

ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS

Procedure Section & Number:	Academic & Student Experience	Effective Date:	October 20, 2023
Policy Owner:	Vice President, Academic and Student Experience	Last Revised:	June 1 , 2023
Policy Administrator:	Chair, Library Services & Research	Review Scheduled:	Every 3 years
Approver:	Executive Committee		
<i>The official controlled version of this document is held with the Policy & Procedure Coordinator.</i>			

A. PROCEDURES

This procedure is intended to ensure that the rights of participants in research are respected and protected, and research is conducted in a manner consistent with the guidelines and standards of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2). This procedure guides the College's Research Ethics Board (REB) in the protection of participants and their rights.

1. Research Ethics Board Membership

- 1.1 The REB shall consist of at least five and no more than twelve members, who shall be gender diversified.
- 1.2 Within the REB membership, at least:
 - 1.2.1 two members shall have expertise in relevant research disciplines, fields or methodologies covered by the REB;
 - 1.2.2 one member shall be knowledgeable in ethics;
 - 1.2.3 one member shall be knowledgeable in the relevant law;
 - 1.2.4 one member shall be a community member who has no affiliation with the College.
- 1.3 A trained student member may be added if the REB is mainly reviewing student research.
- 1.4 Further, no College manager shall serve as a member of the REB.

2. Member Recruitment and Appointment

- 2.1.1 The REB shall advertise widely to recruit qualified individuals to the Board.
- 2.1.2 Interested individuals shall submit an REB membership application form (see Appendix A) as prescribed by the Board.
- 2.1.3 Applications will be reviewed by a panel appointed by the Vice President, Academic and Student Experience.
- 2.1.4 The panel will consider the applicants based on their experience, qualifications, and fit with the REB skills matrix and recommend appropriate applicants for appointment.
- 2.1.5 The President will make the appointments to the REB from the recommended list provided by the panel.

3. Terms of Appointment

- 3.1 Candidates selected for appointment to the REB will sign a letter of appointment setting out the terms of the appointment including a confidentiality of information and conflict of interest agreement.
- 3.2 Appointment to the REB shall be for a term of up to three years.
- 3.3 Appointments to the board shall be distributed over a rolling three-year period to ensure continuity on the Board and provide for the appropriate composition of the membership.
- 3.4 A member may be reappointed to the Board for a second term but may serve no more than six consecutive years.
 - 3.4.1 Notwithstanding the above statement, a member who possesses unique critical experience for whom no replacement may be found may be appointed for another term.
 - 3.4.2 A past member may be reappointed to the Board after an absence of at least one year.
 - 3.4.3 A member seeking re-appointment, who has met the expectations for the role, including regular attendance and timely completion of assigned reviews as confirmed by the Chair, may be recommended by the Board to the Vice President, Academic and Student Experience for re-appointment upon a majority vote supporting confirmation by the current Board members.

4. Substitute Members

- 4.1 Substitute members may be appointed to the Board to serve on an *ad hoc* basis to enable the continued functioning of the board when regular members are unable to participate due to illness, conflict of interest, or unexpected circumstances, or when special expertise or insight is required.
- 4.2 Substitute members shall have the appropriate training, expertise, and knowledge.

5. Preparation and Training of Members

- 5.1 Individual members of the REB must be qualified for their role and duties through training, experience, and expertise. All members shall be required to undertake the training and education necessary to enable them to fulfill their duties. Such training and education must meet the minimum requirements set down by the Board and address any deficiencies of a member.
- 5.2 Education and training opportunities shall be provided to members of the REB to enable and assist them to effectively fulfill their duties. At a minimum, the training in the following areas shall be provided to and expected of each REB member:
 - 5.2.1 an understanding of the TCPS2 and its core principles,
 - 5.2.2 basic ethic principles and standards,
 - 5.2.3 relevant institutional policies, and
 - 5.2.4 legal and regulatory requirements.
- 5.3 Prior to completing any reviews, members of the REB are required to complete the TCPS2 Tutorial Course on Research Ethics (CORE), or any successor to it.

6. Conflict of Interest

- 6.1 Individual members of the REB must be free of any conflict of interest, or perception thereof, in any discussions, deliberations or decision-making whether in the conduct of Board business or reviews of research proposals and reports.
- 6.2 A Board member finding him/herself in a conflict of interest should immediately declare such to the Chair and Board and remove him/herself from any involvement in the discussions, deliberations, or decision-making.

Removal includes removal from the physical setting of the discussion, etc. and from any communications concerning the Board business or reviews from which the identified conflicts arise.

