

Royal Roads University Policy

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Approved By:

Academic Council

Office of Oversight:

AVP Research & Faculty Affairs

A. Purpose

The purpose of this policy is to establish principles, practices and procedures to guide and ensure the ethical conduct of research and scholarship carried out under the auspices of Royal Roads University. It is intended to replace the Royal Roads University Research Ethics Policy accepted by the RRU Academic Council, 17 January, 2007 and applies to research projects presented for review and approval by the RRU Research Ethics Board after 16 February, 2011.

B. General Principles

All research and scholarship shall be carried out in accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, the Tri-Council Policy Statement on Integrity in Research and Scholarship, Access to Information and Privacy Legislation, and Requirements for Certain Types of Research (Appendix Four of the NSERC Researcher's Guide). In the case of any conflict between policy, procedures and practices established by Royal Roads University and those established under the above-mentioned documents, the latter would prevail.

C. Requirement for Ethics Review

This policy applies to the conduct of research and scholarship by all faculty, staff, research associates, research assistants, visiting scholars, and graduate and undergraduate students, irrespective of the present source of their salary or stipend.

Ethics Review Required

An ethics review is required when research involves data collected from human participants including the following:

1. Information collected from living humans through interaction (such as interviews, questionnaires,

surveys, and focus groups) or through intervention (the participant is affected in some way by being placed in a situation to be studied);

2. Secondary non-public sources that identify an individual. Sources include: information gathered by another researcher or institution for another purpose that identifies an individual (for example, interviews about an individual); information gathered by the researcher for another purpose that identifies an individual (e.g., information from a private data base such as from a hospital or school that includes private information from individual(s)). Secondary sources, in this instance, do not refer to public secondary sources (that is, conventional categories of evidence such as books, monographs, and articles);

3. Human remains, cadavers, human organs, tissues, and biological fluids, from individually identified participants, embryos or fetuses;

4. Naturalistic observation that is used to study participants' behaviour in a natural environment. The Tri-Council Policy states: "Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the participants do not know that they are being observed, and hence can not have given their free and informed consent."

Ethics Review Not Required

There are some classes of research involving humans that do not require review and approval by the REB.

1. Research about a living individual involved in the public area, or about an artist, based exclusively on publicly available information;

2. Quality assurance studies, performance reviews or testing within normal educational requirements (however, when such information is used as a secondary non-public source as specified in the section above, an ethical review may be required);

3. Research involving only observation in public settings (as opposed to naturalistic observation) where it is expected that participants are seeking public visibility (for example, a rally or a public meeting);

4. Research involving information from public databases where aggregated information cannot be associated with an individual or specific group;

5. Research involving human participants conducted by RRU academic faculty or staff as outside RRU processes with the understanding that researchers carrying with them RRU's reputation in conducting their research may still require review;

6. Research already in the public domain, such as published articles, journals and archives.

D. Guiding Ethical Principles

In reviewing proposed or ongoing research activity involving human participants, the Research Ethics Board (REB) shall ensure that such activity conforms to the following principles as set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. This policy is available on the Internet.

1. Respect for Persons
2. Concern for Welfare
3. Justice

Research proposals must explicitly address each of these principles, unless clearly not applicable to the specific research activity. The Request for Ethical Review Form is designed to ensure that applicants address all of the principles noted above.

E. Benefits and Risks

Benefits

In order to warrant participation of human participants, researchers and the REB must consider the benefits of the research. This may include consideration in relation to: the participants, the researcher, any sponsors, organizations or communities that may be directly involved, the academic community, and society.

Estimate of Risk

The Tri-Council Policy Statement

[\http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf [1]] defines **Minimal Risk Research** as follows: “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”.

More than Minimal Risk occurs when the possible harms implied by subjects' participation in the research could go beyond those encountered in those aspects of the subjects' everyday lives that relate to the research (for example, any risks relating to confidentiality; vulnerable populations; psychological stress).

F. Mandate of Research Ethics Board

The Research Ethics Board is established by the Vice-President Academic to take a human subject-centred approach when reviewing project proposals to review and to approve, propose

modifications to, reject or terminate any proposed or ongoing research involving human subjects, research involving animals, and research involving radioactive materials, biohazards and other hazardous materials, which is conducted under the auspices of Royal Roads University.

