

 <b>CAPILANO UNIVERSITY</b>		<b>PROCEDURE</b>	
<b>Policy No.</b>	Officer Responsible		
<b>S2021-02-01</b>	<b>Vice President Academic &amp; Provost</b>		
<b>Policy Name</b>			
Research Ethics Procedure: Research with Human Participants - Research Ethics Board			
<b>Approved by</b>	Replaces	Category	Next Review
<b>Senate</b>	<b>S2002-01</b>		<b>2024</b>
<b>Date Issued</b>	Date Revised	Related Policies, Reference	
<b>October, 2021</b>	<b>New</b>	<b>B.506 Standards of Conduct</b>	

## 1. AUTHORITY AND RESPONSIBILITIES OF THE CAPILANO UNIVERSITY RESEARCH ETHICS BOARD (REB)

1.1 The REB exercises the authority of the President and is accountable to the President or their designate in all matters concerning research associated with Capilano University involving human participants or human biological materials.

1.2 The Capilano University REB has the following responsibilities:

- a) Ensures that research involving human participants and/or human biological materials associated with the University does not proceed without the prior approval by the REB or a Faculty or Departmental Ethics Review Committee approved by the REB, unless such research is exempt from REB review in accordance with REB Policy.
- b) Evaluates Applications for Ethical Review (Applications), ensuring proposed research adheres to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants (TCPS)*.
- c) Supports the University research community to become familiar with statutes, regulations, and Tri-Council guidelines pertaining to research involving human participants.
- d) Maintains a record of all active research projects approved by the REB and undertakes ongoing review of projects continuing after initial term of approval.

- e) Investigates reports of non-compliance with the Capilano University Research Ethics Policy, these Procedures, or complaints of improper research involving human participants associated with the University. The REB will only undertake these investigations in relation to the safety and welfare of the research participants.
- f) Maintains records for seven (7) years from the completion of the project, including meeting minutes, Applications submitted and approved, correspondence between the REB and researchers, written reasons pertaining to the acceptance or rejection of Applications, continuing review, amendments, appointment of members, procedures, and records of investigation of allegations of non-compliance with these Procedures and related Policy.

## **2 REB COMPOSITION, ADMINISTRATIVE SUPPORT, APPOINTMENT, AND ROLES OF MEMBERS**

2.1 The REB will be comprised of no fewer than five (5) members and a Chair as follows:

- a) A minimum of two (2) regular members with broad knowledge in the methods or disciplines of research commonly reviewed by the REB;
- b) A minimum of one (1) member with broad expertise in research ethics;
- c) A minimum of one (1) community member who has no affiliation with the University;
- d) A minimum of one (1) REB Chair; and
- e) A minimum of one (1) Research Ethics Officer (ex-officio, non-voting member).

2.2 As the need arises, the REB may involve others on an ad hoc basis to aid in the review of Applications, including seeking expertise in disciplines not well-represented on the REB and/or regarding legal issues relevant to the research. Such individuals are not REB members and do not vote on REB decisions.

2.3 Capilano University will strive to have at least one Indigenous person appointed as a member of the REB.

2.4 Exclusions to REB Membership:

- a) The University's legal counsel will not be a member of the REB.

- b) University administrators may not be members of the REB, nor will they attend REB meetings when Applications are discussed.

#### 2.5 Appointment and Reappointment of REB Members and Chair:

- a) REB Members and the Chair are appointed by the President for a two-year term and may be reappointed for a second two-year term.
- b) Upon resignation of the Chair, and/or at the end of the of Chair's term, the outgoing Chair and the Research Ethics Officer, in consultation with the REB, will recommend to the president appointment of a new Chair.
- c) On an annual basis, the REB Chair and Research Ethics Officer will assess the composition of the REB and recommend to the President appointment and reappointment of members. Recommendations on appointment and reappointment of REB members will be based upon:
  - i. The imperativeness of:
    - a. maintaining expertise in discipline-specific standards, fields and methods covered by the REB, and knowledge of research ethics;
    - b. maintaining an effective balance of new members and members serving a second term;
    - c. having at least one Indigenous member appointed to the REB;
  - ii. Adherence to documented *REB Standard Operating Procedure #001: REB Member Responsibilities and Conduct*; and
  - iii. Expressions of interest from University personnel who wish to be appointed and from members who wish to be reappointed.