- 6.3 A Board member unsure of whether a conflict of interest exists should discuss the matter with the Chair who will then provide guidance to the member.
- 6.4 Where it is not clear whether a conflict of interests exists, or may be perceived to exist, for a member, the default decision shall be to declare a conflict.
- 6.5 Beyond a self-declared conflict of interest, a concern regarding a board member's conflict of interest, or the appearance of a conflict of interest, may be raised by any member of the board, or any other person, and the matter shall be determined by a majority vote of the Board, whose ruling shall be final. A member found to have a conflict of interest shall immediately remove him/herself from the discussion, etc. as described above.
- 6.6 All declarations, discussions and decisions concerning conflicts of interest shall be recorded in the minutes of the Board.

7. Removal of Members

- 7.1 The appointment of an individual to the Board may be terminated if the member cannot or does not fulfill the responsibilities of an REB member.
- 7.2 Circumstances that may lead to the termination of an appointment include, but are not limited to:
 - 7.2.1 excessive absences from meetings,
 - 7.2.2 failure to complete review duties in a timely fashion,
 - 7.2.3 failure to complete review duties in an ethical manner,
 - 7.2.4 failure to attend research ethics training,
 - 7.2.5 determination of research misconduct, and
 - 7.2.6 any behaviour that could compromise or the perceived to compromise a member's ethical judgment.

- 7.3 The circumstances that lead to the review of a member's appointment shall be presented by the REB chair to the appointment panel established by the President.
- 7.4 The appointment panel will review the circumstances, and may choose to interview the member in question, and will make a recommendation to the President concerning the termination or continuation of the appointment of the member.
- 7.5 Upon receipt of the panel report and recommendation, the Vice President, Academic and Student Experience may choose to terminate the appointment of the member to the REB.

8. REB Chair

- 8.1 The primary role of the REB Chair is to provide overall leadership to the REB and guide the REB review process. Within that leadership role, the Chair will ensure that the REB and its review process conform to the requirements of the College and the TCPS2 to protect participants and their rights.
- 8.2 Further, and more specifically, the Chair shall be responsible for:
 - 8.2.1 calling and chairing regular meetings of the REB and other meetings as required,
 - 8.2.2 maintaining and coordinating communications with REB members and the College,
 - 8.2.3 communicating clearly and in a timely fashion the decisions of the REB to the principal investigators and the College,
 - 8.2.4 determining delegated reviews of proposed research,
 - 8.2.5 recommending experts to the REB where required,
 - 8.2.6 ensuring the appropriate recording and documentation of REB meetings and decisions, and the appropriate storage and distribution of the documentation,
 - 8.2.7 monitoring the REB decisions for consistency, and
 - 8.2.8 receiving requests for and facilitating access to information and educational resources for the campus community.

- 8.3 The chair may fully participate in all Board discussions and deliberations but shall not vote except to break an otherwise tied Board vote.

9. Election of Chair

- 9.1 Annually, or as required, the REB shall elect a Chair from among its members. The Chair shall be elected at the first REB meeting for the academic year and shall serve a two-year term.
- 9.2 A member may serve as Chair for no more than two consecutive two-year terms, and in no case may exceed the overall six-year Board term while serving as Chair.

10. Research Ethics Board Meetings and Attendance

- 10.1 To fulfill its responsibilities, the REB shall have regular face-to-face meetings monthly. The dates for the REB meetings for the academic year shall be published on the REB website. When there are no proposals before the Board, members will use this time to engage in ethics training, ethics discussions, or administrative tasks that support the REB infrastructure.
- 10.2 Regular attendance by members at REB meetings is necessary to ensure effective communication and decision-making. Attendance at all meetings is expected of REB members. Under exceptional circumstances, such as emergencies, technology-enabled participation at a distance is acceptable.
- 10.3 For decisions concerning the operations of the REB, a meeting quorum is reached when 50% or more of the REB members, including the Chair are present. For full Board reviews of proposals, quorum is reached when at least five REB members, including the Chair, are present, and the members present satisfy all roles identified above for Board membership.
- 10.4 The REB shall determine and post publicly a schedule of meetings for the year prior to September 1 of each year.
- 10.5 Further, the REB shall hold workshops and/or committee meetings to:
- 10.5.1 enhance the operation of the REB,
 - 10.5.2 facilitate and expedite the discussion of rising issues,
 - 10.5.3 review, consider, or revise relevant policies, and
 - 10.5.4 provide for the training of REB members.

