

A. Statement of Institutional Authority for Research Ethics Boards

The University of Regina has one Research Ethics Board (REB), established and empowered under the authority of the University of Regina Board of Governors and reports to Council through an annual report to the Council Committee on Research. The REB will be independent in its decision making.

B. Mandate and Accountability of the Research Ethics Board

The REB's mandate, on behalf of the University, is to protect the rights and welfare of human participants who take part in research conducted under the auspices of the University. The University of Regina's REB reviews such research to ensure that it meets ethical principles and that it complies with all applicable regulations, guidelines and standards pertaining to human participant protection. These include, but are not limited to, the University of Regina's Policy on Ethics - Research with Humans (RCH 020-010) and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2 2022). As per these policies, the University of Regina requires that all research involving human subjects or human biological materials conducted in its jurisdiction or under its auspices undergo review and approval by the REB prior to initiation of any research-related activities, including recruitment and screening activities, regardless of where the research is conducted.

While it is not a formal part of its responsibilities, the REB may raise concerns about the safety of researchers as part of its review. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution. REB approval would not be withheld based on these concerns alone.

The University of Regina's REB also operates under applicable laws and regulations of the Province of Saskatchewan and of Canada.

The REB reviews and recommends changes as needed to the University of Regina's Policy on Ethics - Research with Humans (RCH 020-010). Changes will be recommended to the Vice-President (Research) and follow relevant policy approval guidelines.

C. Membership of the REB

Given the number of reviews annually and to ensure that appropriate representation from all relevant Faculties and Units on the board, the REB will be larger than the minimal requirements established by the TCPS 2. At a minimum, the REB will be composed of:

- The Chair
- A Co-chair (Indigenous Research) with expertise to review research that involves Indigenous participants or communities.
- A Vice Chair (Student Research)
- One external member knowledgeable in the relevant law,
- At least 3 members of the community with no affiliation to the University
- 2 students

- At least 6 researchers with experience in disciplines, methodologies, and practices relevant to the applications received by the REB. These could include retired faculty members who have previously served on the REB and wish to continue their service. At least one of these shall be knowledgeable in ethics.
- The Research Compliance Officer, ex-officio, non-voting

The REB is committed to Equity Diversity and Inclusion and strives for representation from the five federally designated groups.

D. Terms of Office of the REB

Members of the REB shall be appointed by the Chair of the REB, following a call for new members or through active recruitment when new representative membership is required on the board. REB Chairs are appointed by the Vice President Research or designate. All applicants for membership to the REB will be reviewed by the REB Selection Committee. When choosing members, the REB Selection Committee will take into account the experience of the nominees, the disciplinary representation needed by the REB, representation from the five federally designated groups, and any other membership vacancies. Members of the REB will serve a three-year, renewable term. Terms will be overlapping to preserve experience and continuity of function.

The Chair will serve a two-year, renewable term.

The Co-Chair (Indigenous Research) will serve a two-year, renewable term.

The Vice Chair (Student Research) will serve a two-year renewal term.

Six months prior to the end of the Chair's term, the Vice-President (Research) or designate will discuss with the Chair whether they wish to be renewed, if they are in their first term. If the Chair wishes a renewal term, the REB Selection Committee will review the Chair's first term activities and make a recommendation regarding renewal. In order to assure the University Community can also participate in renewals of current Chairs, a satisfaction survey or request for feedback from those using the REB for their research will be sent out prior to renewal of a current Chair by the Associate Vice President (Research). Anonymous comments by the University community will be included as part of the review by the Selection Committee. If a new Chair is needed, a call will go to the University community to seek expressions of interest. Applicants will need to describe their experience with research ethics, REB service, and have the support of their Dean. The REB Selection Committee will choose from among the eligible applications and recommend the successful candidate to the Vice-President (Research).

The same process will be followed for the Vice Chair (Student Research) position and for the selection of the Co-Chair (Indigenous Research), however, candidates for the role of Co-chair (Indigenous Research) will also need the support of the Associate Vice-President (Indigenous Engagement). The Research Office will provide the Chair's Dean with funds equivalent to two course releases per year to support the Chair. Details regarding how this support will be provided to the Chair should be discussed with the Dean prior to application.

The positions of REB Co-Chair and REB Vice Chair will come with an allowance equivalent to one course stipend per year, which would allow the Faculty to arrange for alternate teaching or other support as negotiated.

Selection Committee

The Selection Committee will be composed of:

- 3 voting REB members

- The Chair and/or the Co-Chair (Indigenous Research) and/or the Vice Chair

- The Research Compliance Officer (non-voting)

- For Chair positions the Associate Vice President Research or a designate will also join the Selection Committee.