#### 2.6 Resignation and Removal of REB Members and Chair:

- a) The REB Chair or an REB Member may resign from the REB before the conclusion of their term upon provision of notice to the REB Chair or the Chair's designee.
- b) The REB Chair or an REB Member should resign immediately upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behavior that could be perceived as compromising ethical judgment.

- c) The REB Chair may remove an REB member in accordance with REB Standard Operating Procedure #001: REB Member Responsibilities and Conduct, or upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behavior that could be perceived as compromising their ethical judgment.
- d) The President may remove the Chair upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behavior that could be perceived as compromising their ethical judgment

2.7 The University will provide the REB with the necessary, ongoing financial and administrative resources to fulfill its responsibilities.

### **3 MEETINGS OF THE REB, QUORUM, DECISION-MAKING AND MINUTES**

3.1 The REB will meet formally in-person on a monthly basis, or as often as necessary to fulfill its responsibilities.

3.2 REB members will have at least five (5) business days' notice of any meeting, and copies of all documents to be considered at the meeting are to be provided with the notice.

3.3 Quorum of the REB will be at least five (5) members, including the Chair, and, at a minimum, will include:

- a) two (2) members with expertise in relevant research disciplines, fields and methods covered by the REB; and
- b) one member knowledgeable in ethics; and
- c) one community member not associated with Capilano University.

3.4 REB Decision-Making

- a) The REB will function impartially, provide fair hearing to those involved, and provide reasoned and appropriately documented decisions.
- b) When the REB issues a non-approval decision, it will provide the applicant the reasons for its decision and an opportunity to reply before making a final decision.
- c) The REB will strive to reach decisions by consensus. Only when necessary will decisions be made by a simple majority vote.

3.5 Meetings with the Applicant

- a) The REB will accommodate reasonable requests from applicants to discuss their applications with the REB.
- b) Applicants are not present at REB meetings when the REB is engaged in discussion leading to a decision.

### 3.6 Minutes

- a) Minutes of all REB meetings will be prepared and maintained by the REB with support of administrative support personnel. The minutes will clearly document REB decisions and the reasons for decisions when related to a non-approval decision.
- b) Meeting minutes will be accessible to representatives of the University, researchers, and funding agencies upon request.

## **4 APPLICATION FOR ETHICAL REVIEW**

4.1 Applicants will submit their applications for Ethical Review by email to [reb@capilanou.ca](mailto:reb@capilanou.ca).

### 4.2 Timing of Submissions:

- a) To be considered at the next scheduled REB meeting, applications must be submitted to the REB at least two (2) weeks prior to the next meeting of the REB.
- b) The REB is under no obligation to review new applications during the faculty vacation period (June 15 to August 15).

4.3 Applications for Ethical Review submitted to the REB must conform to the format and content specified by the REB and presented in language that REB members can readily understand.

4.4 Applications for Ethical Review will be reviewed at a monthly meeting of the REB or by a subcommittee of the REB (Delegated Review).

4.5 Optionally, with approval of the Director, Creative Activity, Research and Scholarship, the REB may delegate its responsibility to review minimal risk course-based student research to a Faculty or Department Ethics Review Committee.

4.6 The REB Chair and/or their designate will determine the appropriate level of review in accordance with the criteria described in Sections 5 through 7.

## **5 LEVELS OF REVIEW: FULL BOARD**

### 5.1 Review of the Full Board (Full Board Review)

- a) Research not meeting the criteria for delegated review or Faculty or Department Ethics Review Committee Review will be reviewed at a meeting of the Full Board.
- b) Full Board meetings require, at a minimum, attendance of a quorum of members, as described in Section 3.3.
- c) The REB will strive to reach decisions by consensus. Where members disagree, areas of disagreement will be discussed with a view to reaching an outcome acceptable to all members. Only when necessary will decisions be made by a simple majority vote. The REB Chair decides whether a decision will be decided by majority vote.
- d) The REB will strive to provide its decisions, and reasons for its decisions, within one (1) week of the meeting at which an application is reviewed.

