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<b>Type:</b>	<a href="#">C – Institutional</a>	<b>Last Approved:</b> Mar. 28, 2019
<b>Executive Responsibility:</b>	President & Vice-Chancellor	
<b>Administrative Responsibility:</b>	Vice-President Academic	<b>Policy:</b> <a href="#">31.03</a>

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STATEMENT:

1. Authority and Responsibilities of the Vancouver Island University Research Ethics Board (REB)

1.1 The REB acts for the President

The REB exercises the authority of the President and is responsible to the President in all matters concerning research involving human participants, either on or off campus.

1.2 Responsibilities of the REB

The VIU REB has the following responsibilities:

1.2.1 Ensure that no research involving human participants proceeds without the prior ethical review and approval by the REB or (in the case of certain undergraduate student projects) by a departmental process approved by the REB.

1.2.2 Establish guidelines for departmental review procedures, and adjudicate applications by departments to review and approve minimal risk, undergraduate student research.

1.2.3 Evaluate Applications for Ethical Review (Applications), ensuring that they meet appropriate professional standards and ethical guidelines for the conduct of research in accordance with the Tri-Council Policy Statement: Ethical Conduct (TCPS) for Research Involving Human Participants. The REB shall adopt a proportionate approach based on the general principle that the higher the risk and vulnerability, the greater the care required in assessing the research.

1.2.4 Maintain a list of all active projects approved by the REB, and review on-going projects (through interviews, written updates from investigators, or other

means) so that the REB is assured that approved Applications are being followed. In reviewing ongoing projects, the provisions for employing a proportionate approach outlined in Section 1.2.3 above also apply.

- 1.2.5 Support the University Community to become familiar with statutes, regulations, and Tri-Council guidelines pertaining to research involving human participants.
  - 1.2.6 Maintain active liaison with appropriate governmental authorities and national research councils in matters concerning research involving human participants.
  - 1.2.7 Investigate reports of non-compliance with Policy 31.03 and these Procedures or complaints of improper research involving human participants under the aegis of the University. The REB will only undertake these investigations in relation to the safety and welfare of the research participants, and may stop the research if needed. Any further disciplinary action falls outside the authority of the REB and is subject to the Integrity and Conduct Policy of the University.
  - 1.2.8 Maintain records including (but not limited to): minutes of meetings; copies of all Applications submitted to the REB; notifications of changes to approved procedures; written reasons regarding the acceptance or rejection of Applications; and records of investigation of complaints or reports of non-compliance with this Procedure and related Policy (31.03).
- 1.3 Responsibilities of the Ethics Officer
- The Ethics Officer has the following responsibilities:
- 1.3.1 Assist employees and students (through presentations, information sessions, and individual consultations) to understand and adhere to statutes, regulations, and Tri-Agency guidelines pertaining to research involving human participants.
  - 1.3.2 Assist employees and students (through presentations, information sessions, and individual consultations) to develop applications that meet appropriate professional standards and ethical guidelines for the conduct of research involving human participants.
  - 1.3.3 Participate in the REB subcommittees responsible for the review of projects that meet the criteria for delegated review. At the regular monthly meeting of REB the Ethics Officer will present for REB review a summary of applications approved in the past month that have been reviewed on a delegated basis.
  - 1.3.4 Participate in REB review of applications that do not meet the criteria for a delegated review.

- 1.3.5 Assist departments to develop procedures for the ethical review of minimal risk, undergraduate student research.
- 1.3.6 In conjunction with the REB, maintain active liaison with appropriate governmental authorities and national research councils in matters concerning research involving human participants.

## 2. VIU REB Membership

### 2.1 Regular Members

REB members are appointed by the President. Appointments shall be staggered to maintain continuity and ensure diversity of opinion. The REB shall consist of no fewer than five (5) voting members, who serve a term of two-years, and may be renewed once. The REB will consist of the following:

- 2.1.1 A minimum of two (2) regular members with broad knowledge in the methods or disciplines of research that are commonly reviewed by the REB.
- 2.1.2 A minimum of one (1) member who has no affiliation with VIU, and is recruited from the community served by VIU.
- 2.1.3 At least one of the above members shall have broad expertise in research ethics.
- 2.1.4 The REB may add one member knowledgeable in law related to privacy and research.
- 2.1.5 One student member.
- 2.1.6 The Research Ethics Officer is an ex-officio non-voting member.

### 2.2 Exclusion(s) to REB Membership

The Institution's legal counsel shall not be a member of the REB.

### 2.3 Chair of the VIU REB

The President shall appoint one member of the REB as Chair, on an annual or bi-annual basis.

### 2.4 Co-opting Expert Advice

As the need arises, the REB may co-opt others to aid in the review of particular Applications. This includes seeking expertise in areas not well represented on the REB and in legal issues relevant to the research. Those so co-opted will be non-voting.

## 2.5 REB Support

The Executive shall arrange administrative support for the VIU REB through a dean's secretary, an executive assistant, or some other appropriate person. The REB administrative support person shall provide administrative assistance to the Ethics Officer and the REB Chair, and is charged with the monthly record of REB minutes.

