respect for free and informed consent;
- Respect for vulnerable persons;
- Respect for privacy and confidentiality;
- Respect for justice and inclusiveness;
- Respect for achieving appropriate balance between potential harms and benefits; and
- Respect for minimal risk – minimizing harm and maximizing benefit.

Members of the *Research Ethics Board* are appointed by the Academic Council with recommendations from the VP Academic and Student Services (VPASS).

Researchers must declare any conflicts of interest or potential conflicts of interest related to their research proposals identifying any relationships between researchers and research participants or any vested interests that might influence research outcomes as per the *Tri-Council Policy Statement*. Researchers must also declare immediately any breaches of the Research Ethics Policy or conditions for approval as they occur once research has commenced.

Complaints about non-compliance with the Research Ethics Policy must be directed to the *Research Ethics Board*. If the *Research Ethics Board* determines that a significant infringement of the policy or procedures has occurred, the Principal Investigator will be notified in writing by the Chair of the *Research Ethics Board*, with a copy to the VPASS. The notice must include specific details of actions to be taken and any deadlines that must be met. If the breach of policy is not rectified within the time frame specified, university approval and support for the research may be withdrawn.

All communications to Research Ethics Committee and Research Board members, Academic Council, applicants and appellants must occur through the University's approved channels of communication (University email or the student information system) for confidentiality purposes.

The Research Ethics Committee

The *Research Ethics Committee* provides for expedited review of student applications for research ethics review. The *Research Ethics Committee*, under delegated authority of the *Research Ethics Board*, has the authority to approve applications from students that involve minimal risk to participants as defined in the *Tri-Council Policy Statement*. Applications for research ethics approval from faculty and other applicants must go to the *Research Ethics Board*.

The *Research Ethics Board* will appoint, with recommendations from the VPASS, a *Research Ethics Committee* of at least 3 members for each faculty or discipline area as required. Members must be UCW faculty who are qualified to review research proposals related to the discipline(s) of the programs that they serve and be trained in the *Tri-Council Policy Statement*. Members will elect a Chair of the *Research Ethics Committee*, to be approved by the *Research Ethics Board*.

Applications

Applications to the *Research Ethics Committee* must be submitted to the Chair at least 10 working days before the research is expected to commence. Student applications require review and approval by the assigned Academic Research Supervisor prior to being submitted to the *Research Ethics Committee*. The Chair will communicate the decision to the applicant in writing normally within 10 working days of receiving the application, providing copies to the Academic Research Supervisor and the Dean or Program Chair.

If the *Research Ethics Committee* determines that an application does not meet the standards for minimal risk, it will be forwarded to the Chair of the *Research Ethics Board* with a written explanation of the reason for the referral. The applicant, Academic Supervisor, and Dean or Program Chair will be notified in writing within 7 working days of the decision to refer the application.

Applications to the Research Ethics Board must be submitted to the Chair at least 10 working days before the next scheduled meeting of the Board. The Chair will communicate the decision to the applicant in writing normally within 14 working days of receiving the application, providing copies to the Chair of the *Research Ethics Committee*, the Academic Research Supervisor, and the Dean or Program Chair where applicable.

Where conditional approval of an application for research ethics review is granted, the Chair of the *Research Ethics Committee* or the *Research Ethics Board* will outline in writing what must be done to amend the application to meet final approval. Applicants must revise the application form and re-submit it within the time frame specified in the conditions. Students must receive approval from the Academic Research Supervisor before submitting an amended application form.

If the amended application does not address the specified conditions or is not received in the required time, the conditional approval may be rescinded.

If an application is denied, the Chair of the Research Ethics Committee or Research Ethics Board will provide written notification to the applicant (with a copy to the Academic Supervisor, Dean or Program Chair if required) outlining the reasons for denial and the right to appeal.

Where students are required to conduct research involving human subjects as a regular activity for a course, the instructor may apply to receive *Research Ethics Committee* approval for that particular research activity. Individual student approval will not be required if blanket approval is received for the course.

If a research activity continues beyond the period of time specified in the approved application or if there have been substantive changes to the research plan or protocol, the researcher must submit a report immediately to the relevant approval body (either the *Research Ethics Committee* or the *Research Ethics Board*). If the Committee or Board determines that a new application for ethics approval is required, the Chair will inform the applicant within 7 working days of receiving the report. The applicant will have 10 working days to submit a new application. The Chair of the Research Ethics Committee or the Research Ethics Board will communicate the decision to approve, approve with conditions or to deny the applicant in writing normally within 14 working days of receiving the new application.

Appeals

A decision by the *Research Ethics Committee* to deny or rescind approval of an application may be appealed within a period of 14 working days of notification of the decision. Appeals are directed to the Chair of the *Research Ethics Board* and must be substantiated with a written explanation of the reasons for the appeal along with supporting documentation. The Chair of the Board will provide a written notification and justification of the decision to the appellant normally within 14 working days of receiving the appeal, providing a copy to the Chair of the Research Ethics Committee (and copies to the Academic Research Supervisor, and the Dean or Program Chair where applicable). The decision of the *Research Ethics Board* will be final.

A decision by the *Research Ethics Board* to deny approval or to rescind approval of an application may be appealed only on the grounds that procedural errors may have materially and adversely influenced the decision. The applicant must direct an appeal with supporting documentation to the Chair of Academic Council within 30 days of notification of the decision from the *Research Ethics Board*. The Chair of Academic Council will ask the VPASS to establish an ad hoc *Research Ethics Appeal Committee* consisting of internal and/or external members who are qualified to review the research ethics application and who had no previous involvement in reviewing the application. The Chair of the *Research Ethics Appeal Committee* will provide a written notification and justification of the decision to the appellant, the Chair of Academic Council and the Chair of the *Research Ethics Board* normally within 30 days of receiving the appeal. The decision of the *Research Ethics Appeal Committee* will be final.