### 5.1 The following are the outcomes and applicable processes of a Full Board Review:

- a) If the REB approves an application as submitted, the REB Chair or Research Ethics Officer will provide a letter of approval to the applicant.
- b) If the REB does not approve an application, the REB Chair and/or Research Ethics Officer will summarize in writing the reasons for the REB's decision, describe the nature of the REB's concerns, and suggest modifications to the proposed research.
- c) Upon receipt of a revised Application, the REB Chair and/or the Research Ethics Officer will determine whether the application is to be approved as resubmitted, reviewed on a delegated basis, or reviewed at a meeting of the Full Board.
- d) The processes of review and resubmission will continue until the REB determines that the project may proceed, or the applicant declines to resubmit the application. At any point during this process, and if requested in writing by the applicant, the REB will reconsider its decision.
- e) If an application is not approved following every effort (as above) to address REB concerns, the researcher has the right to appeal the REB decision.

## **6 LEVELS OF REVIEW: DELEGATED REVIEW**

6.1 Delegated reviews may be completed by a subcommittee of the REB comprised of the REB Chair and one regular REB Member; the Research Ethics Officer, and one regular REB member; or the REB Chair and the Research Ethics Officer.

6.2 The following types of research may be reviewed by a subcommittee of the REB (Delegated Review):

- a) Minimal risk research, defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research;
- b) Research that does not involve persons or groups in vulnerable circumstances, invasive methods, sensitive subject matter, deception or withholding of information from participants;
- c) Continuing review of approved projects for which there has been little or no change from that originally approved;
- d) Resubmitted Applications for research previously reviewed at a meeting of the full REB; and
- e) Multi-jurisdictional research that has been approved by another Canadian Research Ethics Board.

6.3 The REB will strive to provide its decisions, and reasons for its decisions, within two (2) weeks of receipt of a complete application that satisfies the criteria for delegated review.

6.4 Delegated subcommittees will strive to reach decisions by consensus. Where reviewers disagree, areas of disagreement will be discussed with the goal of reaching an outcome acceptable to all reviewers. In instances when reviewers are unable to reach consensus, the REB Chair or the Research Ethics Officer may choose to promote an application to Full Board Review.

6.5 The following are the outcomes and applicable processes of a Delegated Review:

- a) If the REB approves an application as submitted, the REB Chair or Research Ethics Officer will provide a letter of approval to the applicant.

- b) If the REB subcommittee does not approve an application, the REB Chair or Research Ethics Officer will summarize in writing the reasons for the REB's decision, describe the nature of the REB's concerns, and suggest changes to the research and/or application.
- c) Upon receipt of a revised application, the REB Chair and/or the Research Ethics Officer will determine whether the application will be approved as resubmitted or will be reviewed on a delegated basis.
- d) The processes of review and resubmission will continue until the REB subcommittee determines that the project may proceed, or the applicant declines to resubmit the application. At any point during this process, and if requested in writing by the applicant, the REB will reconsider its decision.
- e) If an application is not approved following every effort (as above) to address REB concerns, the researcher has the right to appeal the REB's decision.

6.6 At the regular monthly meeting of the REB, the Research Ethics Officer will provide, for REB information, a summary of applications approved since the last meeting.

## **7 LEVELS OF REVIEW: FACULTY OF DEPARTMENT ETHICS REVIEW COMMITTEE (COURSE-BASED STUDENT RESEARCH)**

7.1 The REB and a Faculty or Department may enter into a *Faculty or Department Ethics Review Agreement* that sets out the conditions under which a Faculty or Department Ethics Review Committee may review minimal risk, course-based student research on behalf of the REB.

7.2 Research that meets all the following criteria may be reviewed by a Faculty or Department Ethics Review Committee approved by the REB:

- a) Course-based student research conducted by a student as part of a course under supervision of faculty;
- b) Minimal risk research, defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research; and
- c) Research that does not involve persons or groups in vulnerable circumstances, invasive methods, sensitive subject matter, deception or withholding of information from participants.

7.3 The Faculty or Department Ethics Review Committee will be comprised of a Chair and at least one other identified Member associated with the relevant Faculty or Department, one of whom must be a current member of the REB.

7.4 Applications for course-based student research are to be submitted to the REB using the REB's Application Form. The REB Chair or Research Ethics Officer will review and determine the appropriate Level of Review and will identify applications appropriate for Faculty Department or Ethics Committee review.

7.5 Faculty or Department Ethics Review Committees will adhere to documented review procedures approved by the REB.

7.6 Twice annually, Faculty or Department Ethics Review Committees will provide to the REB PDF copies of all applications approved by the Faculty or Department Review Committee, including all approved recruitment, consent, and research instruments.