## 2.6 Conflict of Interest

2.6.1 Members of the REB will disclose any actual, potential or perceived personal interest in research reviewed by the REB, and shall be absent during decision-making when these applications are reviewed.

2.6.2 The REB will analyze proposals for conflict of interest and will ensure researchers inform participants during the consent process of any actual, potential, or perceived conflicts.

2.6.3 Conflicts of interest will be managed proportionately. Where conflicts are unavoidable, the ethics review process will be more stringent.

2.6.4 The REB acts independently, at arm's-length from the administration of VIU, and shall maintain its decision-making autonomy even when the University has a strong interest in seeing a project approved.

## 3. Meetings of the REB, Quorum, and Votes

### 3.1 Responsibility to Meet

The REB shall meet formally face-to-face at least ten times a year and as often as necessary to fulfill its responsibilities.

### 3.2 Notice of Meetings

REB members shall have at least five (5) 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

A quorum of the REB shall be at least five (5) members. Quorum shall include a minimum of two (2) members with broad knowledge in the methods or area of research that being reviewed.

### 3.4 Decision-Making

REB review shall be based on detailed research applications or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those

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

### 3.5 Meetings with the Applicant

The REB shall accommodate reasonable requests from applicants to discuss their applications with the REB, but will not be present when the REB is making its decisions.

### 3.6 Minutes

Minutes of all REB meetings shall be prepared and maintained by the REB administrative support person. The minutes shall clearly document REB decisions, reasons for decisions, and any dissenting opinions expressed. Minutes are accessible to authorized representatives of the University, researchers and funding agencies.

## 4. Applications for Ethical Review and Submission

### 4.1 Application Submission

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

### 4.2 Timing of Submissions

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

### 4.3 Application for Ethical Review

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

## 5. Level of Review Assessment

### 5.1 Full Board Review, Delegated Review, and Departmental Review

Applications for Ethical Review will be reviewed at a monthly Full Board Meeting, by Delegated Review (via a subcommittee of the REB), or by a Departmental Review Process approved by the REB.

- 5.2 The following types of research may be reviewed on a delegated basis:
- 5.2.1 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.
  - 5.2.2 Research that does not involve persons or groups in vulnerable circumstances, invasive methods, sensitive subject matter, or occurring cultural contexts potentially unfamiliar to the researcher.
  - 5.2.3 Continuing review of approved projects in which there has been little or no change in the on-going research.
  - 5.2.4 Research that has been previously approved but requires only minor modifications.
  - 5.2.5 Multi-jurisdictional research that has been approved by another Research Ethics Board.

5.3 Research that satisfies all of the following criteria may be reviewed by a Departmental Review Process approved by the REB:

- 5.3.1 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.
- 5.3.2 Research conducted by an “undergraduate student”, defined as any student not in a graduate level program, including students in degree, diploma, certificate, or other programs, completed as part of an undergraduate course under the supervision of faculty.
- 5.2.3 Research that does not involve persons or groups in vulnerable circumstances, invasive methods, sensitive subject matter, or occurring cultural contexts potentially unfamiliar to the researcher.
- 5.3.4 Research that does not involve deception.

5.4 Responsibility for Level of Review Assessment

The REB Chair and/or the Research Ethics Officer will conduct a Level of Review Assessment on all applications to determine whether an application is to be reviewed at a full board meeting, by a REB subcommittee via Delegated Review, or by a Departmental Review Process approved by the REB.

## 6. Full Board Review Process

### 6.1 Anticipated Timeline for Full Board Review

The REB will strive to provide its decisions, and reasons for its decisions, within two weeks of the meeting at which an application is reviewed.

### 6.2 Full Board Review Decision-Making

The REB shall strive to reach decisions by consensus. Where members disagree, areas of disagreement shall 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 particular decision is to be decided by a majority vote. The REB Chair is ultimately responsible for all Full Board REB decisions.

### 6.3 Outcome(s) of a Full Board Review

6.3.1 If an application is approved as submitted, the REB Chair or Research Ethics Officer provides a letter of approval to the applicant.

6.3.2 If the REB 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.

Upon receipt of a revised application, the REB Chair and/or the Research Ethics Officer will determine whether the resubmission requires re-review by the full board at the next full board meeting or may be reviewed on a delegated basis (see Section 7, below).

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.

6.3.3 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 (see Section 10).

## 7. Delegated Review Process

### 7.1 Composition of Delegated Review Subcommittees

Delegated reviews shall 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.

## 7.2 Anticipated Timeline for Delegated Review

The REB shall strive to provide its decisions, and reasons for its decisions, within three weeks of receipt of a complete application that satisfies the criteria for delegated review.

## 7.3 Delegated Subcommittee Decision-Making

Delegated subcommittees shall strive to reach decisions by consensus. Where reviewers disagree, areas of disagreement shall be discussed with a view to 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 elect to promote an application to Full Board Review. The REB Chair or their designate (e.g. the Research Ethics Officer) is ultimately responsible for all delegated REB decisions.