This policy concurs with the Tri-Council Policy Statement which states that: “The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.” Further, the concept of minimal risk (described above) provides the foundation for proportionate review.

As required, the Vice-President Academic may appoint, as sub-committees of the REB, any or all or the following:

1. Expedited Review Committees – to review and recommend (approval, approval with modifications, or rejection of) Requests for Ethical Review in regard to the following categories of research:

- Research that involves minimal risk, but not greater than minimal risk;
- Annual reviews of approved projects in which there has been little or no change in the ongoing research;
- Submissions that indicate that conditions have been met with regard to research that the full REB stipulated for research approval;
- Research that has been previously approved but only requires minor revisions;
- Research that involves a replication of previously approved research;
- Research that has been granted approval by an REB at another institution; or
- Research conducted by hospital personnel involving review of patient records.

2. Faculty Committees for Undergraduate Courses – to review and recommend (approval, approval with modifications, or rejection of) Requests for Ethical Review carried out within formal course requirements. An undergraduate research project should only be reviewed at the faculty level when it does not involve more than minimal risk.

3. Research Involving Animals

At present, research involving animals cannot be carried out under the auspices of Royal Roads University unless the research is sponsored by, or in partnership with, an organization or institution that holds a Certificate of Good Animal Practice (GAP) from the CCAC or unless the research undergoes ethical review at an approved Research Ethics Board affiliated with a Canadian university.

In order for the proposed research involving animals to go forward, approval of both the RRU REB and the sponsoring/partner organization/institution’s REB is required. In the event that the sponsoring/partner organization/institution’s REB approves an ethics proposal while the RRU REB does not approve, the RRU REB’s decision overrides that of the sponsoring/partner organization/institution’s REB.

4. Research Involving Radiation

At present, research involving radiation cannot be carried out under the auspices of Royal Roads University unless the research undergoes ethical review at an approved Research Ethics Board, affiliated with a Canadian university.

In order for the proposed research involving radiation to go forward, approval of both the RRU REB and the sponsoring/partner organization/institution's REB is required. In the event that the sponsoring/partner organization/institution's REB approves an ethics proposal while the RRU REB does not approve, the RRU REB's decision overrides that of the sponsoring/partner organization/institution's REB.

5. Research Involving Biohazards

At present, research involving biohazards cannot be carried out under the auspices of Royal Roads University unless the research undergoes ethical review at an approved Research Ethics Board, affiliated with a Canadian university.

In order for the proposed research involving biohazards to go forward, approval of both the RRU REB and the sponsoring/partner organization/institution's REB is required. In the event that the sponsoring/partner organization/institution's REB approves an ethics proposal while the RRU REB does not approve, the RRU REB's decision overrides that of the sponsoring/partner organization/institution's REB.

G. Membership and Review Processes of the Research Ethics Board and Sub-Committees

1. REB Membership

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

- at least two members have broad expertise in the methods or in the areas of research to be reviewed by the REB;
- at least one member is knowledgeable in ethics;
- at least one member has no affiliation with the institution, but is recruited from the community served by RRU; and
- in cases of biomedical, radiation, and animal research, at least one member is capable of alerting the REB to legal issues and implications (may be appointed on an ad hoc basis).

The membership of the REB should reflect the range of research and scholarship represented at RRU and should ideally include members from each of the RRU Faculties.

Substitute REB members may be nominated in the event that a REB member is ill, on leave, or otherwise unavailable. However, the use of substitute members should not alter the membership structure of the REB.

The Vice-President Academic appoints the Chair of the REB. Members shall serve on the REB for

a term of three years, renewable. A quorum of the REB for meetings to consider Requests for Ethical Review of a more than minimal risk nature is more than half of the members, while respecting the membership requirements (above).

2. Regular Full REB Review

Research that involves greater than minimal risk will require regular review by the full REB (see section F above). In such review, scholarly merit will be reviewed as well. [For biomedical research, the scholarly standards of a research proposal must be reviewed even when the project does not involve more than minimal risk.]