11. Ad Hoc Advisors

- 11.1 All ad hoc advisors shall be required to sign a confidentiality of information and conflict of interest agreements.
- 11.2 Ad hoc advisors will be consulted if the REB lacks the specific expertise or knowledge to review and determine the ethical acceptability of a research proposal.
- 11.3 An ad hoc advisor may provide information, comment, and insight to the Board but may not actively participate in any REB discussion, debate, or decision. The advisor may not vote in any REB decision. An advisor may not be counted towards meeting quorum requirements.
- 11.4 All ad hoc advisors are required to complete the TCPS2 Tutorial Course on Research Ethics (CORE), or any successor to it.

12. REB Records and Documents

- 12.1 The REB shall maintain on file all documents submitted and considered for research project proposals, and minutes of all REB board and committee meetings and other deliberations.
- 12.2 The above documents and records shall be maintained in a secure manner within College facilities.
- 12.3 The above documents and records shall be available to College authorized personnel, researchers, and funding agencies.
- 12.4 The REB shall create and maintain minutes of all REB board and committee meetings. The minutes shall include:
 - 12.4.1 a roll call,
 - 12.4.2 declarations of a conflict of interest and the subsequent handling of them,
 - 12.4.3 records of discussion,
 - 12.4.4 decisions and determinations,
 - 12.4.5 dates of decisions,
 - 12.4.6 a record of the vote on any decision,
 - 12.4.7 if requested by a dissenter, a record of the dissent, and the reasons for the dissent,
 - 12.4.8 titles or names of proposals considered,

12.4.9 documents reviewed during deliberations, and

12.4.10 plans for continuing ethics review.

12.5 In addition, the REB shall maintain general records including, but not limited to, curricula vitae of members, records of members' participation in REB related training.

12.6 The REB will retain all records for a minimum of five years - from the time of completion or termination in the case of a research project - or for a greater length of time if stipulated in applicable governing regulations or College policy.

13. Participants and the REB

13.1 The first priority of the REB is the protection of participants and their rights.

13.2 Permission for research to begin will be granted by the REB if, and only when, the REB is satisfied with the protection provided for participants and their rights, their privacy and confidentiality, and the safeguarding of their information.

14. Participant Consent

14.1 The REB must be satisfied that the research consent process provides for and ensures fully informed consent, fully voluntary consent, withdrawal, or alteration of consent without harm or loss of benefit, and consent safeguards for participants of who lack the capacity to decide for themselves.

15. Participants' Concerns

15.1 Where any participant expresses significant concern about the nature of the informed consent to the use of the research, the researcher shall report their concerns to the REB.

15.2 Participants shall be able to voice their concerns, ask questions, and request information regarding their participation (or potential participation) in research, in confidence, to the REB Chair.

15.3 The Chair, or designate, shall document all communications with the participant(s), and a de-identified record, when anonymity is requested, of these communications will be maintained securely and in the relevant research file.

16. Participants' Privacy and Confidentiality

- 16.1 The REB must be satisfied that the researchers shall comply with all applicable privacy legislation and that, wherever possible, participants are guaranteed privacy and anonymity and their responses will be treated with confidentiality.

17. Safeguarding Participants' Information

- 17.1 The REB must be satisfied that the researchers will appropriately safeguard all participants information during the collection, use, dissemination, retention, and/or disposal of the information.

18. Review and Approval of Research by the Research Ethics Board

- 18.1 No research may begin until the REB has reviewed the research proposal and approved the research. Ongoing research may be required by the REB to undergo periodic review and receive renewed approval by the REB for the continuation of the research.
- 18.2 For research to be considered for ethical review, a complete research ethics review application package must be submitted to the REB, including all final research documents. The application package and requirements are available on the REBs webpage.
- 18.3 Every research proposal will be subject to a full review unless the Chair determines that a delegated review is sufficient and appropriate. Research proposals submitted to the REB for approval will be reviewed initially by the REB Chair who will determine the appropriate level of review (a full review or a delegated review) for the proposal.

19. Delegated Review

- 19.1 A delegated review may be sufficient and appropriate, for example, when:
- 19.1.1 the proposed research involves minimal risk to participants,
 - 19.1.2 the research is course-based and of a pedagogical nature,
 - 19.1.3 when the proposed changes to already approved research involve minimal risk, or
 - 19.1.4 previously approved minimal-risk research requires an annual review and renewal of approval.
- 19.2 A delegated review shall be undertaken by a committee of one or more delegated reviewers selected from amongst the REB membership or, in the

case of a delegated review of course-based research, to a selected reviewer who is not an REB member.