The Selection Committee will review the material provided by candidates, seek clarification where desired, and make a decision based on experience and REB service, taking EDI considerations into account and REB needs at the time of member submission.

E. Meetings of the REB

1. The REB will meet face-to-face regularly. Face-to-face is defined as in person, remotely, or a combination thereof. In the absence of any business, meetings may be cancelled by the Compliance Officer in consultation with the Chair.

2. Additional meetings of the REB, or of a sub-committee of its members, may be called by the Compliance Officer and/or Chair, as necessary.

3. Each meeting will require the involvement of quorum, which is defined as one-third of the total voting membership plus one. Quorum must also meet membership criteria specified by relevant research ethics guidelines and regulations (Article 6.4 TCPS2)ⁱ. In addition, where a proposal of greater than minimal risk is being discussed, members who have the expertise to discuss the proposal must be in attendance in order for quorum to be achieved.

4. Members shall attend REB meetings regularly. If a member is frequently absent, the Chair and the member will discuss whether it is in the member's and the Board's best interests if they withdraw from the REB so the work of the board can continue.

5. Members shall submit reviews in a timely manner, currently members have 7 working days to submit Minimal Risk reviews and Above Minimal Risk reviews must be submitted for Chair review at least 2 working days prior to the scheduled full board meeting. If members are consistently unable to complete reviews on time or are unable to accept reviews consistently, they may be withdrawn from the REB, so the work of the board is not negatively impacted.

6. Members shall notify the Research Office of an anticipated absence at least one day prior to a meeting. Members who cannot attend a meeting are expected to provide written comments to the Research Office for agenda items under review at the respective meeting. This information is provided to other members of the REB and becomes part of the discussion and meeting minutes.

7. Any real, perceived or potential conflict(s) of interest related to the applications under review shall be declared by the member(s) upon receiving the application or at the outset of the meeting. Examples of conflicts of interest include but are not limited to: applications on which they are listed as principal investigator or co-investigator; current or past research collaborations (within the last 5 years) with investigators listed on the application; applications on which students they supervise are listed. Other members of the REB will decide whether the member with the conflict of interest should recuse themselves from related discussions.

8. The REB may seek the confidential opinion or advice of ad hoc advisors/reviewers from among UofR faculty or from external consultants on a particular application to ensure it has the necessary background information and knowledge to review the ethical acceptability of the application. If the REB does not have the expertise to review an application, SHA or USask REBs will review based on the terms of the Tri-institution Ethics Review Reciprocity Agreement.

Ad Hoc Meetings

From time to time, the Chairs may choose to have a meeting between themselves and an applicant. The Compliance Officer will normally attend these meetings. Conversations will be documented to the REB file for future reference via the Notice of Ethical Review process.

F. Responsibilities of the REB

1. To ensure that all research under REB jurisdiction involving human participants and conducted by students, staff and faculty affiliated with the University of Regina, and all research conducted under the auspices of the University of Regina, undergo ethics review and approval prior to being conducted. These activities may be conducted on- or off-campus and may be funded or unfunded.

2. To determine the appropriate level of review for a project based on guidelines – see section below.

3. To review the ethical acceptability of all research projects under REB jurisdiction, involving human participants on behalf of the institution.

In so doing, the REB may: grant ethics approval to; propose modifications to; disapprove; pause; or terminate proposed or ongoing research conducted within the jurisdiction of the University or under its auspices to ensure that a proportionate review of risks and benefits has occurred in accordance with the ethical framework proposed under the TCPS 2 (Chapter 1). Applications can be submitted to the REB at any time. If a project requires Full Board Review and is received by the submission deadline for the next REB full board meeting, it will be placed on the next scheduled agenda. Delegated reviews are processed as they come in and the review process started within 7 working days minimum.

Full Board Review

The REB as a whole will review all applications deemed to be above minimal risk. The REB will reach its decisions concerning the ethical acceptability of research that is undergoing ethics

review through a process of open discussion and consensus. Where consensus cannot be reached, a vote of the quorum present may be taken and recorded. Greater than minimal risk applications are those including, but not limited to, those that

- May pose greater than minimal risk to participants (i.e., physiological, psychological, social, legal, or other) as defined by the TCPS 2, i.e. research in which the probability and magnitude of possible harms implied by participation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research;
- Involve recruitment of persons who may be vulnerable as research participants in the context of a specific study, and/or cannot legally give free and informed consent;
- Include ethically sensitive issues, topics and/or procedures; and
- Represent applications to certain granting agencies that stipulate full REB review.