Definitions

These definitions apply to terms as they are used in this policy.

Word/Term	Definition
Academic Research Supervisor	A UCW Faculty member appointed to supervise student research projects and research activities.
Research	According to the <i>Tri-Council Policy Statement</i> , “research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation” (2010:7). Research may be conducted for purposes of academic scholarship and it may also be required as part of the learning activities for a course.
University members or	Faculty members in full or part-time appointments, researchers working in collaboration

university community	with UCW faculty, emeritus faculty, visiting or adjunct teachers or scholars, students or visiting students, staff, research assistants, administrators, or any other person associated with research at UCW.
Principal Investigator	Researcher with the primary responsibility for the overall direction and administration of the research activity or project.
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 those aspects of their everyday life that relate to the research" (Tri-Council Policy Statement, 2010: 23). This concept is particularly relevant to certain high risk persons or groups in society who are most vulnerable to being harmed or manipulated.

Related legislation

Charter of Rights and Freedoms, Canada

Personal Information and Protection Act (PIPA), B.C.

Personal Information Protection and Electronic Documents Act (PIPEDA), Canada.

B.C. Human Rights Code, B.C.

Related policies

Policy Number	Policy Title
6751	Information Privacy and Security
<u>6750</u>	<u>Records Management Policy</u>

Responsibility

The Vice President Academic and Student Services (VPASS) is responsible for the development of the Research Ethics Policy, for maintaining the currency of the policy and for the implementation of the policy across the university.

The Academic Council is responsible for reviewing and approving the policy and for approving the appointment of members to the *Research Ethics Board* and the *Research Ethics Appeal Committee*.

The *Research Ethics Board* is responsible for ensuring that applications for research ethics approval are in compliance with the Research Ethics Policy and for making recommendations to the VPASS when policies pertaining to research ethics should be revised. The Board approves applications submitted from faculty and other non-student members as well as applications from students that are referred by the *Research Ethics Committee*.

The *Research Ethics Board* is responsible for approving appointments to the *Research Ethics Committee* and for ensuring that the Committee's decisions and processes for review are in compliance with the Research Ethics Policy.

The *Research Ethics Committee* is responsible for ensuring that student research proposals are in compliance with the Research Ethics Policy and that proposals that involve more than minimal risk to participants are referred to the *Research Ethics Board*.

Researchers, students and Academic Research Supervisors are responsible for ensuring that they understand the Research Ethics Policy and the *Tri-Council Policy Statement* and that research activities involving human participants are not conducted without the approvals required by the Research Ethics Policy.

Researchers are responsible for retaining copies of their approved applications and notifications of approval. Students are responsible for submitting research ethics approvals as required for a course or a thesis.

The Chairs or assigned academic support staff members are responsible for keeping all records and correspondence related to applications and decisions in accordance with relevant university policies. Appellants are responsible for keeping their own records of documentation and correspondence related to an appeal.

PROCEDURES

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The student completes the Research Ethics Committee Application Form and submits it to the Academic Research Supervisor for approval and signature. The Academic Research Supervisor reviews the application and signs it once it meets with his or her approval. The student submits the application to the Chair of the *Research Ethics Committee*. The student retains a copy of the Research Ethics Committee Application Form (including required revisions).

When a decision is made, the Chair of the *Research Ethics Committee* sends written notice of the decision to the student with a copy to the Academic Research Supervisor. If approval is conditional, the Chair outlines the conditions that must be met for final approval.

The student responds to any requirements set out for conditional approval, resubmitting the application once it has been approved by the Academic Research Supervisor. The Chair of the *Research Ethics Committee* sends written notice to the student confirming that the conditions for approval have been met or that conditional approval has been rescinded.

The student submits the written notice of approval from the *Research Ethics Committee* or the *Research Ethics Board* (if referral to the Board occurs) as required for a course or thesis.

The Principal Investigator completes the Research Ethics Board Application Form and submits it to the Chair according to the requirements outlined in the Research Ethics Policy, retaining a copy of the submission and the final submission (if revisions are required) along with the written notice of approval from the Board.

To appeal a decision by the *Research Ethics Committee* the appellant writes a letter to the Chair of the *Research Ethics Board* providing a rationale for the appeal along with related documentation. When a decision is made, the Chair sends a letter to the appellant with copies to the appropriate parties.

To appeal a decision by the *Research Ethics Board*, the appellant writes a letter to the Chair of the Academic Council, providing a rationale for a procedural appeal along with related documentation. The Chair of Academic Council asks the VPASS to form a *Research Ethics Appeal Committee*. When the Committee is formed, Chair of Academic Council forwards the letter of appeal and related documentation to the Chair of the *Research Ethics Appeal Committee*. When a decision is made, the Chair sends a letter to the appellant with a copy to the Chair of the Academic Council.

The Chairs of the *Research Ethics Board* and the *Research Ethics Committee* submit annual reports through the VPASS to the Chair of the Academic Council. The VPASS includes a report on the activities of any *Research Ethics Appeal Committees*. The annual reports are submitted to the Secretary of the Academic Council for the permanent record.

APPENDICES

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Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010).
http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

Research Ethics Board Terms of Reference

Research Ethics Committee Terms of Reference

Research Ethics Appeal Committee Terms of Reference

Research Ethics Committee Application Form

Research Ethics Board Application Form