## **8 CONTINUING REVIEW**

8.1 Applications for ethical review are approved for a maximum period of one (1) year. Research may be approved for a shorter time period when appropriate.

8.2 For research continuing after the approved period, prior to expiry, the applicant will submit to the REB an Application for Continuing Review that specifies:

- a) Progress made on the research project to date;
- b) Any changes to procedures or study population implemented or proposed;
- c) Changes to research personnel; and
- d) Any other changes that may affect risk or vulnerability of research participants.

8.3 The REB Chair and/or the Research Ethics Officer will review Applications for Continuing Review and determine if the application is approved, or if further review is required.

## **9 PROPORTIONATE APPROACH TO REVIEW**

The REB will employ a proportionate approach to review. Where risk to participants is high, the REB will employ more rigorous review and oversight as required, such as by requiring more frequent reporting and review of records.

## **10 OBLIGATION TO REPORT UNANTICIPATED ISSUES**

Researchers will report to the REB any unanticipated issues or events that may increase the level of risk to participants or have ethical implications that may affect the welfare of participants.

## **11 CONFLICT OF INTEREST**

- 11.1 Members of the REB will disclose any real, potential or perceived personal interest in research reviewed by the REB and will be absent during REB discussion leading to decisions pertaining to such applications.
- 11.2 The REB will assess proposals for conflicts of interest and will ensure researchers informs participants during the consent process of any real, potential, or perceived conflicts.
- 11.3 The REB acts independently at arm's-length from University administration and will maintain its decision-making autonomy even when the University has a strong interest in an REB decision.

## **12 INVESTIGATION AND FINDINGS OF NON-COMPLIANCE**

- 12.1 In the course of fulfilling its obligation to review research on an ongoing basis, if the REB discovers that a research project has not adhered to, or is not adhering to, a research protocol approved by the REB, the REB may take the following incremental steps to address the situation:
  - a) Notify the researcher of the non-compliance and request that action be taken to address it;
  - b) Notify the researcher that the research is to be halted until the non-compliance is addressed; or
  - c) Notify the Vice President Academic & Provost that a potential breach of Policy has occurred or is occurring.
- 12.2 The REB will investigate allegations of non-compliance with REB Policy and these Procedures, or complaints of improper research involving human participants, when requested by the Office Vice President Academic & Provost. The REB will undertake these

investigations only in relation to the safety and welfare of the research participants and may stop the research to safeguard the well-being of participants.

- 12.3 Disciplinary action is subject to the *Standards of Conduct Policy* of the University (Policy B.506), and thus falls outside the authority of the REB.

### **13 APPEAL**

- 13.1 REB review will be guided by principles of natural and procedural justice in its decision-making. Such principles include providing reasonable opportunity to be heard, opportunity for rebuttal, and reasoned and written grounds for decisions. The researcher is responsible for providing in writing to the REB an explanation of why they believe the REB has misunderstood the Application or applied an inappropriate standard of review.

- 13.2 The REB will not issue a final decision until after all reasonable efforts to reach a mutually agreeable outcome have been exhausted. Because ethics review and the observance of research ethics at the University is based on the collegial relations between the REB and researchers, a request for a formal appeal should be a last resort.

- 13.3 If an applicant believes that the REB has, in its final decision, misunderstood the application or applied an inappropriate standard of review, the applicant has recourse to the appeal process described below.

- 13.4 The REB will establish and maintain an agreement with the Research Ethics Board of another University to serve as an Appeal Committee.

- 13.5 Applicants who wish to appeal a final REB decision will, within 30 days of the REB decision, send a notice of appeal to the Office Vice President Academic & Provost. The notice of appeal should specify the decision being appealed and the reasons for the appeal. The Vice President Academic & Provost will refer the research in question to the Appeal Committee within 10 business days of receipt of the Appeal. Copies of the application, REB decision(s), and all related correspondence will be made available to the Appeal Committee.

13.6 The Appeal Committee will consist of a quorum of the Research Ethics Board of the University with which the Capilano University has an Appeal Agreement.

13.7 The Appeal Committee will notify the applicant, the REB, and the Office of the Vice President Academic & Provost of its decision in writing. Unless otherwise stated in its decision, the decision of the Appeal Committee will be final.