3. Outcomes of the Regular Full REB Review Process

Within a specified time period, determined by the Research Ethics Board:

- There is REB consensus to grant ethical approval and the researcher is notified that the research can begin.
- There is REB consensus that approval cannot be granted without modification and the researcher is asked to modify the proposal to address the concerns of the REB.
- There is REB consensus that ethical approval cannot be granted and that the proposed research cannot be modified to meet the concerns of the REB. The researcher is notified that the proposed research is rejected.
- If consensus cannot be reached, the REB will take additional time to reconsider the proposed research and possible modifications, and may consult with the researcher and/or an impartial individual or individuals with relevant expertise to further inform the REB's decision.

4. Expedited Review Committees

The Expedited Committees will review and recommend (approval, approval with modifications, or rejection of) Requests for Ethical Review for categories of Research noted in Section F above (primarily referring to minimal risk research).

Expedited Review Committee Membership

The Tri-Council Policy Statement explains, "...that the institution may decide that categories of research that are confidentially expected to involve minimal risk may be approved by the chair or another designated member or a sub-committee of the REB."

The full RRU REB will ideally have, at any point in time, a member from each of the Faculties of RRU. This may be a Dean, an Associate or Assistant Dean, a Program Director, a Core Faculty Member, or another designated representative. As members of the REB, the Vice-President Academic may appoint a faculty member as an expedited committee. The Chair may also be appointed as an expedited committee. In many instances the Faculty REB member and the Chair may jointly review minimal review requests.

Expedited Review Committee Process

In expedited review, the expedited committee will review and recommend (approval, approval with modifications, or rejection of) a Request for Ethical Review. The Expedited Committee will convey the outcome to the researcher and convey the outcome to the Chair of the REB.

Members doing the review can refer complex or problematic cases to the full REB for discussion and decision.

If there is doubt about the ethical acceptability of a research proposal reviewed by an expedited review committee, the researcher will be notified and the proposal will go to the full REB for review.

The REB maintains surveillance over the decisions made on its behalf.

The REB will determine appropriate checks for compliance to guidelines.

5. Outcomes of the Expedited Review Committee Process

The following outcomes may result from the review:

- The Expedited Committee grants ethical approval. The Expedited Committee notifies the Chair of the REB and notifies the researcher that the research can begin.
- The Expedited Committee stipulates that ethical approval cannot be granted without modification. The Expedited Committee notifies the Chair of the REB and notifies the researcher to modify the proposal to address the concerns emerging from the review.
- The Expedited Committee stipulates that ethical approval cannot be granted and that the proposed research cannot be modified to meet the concerns identified by the ethical review. The Expedited Committee notifies the Chair of the REB and notifies the researcher that the research must be ended.

6. Faculty Committee for Undergraduate Courses

See Section F above.

1. Membership of Faculty Committee for Undergraduate Courses

An RRU Faculty member (Dean, Associate Dean, Assistant Dean, Program Director, core faculty member, or other representative) may be appointed by the Vice-President Academic to review and recommend (approve, approval with modifications, or rejection of) Requests for Ethical Review.

2. Review Process of Faculty Committee for Undergraduate Courses

The Faculty Committee notifies both the Chair of the REB and the course instructor of the outcome.

3. Outcomes of the Faculty Committee for Undergraduate Courses

The review will result in one of the following outcomes.

- The Faculty Committee grants ethical approval and the Committee notifies the Chair of the REB and the Course Instructor that the research can begin.
- The Faculty Committee stipulates that ethical approval cannot be granted without modification. The Committee notifies the Chair of the REB and notifies the course instructor to modify the proposal to address the concerns emerging from the review.
- The Faculty Committee stipulates that ethical approval cannot be granted and that the proposed research cannot be modified to meet the concerns identified by the ethical review. The Faculty Committee notifies the Chair of the REB and notifies the course director that research cannot begin.

The REB maintains surveillance over the decisions made on its behalf.

7. Animal Care, Radiation Safety, and Biohazards Committees

See section F above.

1. Membership of Animal Care, Radiation Safety, and Biohazards Committees

As required, the Vice-President Academic may appoint, as subcommittees of the REB, any or all of: an Animal Care Committee, a Radiation Safety Committee, or a Biohazards Committee.

Where required, an individual or individuals with expertise in any of the areas involving animals, biohazards or radioactive substances may be recruited on an as-needed basis to act as a Committee for review of the Requests for Ethical Review in these areas.

2. Review Process of the Animal Care, Radiation Safety, and Biohazards Committees

The Committee will review and recommend regarding Requests for Ethical Review. The Committee will notify both the Chair of the REB and the researcher of the outcome.

