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YUKON UNIVERSITY RESEARCH ETHICS BOARD TERMS OF REFERENCE



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Yukon University Research Ethics Board - Terms of Reference

The Yukon University Research Ethics Board (REB) governs the ethical conduct of research involving human participants and ensure that all such research complies with the most recent version of the <u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS2 2018</u>, the YukonU Research Ethics Policy and other relevant legislation, policies and guidelines. All research involving human participants requires REB review and approval before any activity commences.

The jurisdiction of the YukonU's REB covers all research involving human participants:

- conducted by members of the Yukon University (YukonU) community
- undertaken under the auspices of, or in official affiliation with, YukonU; or
- that uses University equipment, facilities, space, resources, employees, or students
- Student course-based research also fall with the scope of REB review.

1. Mandate

The Yukon University Research Ethics Board (REB) ensures that all research carried out by investigators meets the highest ethical standards as per the <u>Tri-Council Policy Statement: Ethical Conduct for</u> <u>Research Involving Humans - TCPS2 2018</u>. The REB has been established by the authority of the Yukon University President to:

- 1.1. review proposed or ongoing research involving human participants which is conducted within the University's jurisdiction or under its auspices, by their faculty, staff, students, or affiliated researchers regardless of where the research is conducted, in accordance with the TCPS 2;
- 1.2. approve, reject, propose modifications to, or terminate such research based on this review;
- 1.3. ensure all researchers and support personnel affiliated with the University are familiar with and understand the ethical issues, principles, standards, policies and procedures to which they must adhere;
- 1.4. monitor all human research protocols for compliance with the principles established by the Tri-Council, and other funding agencies;
- 1.5. terminate any research that causes undue harm or distress to the participant(s) while research Is being done;
- 1.6. suspend any research that begins without the required approval, or which deviates from an approved protocol by the REB;

2. Accountability and Authority

The YukonU REB Terms of Reference are approved by the Associate Vice President Research Operations (AVPRO), on behalf of the President.

2.1. The REB has been established under the authority of the Office of the President, Yukon University. The REB is a standing board of Yukon University that reports directly to the President.



- 2.2. The REB Co-Chairs in collaboration with the REB Coordinator will report annually on the REB's activities to the President.
- 2.3. The REB reports to the President any breaches of compliance with approved protocols and standard operating procedures (SOP's) or other standards of practice. The REB will attempt to correct these breaches.
- 2.4. The REB is independent of the Board of Governors and Senior Administration in its decisionmaking with respect to its mandate under the TCPS 2. All entities and offices shall respect the independence, accountability and authority delegated to the REB and may not override an REB decision to approve or reject a research proposal.
- 2.5. An REB approval applies only to the ethical acceptability of the research and does not, in itself, constitute authorization for the research to proceed. Additionally, Yukon University may refuse to allow certain research within its jurisdiction to proceed, despite the REBs decision on the ethics of the research.
- 2.6. All REB members (including alternates) will sign confidentiality agreements and conflict of interest agreements.

Yukon University provides administrative resources to the YukonU REB for the effective and efficient operation of the YukonU REB to fulfill its mandate. Yukon University ensures that the REB is able to operate effectively and independently in its decision making, and supports and promotes the independence of the REB in its decision making so that it may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest.

3. Functions and Responsibilities

The REB will:

- 3.1. Ensure to the best of their ability that no research is started without prior REB approval through an application review process.
- 3.2. Review research proposals for scientific rigor, ethical considerations, appropriate funding and methods and adequate facilities/supports as outlined in the application form.
- 3.3. Approve or reject proposals, and may suspend any research that is taking place without the required approval, or that is in violation of the procedures proposed in the research project. Researchers must obtain REB approval for the research or for changes in the research previously approved by the Board before proceeding with said research.
- 3.4. Specify in writing the exact reasons for rejection or necessary modifications of a research proposal.
- 3.5. Conduct yearly reviews of ongoing research for compliance with the terms of the approved proposal based on the researcher submitted renewal application. As well as additional monitoring in specific cases as determined in an initial review.
- 3.6. Terminate any ongoing research that ceases to meet policy standards and deviates from the protocol originally approved by the REB.



