Royal Roads University Research Ethics Policy
Approved by RRU Academic Council – 9 October 2019

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 previous versions of the Royal Roads University Research Ethics Policy and applies to research projects presented for review and approval by the RRU Research Ethics Board after July 20, 2000.

B. General Principles
All research and scholarship shall be carried out in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), the Tri-Agency Framework: Responsible Conduct of Research, and Freedom of Information and Protection of Privacy Legislation. 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 database 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. Non-participant observation where the researcher observes, but is not a participant in, the action (also known as "naturalistic observation"). The TCPS 2 states: "Because the knowledge that one is being observed can be expected to influence behaviour, research involving non-participant or covert observation generally requires that the participants not know that they are being observed for research purposes. Typically the researcher has no direct interaction with the individuals being observed and therefore their consent is not sought."

**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 three core principles set out in TCPS 2.

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 the principles noted above.

**E. Benefits and Risks**

**Benefits**
In order to warrant participation of humans, 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**

*TCPS 2* defines **Minimal Risk Research** as follows: “research in which the probability and magnitude of possible harms implied by participation in the research are 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 participation in the research could go beyond those encountered in those aspects of the participants’ 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 Research to take a participant-centred approach when reviewing project proposals to review and to approve, propose modifications to, reject or terminate any proposed or ongoing research involving humans, 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 *TCPS 2* 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, at the request of the Vice-President Research, the Vice-President Academic and Provost may appoint, as sub-committees of the REB, any or all or the following:

1. **REB Delegate**— to review and recommend (approval, approval with modifications, or rejection of) Requests for Ethical Review in regard to the following categories of research:
   1. Research that involves minimal risk, but not greater than minimal risk;
   2. Annual reviews of approved projects in which there has been little or no change in the on-going research;
   3. Submissions that indicate that conditions have been met with regard to research that the full REB stipulated for research approval;
   4. Research that has been previously approved but only requires minor revisions;
   5. Research that involves a replication of previously approved research;
6. Research that has been granted approval by an REB at another institution; or
7. 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.

3. Research Involving Animals
   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 Canadian Council on Animal Care or unless the research undergoes
   ethical review at an approved Research Ethics Board affiliated with a Canadian
   university. Researchers must keep RRU apprised of the decision of the other
   organization’s review and the outcomes of the research.

4. Research Involving Radiation
   Research involving radiation 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 with appropriate certification and facilities to
   accommodate the research. Researchers must keep RRU apprised of the
   decision of the other organization’s review and the outcomes of the research.
   The outcomes will follow the Nuclear Safety and Control Act.

5. Research Involving Biohazards
   Research involving biohazards 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 with appropriate certification and facilities to
   accommodate the research. Researchers must keep RRU apprised of the
   decision of the other organization’s review and the outcomes of the research.
   The outcomes will follow the Human Pathogens and Toxins Act.

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:
   1. at least two members have broad expertise in the methods or in the areas
      of research to be reviewed by the REB;
   2. at least one member is knowledgeable in ethics;
   3. at least one member has no affiliation with the institution, but is recruited
      from the community served by RRU; and
4. 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.

At the request of the Vice-President Research, the Vice-President Academic and Provost 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. REB Delegates

REB Delegates 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).
Delegated Review

*TCPS 2* 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 Schools of RRU. This may be the Dean, School Director, a Faculty Member, or another designated representative. As members of the REB, and at the request of the Vice-President Research, the Vice-President Academic and Provost may appoint a faculty member as a delegate of the REB. The Chair may also be appointed as a delegate of the REB. For minimal risk research, a Faculty REB member may review requests.

**Delegated Review Process**

In a delegated review, the REB delegate will review and recommend (approval, approval with modifications, or rejection of) a Request for Ethical Review. The REB Delegate will convey the outcome to the researcher and convey the outcome to the Office of Research Ethics. The Office of Research Ethics keeps a record of all decisions.

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 REB delegate, 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 Delegated Review Process**

The following outcomes may result from the review:

1. The REB Delegate grants ethical approval. The REB Delegate notifies the Office of Research Ethics and notifies the researcher that the research can begin.

2. The Delegate stipulates that ethical approval cannot be granted without modification. The Delegate notifies the Office of Research Ethics and notifies the researcher to modify the proposal to address the concerns emerging from the review.

3. The REB Delegate 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 REB Delegate notifies the Office of Research Ethics and notifies the researcher that the research must be terminated.