- 19.3 The decision of the committee undertaking the delegated review shall be reported to the Chair, who shall report the decision to the REB at the next scheduled meeting.
- 19.4 The reviewer(s) conducting a delegated review may approve the proposal, request revisions to the proposed research upon which approval is conditional, or refer the proposal to the full Board. An approval or conditional approval arising from a delegated review may be communicated, by the Chair, to the proposing researcher prior to informing the REB of the decision.
- 19.5 In the case of a research proposal that is referred to the Board by the delegated reviewer(s), a full review must be undertaken by the REB. After that review, a final decision will be communicated to the proposing researcher.

20. Delegated Review of Course-Based Research

- 20.1 Research arising out of a course of instruction that is intended solely for pedagogical purposes (e.g., the objective of the activities is to provide students with exposure to research methods in their field of study) and involves no more than minimal risk to participants may be eligible for a delegated review.
- 20.2 Further, for such course-based research, the review may be delegated to selected reviewers who are not members of the REB. For example, the faculty member teaching the course within which the course-based research takes place may be designated as the delegated reviewer.
- 20.3 Reviewers who are designated to undertake delegated reviews of course-based research shall have the experience, expertise, training, and resources required to effectively review the ethical acceptability of the proposed research and ensure consistency with REB expectations, this Policy, and the TCPS2.

21. Full Review

- 21.1 A full REB review shall:
 - 21.1.1 take place in a face-to-face REB meeting,

- 21.1.2 have, for all proposals received by the REB, except those identified for a delegated review, the complete application copied and distributed to all members of the REB,
 - 21.1.3 have at least five REB members present, and the members present shall satisfy all the roles identified for REB members,
 - 21.1.4 not have REB members with a conflict of interest in the deliberations or the vote of the REB, and
 - 21.1.5 have decisions made by a majority vote of the REB members who are present at the meeting.
- 21.2 The applicant may be required to be present at the REB meeting to discuss the proposed research and answer questions the REB may have about the research but may not be present when the REB is considering and making its decision.
- 21.3 The REB will review, examine, and consider the research proposal to determine its compliance and consistency with the Board's expectations, this Policy, and the TCPS2.
- 21.4 If there are questions that must be addressed or additional information that is required prior to a determination, the REB may defer its decision until all outstanding questions and information requirements are addressed.
- 21.5 Following its deliberations, the REB shall approve, not approve, or require modifications to the proposed research.
- 21.5.1 When modifications to the research plan or methodology are required, the REB may withhold approval until it reviews and is satisfied with the modifications.
 - 21.5.2 In those cases where the REB withholds approval until it is satisfied with the modifications, the Board may permit the Chair and at least one other member of the Board to review the proposed modifications and, if appropriate, approve the modifications and grant approval for the proposed research. If, under these circumstances, the proposed modifications are not approved, the applicant will be invited to the next Board meeting to discuss the application prior to the final decision being made.

22. Communication of REB Decisions

- 22.1 The Chair of the REB shall be responsible for communicating, in writing, all decisions concerning proposals to the members of the REB, the proposal originator and the College.
- 22.2 The Chair shall ensure that a full and detailed record of the decision is forwarded to the appropriate College department.

23. Reconsideration of REB Decisions

- 23.1 A researcher has the right to have an REB decision reconsidered.
- 23.2 If a researcher is dissatisfied with an REB decision, the researcher may request a formal reconsideration of the decision.
- 23.3 The researcher has the responsibility to make the request in a timely fashion, typically within five working days of being notified of the REBs decision and clearly establish and justify the grounds for the reconsideration request.
- 23.4 The Board shall honour the request and undertake a reconsideration of its decision guided by the principles of natural and procedural justice, including:
 - 23.4.1 a reasonable opportunity for the researcher to be heard,
 - 23.4.2 the provision of an explanation of the reasons for the REBs opinions and decisions,
 - 23.4.3 the opportunity for the researcher to provide a rebuttal,
 - 23.4.4 the application of fair and impartial judgment, and
 - 23.4.5 the completion of the reconsideration in a timely manner.
 - 23.4.6 The decision of the Board at the conclusion of the reconsideration shall be communicated to the applicant, with reasons for the decision, and to the College, and shall be considered the final decision of the Board.

24. Continuing Research Ethics Review

- 24.1 On-going research shall be subject to periodic reviews by the REB.
 - 24.1.1 The frequency and the level of the periodic reviews shall be consistent with the level of risk in the research.

24.1.2 Funded programs of research shall also follow the continuing reporting requirements of the funding agency.

25. Modifications to Approved Research

25.1 Modifications to approved research may not be initiated without prior REB review and approval.

25.2 Notwithstanding the above statement, where it is necessary to eliminate apparent immediate hazards to participants

25.2.1 the necessary changes or modifications should be implemented immediately, and

25.2.2 the researcher shall then immediately notify the REB and arrange for REB review and approval of the changes.