## 7.4 Outcome of a Delegated Review

7.4.1 If an application is approved as submitted, the REB Chair or Research Ethics Officer shall provide a letter of approval to the applicant.

7.4.2 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.

Upon receipt of a revised application, the REB Chair and/or the Research Ethics Officer will determine whether the resubmission requires re-reviewed by the entire subcommittee or shall be reviewed by the REB Chair or Research Ethics Officer.

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.

7.4.3 If an application is not approved following every effort (as above) to address REB concerns, the researcher has the right to appeal the VIU REB decision (see Section 10).

## 7.5 Reporting of Delegated Reviews to Full Board

At the regular monthly meeting of REB, the Research Ethics Officer will present for REB review a summary of applications approved since the last meeting that have reviewed on a delegated basis.



## 8. Departmental Review Process

### 8.1 Departmental Review Agreement

The REB and a Department or Faculty may enter into a Departmental Review Agreement that sets out the conditions under which a Departmental Review Committee may review undergraduate, minimal risk research on the behalf of the REB. At a minimum,

- 8.1.1 The Departmental Review Committee will be comprised of a Chair and at least one other identified Member, one of who must have served on the REB or be currently serving on the REB.
- 8.1.2 All Applications for undergraduate research are to be submitted to the REB using the REB's Application Form. The REB Chair or Research Ethics Officer will determine the appropriate Level of Review, whether at a monthly REB meeting, by a REB subcommittee, or by a Departmental Review Process approved by the REB.
- 8.1.3 The Departmental Review Committee will bi-annually provide to the REB PDF copies of all applications approved by the Departmental Review Committee.

## 9. Continuing Review

### 9.1 Term of Approval and Renewal

Applications for ethical review are approved for a maximum period of one year. If the REB deems it appropriate, research may be approved for a shorter time period.

### 9.2 Processes of Continuing Review

- 9.2.1 For research continuing after the approved period, prior to expiry the applicant will submit to the REB an Application for Continuing Review that specifies:
  - i. the progress that has been made in the research project;
  - ii. any changes to procedures that have been carried out or are proposed;
  - iii. any changes to research personnel
  - iv. any other changes that may affect risk and vulnerability of research participants.
- 9.2.2 The REB Chair and/or the Research Ethics Officer will review Applications for Continuing Review and determine if the application is approved, or require further review at a monthly REB meeting or by a subcommittee of the REB.

### 9.3 Proportionate Approach to Continuing Review

The REB will employ a proportionate approach to continuing review. Where risk to participants is high, the REB may determine that more extensive continuing review is required, such as by requiring more frequent reporting, monitoring of the consent process, review of records, and site visits.

### 9.4 Obligation to Report Unanticipated Issues

The research shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has ethical implication that may affect participants' welfare.

## 10. Investigation and Findings of Non-Compliance

### 10.1 Non-compliance Discovered in the Course of Continuing Review

In the course of fulfilling its obligation to review research projects on an ongoing basis, if the REB discovers that a research project has not adhered to, or is not adhering to, the research protocol approved by the REB, the REB may take the following incremental steps to address the situation:

- i. Notify the researcher of the non-compliance and request that action be taken to address it;
- ii. Notify the researcher that the research is to be halted until the non-compliance is addressed;
- iii. Notify the Office of the Provost and Vice President Academic that a potential breach to the Integrity and Conduct Policy (31.10) has occurred or is occurring.

### 10.2 REB to Investigate When Requested

The REB will investigate allegations of non-compliance with Policy 31.03 and these Procedures, or complaints of improper research involving human participants under the aegis of the University, when requested by the Office of the Provost and Vice President Academic. The REB will only undertake these investigations in relation to the safety and welfare of the research participants, and may stop the research if necessary.

### 10.3 Disciplinary Action Outside the Scope of REB Jurisdiction

Disciplinary action is subject to the Integrity and Conduct Policy of the University, and thus falls outside the authority of the REB.

## 11. Appeals

### 11.1 Process Prior to Final Appeal

Because ethics review and the observance of research ethics at VIU is based on the collegial relations between the REB and researchers, a request for appeal should be the last resort.

The REB will not issue a final decision until after all reasonable efforts to reach a mutually-agreeable outcome have been exhausted. In the event that 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.

### 11.2 REB to Maintain an Appeal Agreement with the Research Ethics Board of Another University

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

### 11.3 Notification of Appeal

Applicants who wish to appeal a final REB decision should send a notice of appeal to the Office of the Provost and Vice President, Academic. The notice of appeal should specify the decision being appealed and the reasons for the appeal. The Provost and Vice President, Academic will refer the research in question to the Appeal Committee. Copies of the application, REB decisions, and all related correspondence shall be made available to the Appeal Committee.

### 11.4 Decisions

The Appeal Committee will notify both the applicant and the REB of their decision in writing. Unless otherwise stated in their decision, the decision of the Appeal Committee will be final.

### 11.5 Appeal Committee Members

The Appeals Committee shall consist of a quorum of the Research Ethics Board of the University with which VIU has an Appeal Agreement.

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