6. **Faculty Committee for Undergraduate Courses**
See Section F above.

1. **Membership of Faculty Committee for Undergraduate Courses**
   An RRU Faculty member (Dean, School Director, Faculty member, or other representative) may be appointed at the request of the Vice-President Research, by the Vice-President Academic and Provost, 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 Office of Research Ethics 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.
   1. The Faculty Committee grants ethical approval and the Committee notifies the Office of Research Ethics and the Course Instructor that the research can begin.
   2. The Faculty Committee stipulates that ethical approval cannot be granted without modification. The Committee notifies the Office of Research Ethics and notifies the course instructor to modify the proposal to address the concerns emerging from the review.
   3. 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 Office of Research Ethics and notifies the course director that research cannot begin.

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

**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 begun without approval may be rejected without further review.

**Submissions are to be made on the 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 Office of Research Ethics. The Office of Research Ethics will distribute to the REB or appropriate Delegate of the REB.

**Turn-around time is generally four weeks for full REB review.** Delegated 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 Vice-President Research. The appeal may also be referred to 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-Agency 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 Delegate and REB subcommittee, shall forward their decisions and the reasons for them to the Office of Research Ethics.

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

The Office of Research Ethics 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

*TCPS 2* underscores the great importance of free and informed consent in ethical research involving humans.

Research governed under this RRU policy may begin only when prospective participants (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
participant 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. Where informed consent in writing is not 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 **TCPS 2**):

- The waiver or alteration is unlikely to affect the welfare of participants;
- 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 participants 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 participants 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 Participants**

The researcher should provide the participant 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.

**Decision-Making Capacity**

**TCPS 2** provides guidance for involving individuals who may lack the capacity to consent to participate in research: Such individuals should neither be unfairly excluded from the potential benefits of research, nor should their lack of decision-making capacity be used to inappropriately include them in research.

**Research in Emergency Health Situations**

Please refer to **TCPS 2 Chapter 6**.

**J. Privacy and Confidentiality**

Privacy and confidentiality refer to all aspects of the access, control and dissemination of information derived from the participants. When a participant 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 participant 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, digital, 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.

**Consent and Secondary Use of Identifiable Information for Research Purposes**

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. *TCPS 2* provides further guidance for researchers intending use of secondary non-public data and databases.

**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 Indigenous Peoples**

In collaboration with Indigenous peoples, RRU seeks to be involved in research activity co-created for the benefit of Indigenous peoples. The relationships RRU maintains with Indigenous peoples and communities locally, nationally, and internationally are vitally important to the university. RRU therefore seeks to be proactive in meeting the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Chapter 9: Research Involving the First Nations, Inuit, and Métis Peoples of Canada* and has established guidelines for the conduct of research, scholarship, evaluation, and creative endeavours that extend the commitment found in the Tri-Council Policy. Any project involving Indigenous peoples will be reviewed through this lens by the RRU Research Ethics Board. Throughout these guidelines, the term Indigenous will be understood to refer to First Nations, Inuit, Métis, and non-status peoples in Canada as well as to Indigenous peoples around the world. RRU’s guidelines extend the concept of ethical research to research, scholarship, evaluation, creative endeavours, and any other activity that involves accessing information from Indigenous communities and individuals to include any such work involving Indigenous lands or Indigenous artefacts.
Guidelines

1. Leaving Participants Better Off
   a. Ensure there is a benefit to participation. While the norm in research is to do no harm, RRU strives to leave participants better off as a result of participation in research. Long-term or generalized benefits to society do not, by themselves, meet this desired standard.
   b. When compensation is offered, provide compensation for time, effort, and expertise in a manner that reflects community protocols and norms and is representative of a mutual exchange relationship. Consult with community representatives before determining the nature of compensation.
   c. Consider helping build community skills and capacity by offering free workshops addressing the community’s immediate learning needs.
   d. Commit to publishing and disseminating research findings in Open Access or other publicly available outlets.
   e. Provide direct feedback and results to communities, organizations, and individuals involved.

2. Reflexivity on the Part of Researchers
   a. Ensure that Non-Indigenous and Indigenous members of the research team consider their own backgrounds and positions and the ways in which these may have an effect in the course of research.
   b. Familiarize oneself with the history of research involving Indigenous peoples in general, and the communities involved in the research specifically, to understand the potential harmful consequences of research, the effects of research fatigue on an over-researched and often marginalized community and the necessity of building and maintaining trust.
   c. Understand the diversity of Indigenous peoples (for example, in Canada, individual First Nations, Inuit, and Métis, on-reserve, off-reserve, status, non-status).