- 3.7. Maintain strict confidentiality of applications.
- 3.8. Facilitate the education of:
 - 3.8.1.members of the REB by ensuring that they are provided with a basic understanding of the principals involved in research ethics review and continuing education opportunities as they become available. Additionally, through the REB Coordinator, be a resource for:
 - 3.8.1.1. inquiries about ethical issues in research
 - 3.8.1.2. consultation and advice for the University, its members, and the public on matters or issues related to research ethics.
 - 3.8.2. University individuals involved in research activities
- 3.9. Ensure that all human participant research protocols presented to the REB receive appropriate ethical review.
- 3.10. Suspend any research that is taking place without the required approval, or that is in violation of the procedures proposed in the in the research project submission. Researchers ust obtain the Boards approval for the research or for changes to the research by the Board before proceeding with their research.

4. Board Operations

- 4.1. The REB will determine if it is the appropriate body to review a given application and whether the application is within its jurisdiction or expertise.
- 4.2. If necessary, the REB will invite an ad-hoc member to advise on an application that the REB feels is outside of its expertise.
 - 4.2.1.All protocols will undergo a preliminary review by the REB Coordinator and Co-Chairs to determine the appropriate level of review.
 - 4.2.2.All decisions of the REB shall be reached by consensus whenever possible. If one or more members have a serious concern with respect to ethics, the matter is discussed further until resolution and/or the researcher is contacted for additional information. If an REB cannot achieve consensus, however, the decision shall be based on majority vote with the Chair's vote serving as a tie-breaker.
- 4.3. Researchers have the right to request a reconsideration of decisions by the REB affecting their research project. The REB will discuss the application again at the next meeting but has no obligation to change its decision.
 - 4.3.1.All disagreements will be communicated to the researcher upon request of reconsideration.
 - 4.3.2.Researchers will be given an opportunity to clarify the proposal and/or provide more information to the REB.
- 4.4. The researcher may request an appeal if they remain unsatisfied with the REBs decision.



4.4.1. Appeals are done by the Aurora College REB.

4.4.2. Decisions made by the appeal REB are final and binding.

4.4.3. The process for requesting appeal is outlined in Yukon University policy AR-03.

5. Membership

The composition of the YukonU's REB complies with the requirements of the TCPS2. The Research Ethics Board will be appointed by the Yukon University President and will consist of at minimum six members of whom:

- 5.1. At least two (2) are YukonU staff members, that have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- 5.2. At least one YukonU staff member who has knowledge or experience in research ethics;
- 5.3. At least one member is not an employee or student of Yukon University, but is recruited from the Yukon community;
- 5.4. At least one member is a representative of Yukon First Nations;
- 5.5. As needed, one ad hoc member who has no affiliation with Yukon University but who is recruited from the Yukon community and has expertise in the subject area under review. This member may be nominated by the Chair to ensure fair and thorough review of proposals;
- 5.6. For research involving students as participants, one ad hoc member is a full-time student at the Yukon University;
- 5.7. The Board may add one member knowledgeable in the relevant law for biomedical research;
- 5.8. Three (3) alternate members who must be approved by the REB through consensus. The use of alternate members should not, however, alter the membership structure as outlined in this Terms of Reference.
- 5.9. The REB Co-Chairs will be appointed from among current members of the REB through majority consensus. Due to workload issues, the REB may function with two Co-Chairs.
- 5.10. The Co-Chair(s) ensures that the REB review process conforms to the requirements of the TCPS2 and University policies, provides overall leadership for the REB, and facilitates the review process by:
 - 5.10.1. calling and chairing regular meetings of the REB
 - 5.10.2. determining, in consultation with REB members, whether a research proposal requires full or delegated review
 - 5.10.3. communicating decisions to researchers in writing, in collaboration with the REB Coordinator, within 15 working days of the scheduled review date, and
 - 5.10.4. ensuring that all REB meetings and decisions and all communications with researchers are documented and that these records are filed with the Research Services office by the REB Coordinator.



- 5.10.5. submitting an annual activity report with the support of the REB Coordinator to the President of Yukon University. At a minimum the report shall contain the reporting period, membership, activities and accomplishments.
- 5.11. To ensure the independence of REB decision making, senior administrators do not serve on the REB.
- 5.12. All full and alternate members are voting members and act as reviewers.
- 5.13. All REB members shall have or acquire knowledge regarding research ethics involving humans.
- 5.14. At a minimum, all REB shall be knowledgeable about the TCPS2 and must complete TCPS2 CORE tutorial and file their completion certificates with the REB Office.
- 5.15. They shall make constant effort to remain current in an evolving research ethics environment.