The REB's deliberations and decisions will be documented in comprehensive, confidential minutes and review documentation that are securely maintained in the Research Office. All files, however, are available to University personnel who need to review them in the course of their duties.

Detailed written feedback from the REB including its decision on the ethical acceptability of the research shall be communicated to the researcher(s), by the Research Office. Feedback is based on the minutes and submitted written comments by members of the board and of the discussion of the research project by the full REB or, for minimal risk studies, through official review documentation and correspondence with researchers.

The REB may, where appropriate, request that the Principal Investigator (PI) or his/her designate attend a meeting to provide further information about and/or to discuss his/her research. The REB will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about his/her research.

Delegated Review

The REB delegates to a selection of REB members (normally two) as reviewers and the Chair, authority to review the ethical acceptability of research projects under REB jurisdiction that may pose no greater than minimal risk to participants (i.e., physiological, psychological, social, legal, or other) on behalf of the institution.

The REB delegates to the Compliance Officer and Chair, authority to review the ethical acceptability of research projects under REB jurisdiction that are of the lowest risk. Lowest risk is defined as projects where the probability and magnitude of expected harm are each very low, including, but not limited to, online anonymous surveys, research that is not asking sensitive questions or the secondary use of data which has been de-identified and is not of a sensitive nature that would pose additional risk to participants or their data.

The REB delegates to the Compliance Officer, Research Office, by virtue of their membership on the REB, authority to conduct:

1. Ethics review and approval of modifications to ongoing research under its jurisdiction, where those modifications do not increase the risk factor of the research to beyond minimal risk.
2. Annual ethics review and approval of research under its jurisdiction that continues beyond one year where there are no proposed changes that increase the risk of the research to beyond minimal risk.
3. Annual renewals of above minimal risk research in which there has been no significant changes to the research and no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB.
4. Ethics review and approval of minimal risk, undergraduate, course-based projects.
5. Ethics review and approval of projects with REB approval from other academic institutions.

Responsibilities of the REB Chair

The REB Chair is responsible for:

- Ethics review and approval of all revised materials and related documents associated with the ethics review feedback process involving minimal and greater than minimal risk research.
- Ensuring that the REB review process conforms to the requirements of the Tri-Council Policy Statement.
- Participating in and ensuring the provision of ongoing training and mentorship to REB members
- Chairing REB meetings
- Overseeing the review of all submissions, study amendments, study renewals and closures;
- Writing the Notice of Ethical Review, (NER), reviewing the NER responses and, if acceptable, granting approval for all REB applications;
- Reviewing unanticipated problem reports including but not limited to serious adverse events and protocol deviation reports;
- Provision of correspondence to applicants, as required;
- Meetings with researchers, departments, colleges, research centres, and affiliated institutions as required in relation to submissions for ethics approval and ongoing studies;

Consulting with Research Office staff in the development of policies, procedures and templates related to research with humans.

Completing administrative duties as required for the normal functioning of the REB;

- While respecting the integrity, confidentiality, and independence of the ethics review process, communicating, either directly to the Associate Vice-President (Research) or through the Research Office staff, any matter that may be of concern to the responsible management of research by the University or its appropriate affiliated institutions;

- Reporting to the Council Committee on Research annually;
- Supporting Inquiries by the VP (Research) under the Research and Scholarly Integrity Policy (GOV-022-025) that involve studies reviewed and approved by the REB, by providing all relevant documents and correspondence relevant to the inquiry and be available to provide information on the REB review.

The Co-chair (Indigenous Research) is responsible for the following:

- Participating in and ensuring the provision of ongoing training and mentorship to researchers and REB members with respect to Chapter 9 of the TCPS 2, the principles of OCAP®, Indigenous research methodologies and other topics relevant to research with Indigenous participants, communities, and their data.
- Writing the Notice of Ethical Review, (NER), reviewing the NER responses and, if acceptable, granting approval for all REB applications a) conducted on First Nations, Inuit or Metis lands; b) where recruitment criteria include Indigenous identity as a factor for the study; c) seeking input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics; d) where Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; or e) interpretation of results refer to Indigenous communities, peoples, language, history, or culture;
- Corresponding with applicants, as required;
- Attending meetings with researchers, departments, colleges, research centres, and affiliated institutions as required in relation to projects meeting any of the criteria a-e listed above;
- Consulting with Research Office staff in the development of policies, procedures and templates related to research with Indigenous participants, communities, or their data;
- While respecting the integrity, confidentiality and independence of the ethics review process, communicating, either directly to the Associate Vice-President (Research) or through the Research Office staff, any matter that may be of concern to the responsible management of research by the University or its appropriate affiliated institutions.