3. Primacy of Relationships as Foundation for Research
   a. Appreciate that one’s particular research impacts the overarching relationship RRU has with Indigenous communities and organizations, even if the research only involves one individual or community.
   b. Appreciate that relationships precede any specific research endeavor and that they are impacted by the conduct of research.
   c. Understand that being in a relationship requires responsibility and accountability.

4. Indigenous Control and Respect
a. Respect community partners as nations, not stakeholder groups, with jurisdictions over research in their communities and on their traditional territories.

b. Respect Indigenous ways of knowing and being.

c. Familiarize oneself with and respect Indigenous methodologies and methods.

d. In research involving First Nations, familiarize oneself with the principles of Ownership, Control, Access, and Possession (OCAP®) prior to finalizing one's research design. Consider completing the OCAP® online course for certification. (OCAP® is a registered trademark of the First Nations Information Governance Centre (FNIGC).)

5. Community Engagement

a. Engage community at all stages of the research project, as appropriate, including identification of research questions, study design, implementation, interpretation of results and knowledge translation.

b. Acknowledge and enable individuals' and communities' capacity to participate in research.

c. Carefully assess which individuals and organizations are selected to represent Indigenous communities and on what grounds.

d. Understand and use language appropriately to explain the researcher's approach to research methods and consultation processes and to define concepts such as community consultation, community engagement, community participation, partnerships, community review, and community control as applicable so that the communities can have clear expectations with regard to the process.

e. Learn and respect community protocols for engagement, compensation, accountability, disputes, and acknowledgments.

6. Indigenous Lands and Artefacts

a. Learn and respect Indigenous community protocols for conducting research, evaluation, or creative endeavours on Indigenous lands or with Indigenous artefacts.

b. Respect Indigenous Nations' jurisdiction over research in their communities and on their traditional territories.

c. Respect Indigenous ways of knowing and being in regard to access, handling, and control over land and artefacts.

d. Take responsibility for any impact the conduct of research may have on the ecosystem where the research is conducted (e.g., land, water, plants).

e. Make research available to relevant Indigenous people, communities, and/or organizations.

M. Clinical Trials and Human Genetic Research
In the event that any RRU research involves clinical trials or human genetic research, *TCPS 2 Chapters 11 through 13* would prevail.

**N. Research Involving Children and Youth**

The TCPS 2 section on vulnerable participants *Chapter 4*, Fairness and Equity in Research Participation specifically addresses research with youth. Key excerpts follow: Children have varying degrees of maturity — metabolically, immunologically and cognitively — that may present important challenges for research design and the consent process, depending on the nature and complexity of the research. In addition to the vulnerability that arises from their developmental stage, children may also lack the decision-making capacity to decide whether or not to participate in research (see *Article 4.6*). As well, physical or psychological harms a child may experience in a research setting may have long-lasting consequences.

Researchers should not exclude children from research unless there is a valid reason for doing so. Participation of children in research is justifiable when the research objective cannot be achieved with adult participants only. When considering the inclusion of children in research, researchers and REBs shall consider a child’s stage of physical, physiological, psychological, and social development to ensure adequate protections for the child’s welfare. Where children have not yet attained the capacity to decide for themselves whether or not to participate in research, researchers shall seek consent from an authorized third party while ascertaining the child’s assent or dissent, as outlined in *Chapter 3*. Note that *Article 4.6* equally applies to children.

To be ethically acceptable, the participation of those who lack the capacity to decide for themselves shall be necessary and appropriate to address the research question. Researchers and REBs shall consider the level of risk to which participants who lack decision-making capacity are exposed, and the prospect of direct benefits accruing to the participants. Their participation should generally be limited to research of minimal risk as defined in this Policy (see *Chapter 2* for the definition of minimal risk).

Research involving youth at RRU requires full ethical review if the research population is under eighteen years of age. All of the articles in the Vulnerable Population Section of the Request for Ethical Review need to be considered including a criminal record check, signed consent by the parent or guardian or authorized third party, as well as, where feasible, signed assent of facsimile from the youth.

On a case by case basis, research involving youth, without parental, guardian, or authorized third party consent, may be carried out by experienced researchers and upon full ethical review.

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

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