6. Terms of Appointment

- 6.1. Members may serve a two (2) year terms, except for student members who may only serve one (1) year terms. Terms may be renewed to a maximum of three (3) consecutive terms or six (6) consecutive years of service.
- 6.2. Members wishing to serve on the REB after six (6) consecutive years of service may reapply after a period of one (1) year after their membership has expired.
- 6.3. Membership will be staggered to ensure appropriate balance and to maintain continuity.
- 6.4. Normally, not more than one-half of the REB members change on a yearly basis.
- 6.5. Term renewal will be based upon recommendations of the continuing members of the REB.
- 6.6. When it is anticipated that the REB will require new members, the REB Coordinator under the advisement of the Co-Chairs will inform the Yukon University community of the need for members and the expertise to be filled on the REB.
 - 6.6.1.After receiving expressions of interest or nominations, the Chair(s) and the existing REB members will review them and select individuals who meet the relevant expertise requirements.
 - 6.6.2. The REB Coordinator then informs the President of the names of the individuals recommended for appointment as new members for the REB.

7. Meetings and Attendance

- 7.1. The REB will meet within four (4) weeks of receiving an application.
- 7.2. The REB shall meet face-to-face each month between the months of September and June. Approximately one (1) to two (2) meetings may be scheduled as required during the summer months. Dates are established at the beginning of the year and are made available to the University community via the Yukon University website.



- 7.3. The REB will discuss any general issues, revise policies or conduct business related to its mandate and enhance operations of the REB at these regularly scheduled meetings.
- 7.4. Researchers and faculty members seeking ethics review and approval may attend meetings of the REB either at their own request or at the request of the REB. However, only REB members may be present for decision-making on applications under review.
- 7.5. The Chair/Co-Chairs sets the agenda for each meeting in consultation with other members of the REB and the REB Coordinator.
- 7.6. Quorum is required for any decisions relating to policies and procedures.
- 7.7. Meetings will be face-to-face whenever possible. However, if necessary, the Board may make decisions via telephone or email organized by the Co-Chairs or REB Coordinator as authorized by the REB. This is provided that the research to be reviewed has been approved for delegated review.
- 7.8. Delegated review requires that the research:
 - is minimal risk,
 - does not involve deception,
 - all relevant documentation is provided
 - 7.8.1.Proposed research projects that require only delegated are reviewed by at least two members of the REB with expertise relevant to the project in question.
 - 7.8.2. Delegated review is conducted through ad hoc meetings between the REB members delegated to conduct the review. These meetings are organized as applications come in and in such a way as to render decision as quickly as possible (normally within 15 working days of receipt of the review application).
 - 7.8.3.Delegated review requires the consensus of all REB members reviewing the application. If no consensus can be made, the application will go to full review. Decisions taken with this method should be noted on the agenda and included in the minutes of the next formal meeting.

Attendance

- 7.9. REB members will be required to attend at least 50% of meetings per academic year.
- 7.10. Members must notify the REB Chair or the REB Coordinator if they are unable to attend any meeting as far in advance as possible.
- 7.11. Unexpected circumstances such as emergencies may prevent individual members from attending the REB meeting. In these exceptional cases, input from the member(s) by the use of phone or video link is acceptable.
- 7.12. If a member is absent for more than 50% of the meetings, the REB Chair/Co-Chairs shall review whether that member should continue to serve on the REB in a report to the University President.



7.13. Frequent, unexplained absences will be construed as notice of resignation.

Quorum

- 7.14. A quorum of the Board will be at least 50% of the REB membership or five (5) members, whichever is higher. The quorum will possess the range of expertise reflected in the membership.
- 7.15. The REB will accommodate reasonable requests from researchers to participate in discussions about their proposals, but they may not be present when the REB makes its decision.
- 1.7. In unexpected circumstances, or if the REB members are geographically dispersed, input from members may be allowed by other technological means, such as telephone, web conferencing etc.

8. Record Keeping and Administrative Support

The REB will be provided human resources, office space and support services from the Research Services office in order to fulfill the REB duties. The REB Coordinator will serve as a resource person.