The REB is responsible for ensuring that projects abide by necessary standards, regulations and guidelines

3. Outcomes Animal Care, Radiation Safety, and Biohazards Committees

The outcomes will follow the guidelines specified in the Canadian Council on Animal Care, the Atomic Energy Control Board regulations, and Laboratory Biosafety Guidelines, published by MRC (1990) and adopted by NSERC.

H. General Procedures

Any research project within the mandate of the REB and carried out under the auspices of RRU must be reviewed and approved by the REB before work is started. Projects that have been started without approval may be rejected without further review.

Submissions are to be made on the attached Request for Ethical Review Form. As this form is designed to deal with a range of possible projects, not every question is applicable to every project. Where inapplicable, state “N/A”.

All Requests for Ethical Review should be forwarded to the Research Ethics Coordinator in the RRU Office of Research. The Research Ethics Coordinator will distribute to the REB or appropriate Sub-Committee of the REB.

Turn-around time is generally four weeks for full REB review. Expedited review will normally require less turn around time than four weeks. To ensure the quickest possible review, ensure that applications are complete.

Approvals may be granted for up to one year. For projects of longer duration applicants should submit a request for extension (for up to 4 additional years).

Reconsiderations. Researchers have the right to request reconsiderations of decisions affecting their research project. The REB has an obligation to provide a reasonable opportunity for the researcher to discuss the decision.

Appeals. Decisions of the REB may be appealed to a Research Review Committee established by the VP Academic. The VP Academic may, if so desired, use another institution’s REB as an appeal board. Membership of the Research Review Committee shall include one member from each of the Faculties selected by the Faculty Deans together with at least one member from an REB or REB appeal committee from another university or other research centre that receives funding from Tri-Council sources.

Conflict of Interest. Where an REB reviews a proposal in which a member of the REB has a personal interest, the member shall fully disclose the nature of the conflict of interest, and shall not be present when the REB is discussing the project or making its decision.

Monitoring. Each research proposal shall include a proposed continuing review or monitoring process appropriate to the proposal. This shall minimally include an annual report to the REB confirming that research is proceeding as initially approved and prompt notification when the project has concluded. The level of monitoring for ongoing research will be commensurate with the proportionate approach to ethics review.

Review of Multi-Centred Research. In the case of research involving more than one institution, the REB shall communicate with and coordinate its review with the REBs of the other research centres.

Review of Research in Other Jurisdictions or Countries. Research to be carried out in other jurisdictions shall be reviewed by both the REB and by an agency with equivalent jurisdiction and safeguards in the host jurisdiction, where such an agency exists. In all circumstances, the REB shall ensure that appropriate ethical standards and practices are proposed for the conduct of the research, regardless of its location.

Record Keeping. Each Expedited Committee, Faculty Committee and the Animal Care, Radiation Safety, and Biohazards Committees, shall keep a record of their decisions and the reasons for them.

These will be forwarded on a regular basis to the Chair of the REB and the Office of the Associate Vice-President Research.

The full REB shall prepare and maintain minutes including decisions, the reasons for them, and any dissents.

The Office of the Associate Vice-President Research shall store a copy of all records and minutes in order to facilitate internal or external audits or reconsiderations or appeals.

I. Requirement for Free and Informed Consent

The Tri-Council Policy Statement underscores the great importance of free and informed consent in ethical research involving human subjects.

Research governed under this RRU policy may begin only when prospective subjects (or authorized third parties) have been given an opportunity to provide free and informed consent about their participation. The research must make clear to the subject the opportunity to withdraw at any point in the research study. Free and informed consent is to be given voluntarily without undue influence.

Ordinarily, free and informed consent will be given in writing. See sample of Informed consent form attached to the Request for Ethical Review form. Where informed consent in writing is not culturally appropriate, or where there are other good reasons for not obtaining written consent, the researcher must document the alternative procedures used to indicate free and informed consent.

The requirement to obtain informed consent may be waived or modified with research in which the following conditions can be documented (in accordance with the Tri-Council Policy Statement):

- The waiver or alteration is unlikely to affect the welfare of the subjects;
- The research involves no more than minimal risk;
- The research could not be practically carried out without a waiver or alteration;
- The waiver or alteration does not involve therapeutic intervention;
- The subjects are provided with additional information, where possible and appropriate, will be provided with additional pertinent information after the study.