Vice Chair (Student Research) is responsible for:

- Writing the Notice of Ethical Review, (NER), reviewing the NER responses and, if acceptable, granting approval for REB Student applications;
- Reviewing unanticipated problem reports including but not limited to serious adverse events and protocol deviation reports;
- Corresponding with applicants, as required;
- Attending meetings with researchers, departments, colleges, research centres, and affiliated institutions as required in relation to submissions for ethics approval and ongoing studies.

The Vice Chair or Co-chair may also be required to take over Chair responsibilities such as:

- Follow up on studies currently under review.
- Address Researcher concerns with the review process.
- Chair REB meetings.

Responsibility for Record Keeping and Research Ethics Education

The Research Office ensures that:

1. REB members are provided with opportunities for research ethics education during their tenure on the REB beginning with a new member orientation session.
2. Comprehensive, accurate records (all documents and associated correspondence) of the initial and continuing (i.e., modifications, annual) ethics review and approval processes are securely maintained in the Research Office for all research under its jurisdiction.
3. REB meeting dates and submission deadlines are easily accessible by researchers through information posted on the Research Office website.
4. Timely information and regular reports are received on any unanticipated issues (events) that have occurred in association with research under its jurisdiction.
5. UofR guidelines, procedures and sample materials related to the conduct of research with humans are reviewed and updated on a regular basis (e.g., annually) to ensure that they remain current in an evolving research ethics environment.
6. Educational activities (e.g., in-class presentations, seminars and workshops) are provided to UofR students, faculty and staff involved in research with human participants.
7. Legal or other advice is sought by the Compliance Officer, as required, on matters related to the protection of human participants in research.
8. Where appropriate, the Compliance Officer will coordinate with other departments on campus responsible for health and safety to ensure recommendations by the REB are consistent with what is required by those offices.
9. Timely information on guidelines, procedures, and other matters related to the conduct of research with human participants is provided to the REB as well as student, staff and faculty researchers who conduct research with humans.
10. Supporting Inquiries by the VP (Research) under the Research and Scholarly Integrity Policy (GOV-022-025) that involve studies reviewed and approved by the REB, by providing all relevant documents and correspondence relevant to the inquiry and be available to provide context on the REB review.

G. Reconsideration and Appeal of REB Decisions

1. Reconsideration Process

A Principal Investigator may make a written request for reconsideration of an REB decision when ethics approval is not granted, or when ethics approval is conditional on revisions that the Principal Investigator (PI) believes may jeopardize the feasibility or integrity of the research. The Compliance Officer, Research Office, will refer such a request, including documentation and supporting materials received for reconsideration from the PI, to other members of the REB for

discussion at its next meeting. The REB will review the written documents, and where appropriate, will request an informal meeting with the PI (or his/her designate). Following consideration of all additional information (verbal and written), the REB will reach a final decision with respect to its position on the original decision. Every attempt will be made by the Research Compliance Officer and REB, in consultation with the PI, to reach a resolution by this informal route.

2. Appeal Process

In the event the matter cannot be resolved through a reconsideration or informal process, the institution shall provide the PI with prompt access to an established appeal process through which the PI may appeal the REB's decision. An appeal can be requested for procedural or substantive reasons and a formal request for an appeal can be submitted to the Vice President Research (VPR). An Ad Hoc appeal committee shall be appointed by the VPR, ensuring that members of the appeal committee will have expertise and knowledge to be able to competently judge the ethical acceptability of the research ethics application under review. Members of the REB whose decision is under appeal shall not serve on the appeal committee. The appeal committee will act impartially in its review of documentation provided by the REB and the PI (or designate), and will consult with others as required, including but not limited to, members of the REB and the PI (or designate). The appeal committee will issue a written report with its decision on the matter and provide the rationale for its decision to the VPR as per the REB Appeal Process (<https://www.uregina.ca/research/ors/human-research/appeals-committee.html>). It may approve, reject or request modifications to the research proposal. The appeal committee's decision will be final.

H. Multijurisdictional Research

1. Research Ethics Boards of Saskatchewan - Reciprocity Agreement

The Research Ethics Boards in the province of Saskatchewan have moved to a policy of full reciprocity. Applications approved by the REBs of the University of Saskatchewan, University of Regina, or Saskatchewan Health Authority, will be accepted by both of the other two institutions without the need for additional REB review.

ⁱ Quorum for REB meetings shall consist of at least five REB members, of whom at least:

- a. Two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- b. One member is knowledgeable in ethics;
- c. One member is knowledgeable in the relevant law. That member will not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
- d. One community member has no affiliation with the institution.