The duties and activities of the Coordinator includes:

- 8.1. providing the administrative supports to the Co-Chairs and REB members, including the screening and review of research ethics protocol submissions to ensure completeness, handling necessary revisions, soliciting and processing annual renewals and file closures, accepting information on adverse events and facilitating needed actions by the Co-chairs, keeping accurate records of all decisions and research files, and attending all meetings of the REB.
- 8.2. ensuring that research ethics protocols are processed as soon as possible following submission of completed protocols
- 8.3. preparing and maintaining comprehensive records of its activities including the following:
 - 8.3.1.minutes of REB review meetings documenting decisions, their rationale, and any dissenting opinions;
 - 8.3.2.minutes of general meetings summarizing discussions, decisions, action items and assignments;
 - 8.3.3.copies of all research proposals reviewed, certificates of approval, approval sample consent forms, progress reports and incident reports submitted by researchers;
 - 8.3.4. records of continuing review activities;
 - 8.3.5.copies of all correspondence between the REB and researchers
 - 8.3.6.a list of REB members and contact information; and
 - 8.3.7. written procedures for the REB
- 8.4. Facilitating and / or carrying out the reporting of the outcomes of ethics protocol review to the researchers, receiving follow-up modifications and resubmissions as appropriate, providing



summaries of how questions and modifications are dealt with by researchers to the Co-Chairs and, if appropriate, to Board members reviewing the protocol so as to facilitate completion of requested modifications and eventual clearance to proceed.

- 8.5. supporting the Co-Chairs in signing off on approved protocols and renewals and processing all modifications.
- 8.6. preparing agendas in consultation with the Co-Chairs and minutes (including records of attendance, decisions, dissents, and reasons for them)
- 8.7. Filing all REB records with the Research Services office, where they are maintained in accordance with YukonU's Information Access and Protection of Privacy Policy and relevant territorial and federal legislation.
 - 8.7.1.Records will be managed as follows:
 - 8.7.1.1. Minutes will be kept from the meetings and placed with the appropriate files with the REB Coordinator;
 - 8.7.1.2. The REB Coordinator will keep a permanent record of all final research proposals and any decisions made by the REB.
 - 8.7.1.3. Minutes of all REB meetings will be taken by the REB Coordinator or substitute and will clearly document REB decisions and any dissents including the reasons for them.
 - 8.7.1.4. Other materials, guides and information will be maintained and housed through the REB administrative supports by the Coordinator.
- 8.8. ensuring timely filing of yearly reports for ongoing research and providing clearance to continue where warranted. Where approval by the REB was conditional on more than annual monitoring, the Coordinator will ensure that this more frequent monitoring occurs and reports any concerns to the Co-Chairs.
- 8.9. receiving adverse events reports; ensuring such adverse events are brought to the attention of the Co-Chairs; supporting the Co-Chairs in the resolution of any adverse events; and reporting at regular REB meetings as to the nature of any adverse event and their resolution.
- 8.10.serving as a resource to the research community; communicating with, educating and advising researchers on guidelines, procedures and other matters relating to the conduct of research with human participants, and continuously improving the web site and resources for the research community.
- 8.11. establishing policy and practices in consultation with the Co-Chairs to manage an ongoing monitoring system in accordance with best practices.
- 8.12. monitoring approved research protocols and ongoing ethics review
- 8.13. coordinating educational events for REB members



9. Conduct, Confidentiality, and Conflicts of Interest

- 9.1. The REB shall function impartially, provide a fair hearing to those involved in reviews, and provide reasoned and appropriately documented opinions and decisions.
- 9.2. The REB perform reviews in strict confidence in order to protect and respect the rights and intellectual property of both researchers and participants.
- 9.3. REB members have an obligation to ensure that the fairness and transparency of research ethics review are not compromised by real, potential, or perceived conflicts of interest with any researcher, research team, or research proposal submission. Disclosure of conflicts of interest shall comply with YukonU's Conflicts of Interest Policy (PO-04).

10. Process for Modifying the Terms of Reference

- 10.1. These Terms of Reference will be re-examined every 2 years, or with any relevant Tri-Council or YukonU policy revisions, whichever occurs first.
- 10.2. The Chair/Co-Chairs of the REB in collaboration with the REB Coordinator ensures that any modifications meet the requirements of the most recent version of the TCPS2 and YukonU policies.