If research incorporates randomization or blinding in clinical trials, and if the subjects are informed of the probability of being randomly assigned to a category, such research is not regarded as a waiver or alteration of the requirements for consent.

Informing Potential Subjects

The researcher should provide the subject with information that they are invited to participate in the research, a statement outlining the research purpose, the identity of the researcher, the research procedures, the length of the participation, an indication of how the research findings will be used, the possible harms and benefits of the research, and additional pertinent information where relevant.

Competence

The Tri-Council Policy Statement identifies three conditions for recruiting individuals who are not legally competent as subjects. Individuals who are not legally competent shall only be asked to become research subjects when: the research question can only be addressed using individuals from within the identified group(s); free and informed consent will be sought from their authorized representative(s); and the research does not expose them to more than minimal risk without the potential for direct benefits for them.

Researchers who have identified subjects who are not legally competent should refer to Section 2, Subsection E of the Tri-Council Policy Statement.

Research in Emergency Health Situations

Please refer to Section 2, Subsection F, Article 2.8 of the Tri-Council Policy Statement.
[\http://www.pre.ethics.gc.ca/english/policystatement/section2.cfm#2F [2].]

J. Privacy and Confidentiality

Privacy and confidentiality refer to all aspects of the access, control and dissemination of information derived from the subjects. When a subject volunteers information, the researcher has an obligation not to share that information with others unless there is free and informed consent. The researcher should clearly indicate to the subject the degree to which confidentiality can be expected. The Tri-Council Policy Statement indicates that anonymity is generally the best protection of the confidentiality of personal information and records.

REB approval for the interview procedure is required when researchers plan to access identifiable personal information through personal interviews (face to face, telephone, electronic, other).

REB approval is also required for accessing private information through surveys, questionnaires and the collection of data. The researcher shall provide the REB with information on the type and purpose of data to be collected, limits on use and disclosure, modes of observation that identify individuals, safeguards for confidentiality and for security of information, possible links between the data gathered for the research and other personal or public records.

Secondary Use of Data

If data from records collected for a purpose other than the proposed research (i.e. secondary data) can be linked to individuals and when there is a possibility that individuals could be identified in published reports, then REB approval is required. Researchers intending use of secondary non-public data and databases should refer to Section 3, sub-section 3, of the Tri-Council Policy Statement.

K. Inclusion

Within the ethics framework, inclusion refers to the overall benefits and burdens of research being distributed fairly. The REB should consider whether the research causes members of society to bear an unfair share of the burden of the research. Consideration should also be given to the potential for members of society to be unfairly excluded from the benefits of the research.

L. Research Involving Aboriginal Peoples

The Tri-Council Policy Statement recognizes that some of the research involving individual aboriginal people also involves the community or group to which they belong. It also recognizes the importance of several documents specifically relevant to Aboriginal peoples (prepared by the Royal Commission on Aboriginal Peoples, the Association of Canadian Universities for Northern Studies, and the Inuit Circumpolar Conference). These documents identify good practices for research with aboriginal communities.

The Tri-Council Policy Statement (2nd edition, released 2010) has, in Chapter Nine, “Research Involving First Nations, Inuit and Métis Peoples of Canada” developed “a framework for the ethical conduct of research involving Aboriginal peoples premised on respectful relationships, and encouraging collaboration and engagement between researchers and research participants; sets out twenty-two articles that incorporate former good practices; and draws on substantial public consultations”.

http://www.pre.ethics.gc.ca/pdf/eng/tcps2/Table%20of%20Concordance_2nd_Ed_2010_to_1st_Ed_1998.pdf [3].]

M. Clinical Trials and Human Genetic Research

In the event that any RRU research involve clinical trials or human genetic research, sections seven and eight of the Tri-Council Policy Statement would prevail.

O. Integrity in Research and Scholarship

Researchers are also advised to refer to the Royal Roads University Policy on Integrity and Misconduct in Research and Scholarship.



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Links

[1] http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

[2] <http://www.pre.ethics.gc.ca/english/policystatement/section2.cfm#2F>

[3] http://www.pre.ethics.gc.ca/pdf/eng/tcps2/Table%20of%20Concordance_2nd_Ed_2010_to_1st_Ed_1998.pdf