25.2.3 A researcher seeking to modify previously approved research shall submit to the REB a request for changes.

25.2.4 The change request will be reviewed through either a delegated or full review, as determined by the Chair.

25.2.4.1 If the decision is that a full review is required, the Chair shall so inform the College.

25.2.5 A review of a request for modification (whether a delegated or full review) shall be governed by the same policies and processed in the same manner as an initial proposal review.

26. Reporting Unanticipated Issues

26.1 The researcher must notify the REB, as soon as possible, of any adverse or unanticipated issue or event that may have ethical implications or increase the level of risk to participants during the research.

26.1.1 The reporting of the unanticipated issue shall include a description of the issues or incident, as well as details of how the researcher dealt with the situation.

26.1.2 The REB may require researchers to adjust their procedures to prevent recurrence.

27. Research Completion

27.1 The Completion of research is a change in activity that must be reported to the REB.

27.1.1 A final report allows the REB to close its files.

27.1.2 As well, the final report will provide the REB with information that may be used in the evaluation and approval of related studies.

28. Appeal of an REB Decision

28.1 A researcher has the right to appeal an REB decision.

28.2 A decision of the REB may be reversed only by the REB through reconsideration, or by a Research Ethics Appeal Board (REAB).

28.3 A researcher has the right to appeal to a Research Ethics Appeal Board.

28.4 The College shall provide for a Research Ethics Appeal Board. The College shall use the established REB of another college or institution that has no prior knowledge of or exposure to the research that is the subject of the appeal.

28.5 An appeal to the REAB must be made consistent with the following requirements.

28.5.1 The researcher has exhausted the Reconsideration process and the REB has issued a final decision.

28.5.2 The researcher must initiate the appeal within 30 days of the issuance of the written decision by the REB.

28.5.3 The researcher must inform, in writing, the REB and the College of the request for an appeal.

28.5.4 The appeal must be made in writing to the Chair of the REAB.

28.5.5 The appeal application must include all supporting documents.

28.6 The Research Ethics Appeal Board may sustain, modify, or reverse a decision of the REB.

28.7 The decision of the Research Ethics Appeal Board will be made in a timely fashion and communicated in writing to the researcher and the REB.

28.8 The decision of the Research Ethics Appeal Board is final.

29. Modifications of this Policy

- 29.1 The REB has the right, within the guidelines laid out by the Tri-Council, to recommend changes to this policy.
- 29.2 Any recommendation for changes must be approved by a majority of the members of the REB.
- 29.3 The consideration and implementation of REB-recommended changes to this policy will be considered and implemented consistent with College policy.

B. DEFINITIONS

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|------------------------|---|
| (1) Autonomy | Defined as the ability to deliberate about a decision and to act based on the deliberation. |
| (2) College | Defined as Keyano College |
| (3) Participant | An individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s). Also referred to as a "human participant," and in other policies/guidance as "subject" or "research subject". |
| (4) Research | For the purposes of the College REB, research is defined as an activity designed to test a hypothesis, permit conclusions to be drawn and develop or contribute to generalizable knowledge, using scientific methods and standardized protocols. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. |
| (5) Researcher | Defined as a person who anticipates undertaking or in any way being engaged with research of any type involving human participants; conducts academic or scientific research on behalf of Keyano College. For example, but not limited to, full-time or part-time employees, contract employees, unpaid associates, volunteers, students, industry partners, etc. |

C. RELATED LEGISLATION

- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS2\).](#)

D. RELATED DOCUMENTS

- Research Ethics Board Application
- Research Ethics Board Reviewer’s Checklist
- Ethical Conduct for Research Involving Humans Policy

E. REVISION HISTORY

Date (mm/dd/yyyy)	Description of Change	Sections	Person who Entered Revision (Position Title)	Person who Authorize d Revision (Position Title)
06/01/2023	New procedure created to reflect new REB structure in line with Tri-Council requirements	All	Sarah Schmidt, Chair of Library Services and Kelly Keus, Technology and Online Learning Librarian	Sandra Efu, Vice President Academic and Student Experience

Appendix A:
REB Membership Application Form

INSTRUCTIONS: <ol style="list-style-type: none"> 1. Complete all sections of this form. Please include N/A if a section is not applicable. Incomplete applications will not be reviewed. 2. Attach a copy of any relevant certificates of training completion, permits and documentations that may be required. 3. Submit this form to reb@keyano.ca. 	
Name (first, last):	
E-mail address:	
Current role:	
Current department:	
Why are you interested in joining the REB?	
Research background and experience:	
Areas of expertise:	