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STATEMENT:

1. Authority and Responsibilities of the VIU REB

1.1 The VIU REB Acts for the President

The Vancouver Island University Research Ethics Board (VIU REB) exercises the authority of the President and is responsible to the President in all matters concerning research involving human subjects, either on or off campus.

1.2 Responsibilities of the VIU REB

The VIU REB has the following responsibilities:

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

1.2.2 Establish guidelines for local (departmental or area) review procedures for undergraduate student projects and adjudicate applications by departments or areas to use their own procedures to approve student projects. Before accepting local procedures as a substitute for its own, the VIU REB will (at a minimum) have to be assured that all undergraduate students undertaking research involving human subjects have received formal instruction in research ethics, that these undergraduate students have prepared a statement on ethical issues similar to that required by the VIU REB (see sec. 4.4 below), and that this statement has been reviewed and approved, with signatures, by at least two members of the department or area, normally the course instructor and coordinator or dean. The VIU REB must review the form and operation of all approved local procedures on an annual basis. VIU REB approval of local review procedure can be withdrawn at any time.

- 1.2.3 Evaluate Applications for Ethical Reviews (Applications), ensuring that they meet appropriate professional standards and ethical guidelines for the conduct of research in accordance with the Tri-Council Policy Statement (TCPS) Guidelines for Research Involving Human Subjects. The VIU REB will adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research (TCPS, Sec. 1-D1 <link: <http://pre.ethics.gc.ca/english/policystatement/section1.cfm#1D6>>).
 - 1.2.4 Maintain a list of all active projects approved by the VIU REB, and review ongoing projects according to the projects schedule (through interviews, written updates from investigators, or other means) so that the VIU 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(c) above also apply.
 - 1.2.5 Maintain current copies of statutes, regulations, and Research Council guidelines pertaining to research involving human subjects, and help relevant members of the University community to become familiar with them.
 - 1.2.6 Maintain active liaison with appropriate governmental authorities and national research councils in matters concerning research involving human subjects.
 - 1.2.7 Investigate reports of non-compliance with Policy 31.03 and these Procedures or complaints of improper research involving human subjects under the aegis of Vancouver Island University (VIU). The VIU REB will only undertake these investigations in relation to the safety and welfare of the research participants, and may thus stop the research, if needed. Any further disciplinary action falls outside the authority of the VIU REB and is subject to the appropriate integrity policy of the University.
 - 1.2.8 Maintain and retain records, including (but not limited to): minutes of meetings; copies of all Applications submitted to the VIU REB, plus any 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 policy and procedure.
- 1.3 Responsibilities of the Ethics Officer
 - 1.3.1 Participate in the VIU REB subcommittee responsible for the review of projects that meet the criteria for an expedited review. At the regular monthly meeting of VIU REB the Ethics Officer will present for VIU REB review a summary of those Applications in the past month that have been subjected to an expedited review.
 - 1.3.2 Participate in VIU REB review of Applications that do not meet the criteria for an expedited review.

- 1.3.3 Assist faculty and students (through presentations, information sessions, and individual consultations) in developing Applications that meet appropriate professional standards and ethical guidelines for the conduct of research.
- 1.3.4 Assist departments and areas in developing local review procedures for student projects.
- 1.3.5 In conjunction with VIU REB maintain current copies of statutes, regulations, and Research Council guidelines pertaining to research involving human subjects, and help relevant members of the University community to become familiar with them.
- 1.3.5 In conjunction with VIU REB maintain active liaison with appropriate governmental authorities and national research councils in matters concerning research involving human subjects.

2. VIU REB Membership

2.1 Regular Members

The VIU REB members are appointed by the President. Appointments are staggered to maintain continuity and ensure diversity of opinion. The VIU REB shall consist of no fewer than five (5) voting members (comprised of both men and women,) who serve for two-year terms that may be renewed once. All members are required to complete the TCPS Tutorial <link: <http://pre.ethics.gc.ca/english/tutorial/>>. The VIU REB will consist of the following:

- 2.1.1 A minimum of two (2) permanent members with broad knowledge in the methods or area of research that are covered by the VIU REB.
- 2.1.2 One (1) member who has no affiliation with VIU, but is recruited from the community served by VIU. A second community member may be added if the VIU REB size is increased.
- 2.1.3 At least one of the above members will be considered to have broad expertise in ethics.
- 2.1.4 The VIU REB may add one member knowledgeable in the relevant law for the review of biomedical research.
- 2.1.5 One student member.
- 2.1.6 The Ethics Officer is an ex-officio non-voting member.

2.2 Exclusion(s) to VIU REB Membership

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

2.3 Chair of the VIU REB

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

2.4 Co-opting Expert Advice

As the need arises, the VIU REB is free (by majority vote) to co-opt others to join it for one or two meetings, especially for the review of Applications. This includes seeking expertise in areas not well represented on the VIU REB and in legal issues relevant to the research. Those so co-opted will be non-voting.

2.5 VIU REB Support

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

2.6 Conflict of Interest

The VIU REB shall adhere to the "conflict of interest" guidelines as outlined in TCPS Sec. 1-E <link: <http://pre.ethics.gc.ca/english/policystatement/section1.cfm#1E> and Sec. 4:

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

2.6.2 The VIU REB will analyze proposals for conflict of interest and will ensure that researchers inform participants during the free and informed consent process of any potential or real 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 Members of the VIU REB will not be present when their own research is reviewed. As well, they will not participate in decision-making for researchers with whom they have been in direct academic conflict or collaboration.

2.6.5 The VIU REB acts independently, and at arm's-length from the administration of VIU; thereby, maintaining its autonomy over ethical questions even when the institution has a strong interest in seeing a project approved.

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

3.1 Responsibility to Meet

The VIU 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

The Chair of the VIU REB shall ensure that VIU REB members have at least five (5) days notice of any meeting and that copies of all documents to be considered at the meeting are provided with the notice.

3.3 Quorum

A quorum of the VIU REB will be at least five (5) members. The quorum will possess the range of expertise reflected in the membership. This quorum includes a minimum of two (2) permanent members with broad knowledge in the methods or area of research that are covered by the VIU REB.

3.4 Decision-Making

The VIU REB review shall be based on detailed research proposals or, where applicable, progress reports. The VIU REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. When the VIU REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision (see TCPS, Sec. 1-D4 <http://pre.ethics.gc.ca/english/policystatement/section1.cfm#1D4>).

Every effort will be made to reach decision by consensus: only when necessary will decisions be made by a simple majority vote. All decisions will be recorded in the minutes.

Every effort will be made to review proposals at face-to-face meetings. However, if necessary, the VIU REB may make decisions via telephone or e-mail vote organized by the Chair, provided that: (a) the research to be reviewed is of minimal risk; (b) does not involve deception; (c) the rule about five days' notice is followed and all VIU REB members are sent copies of all the relevant documentation; (d) all members vote; and (e) there is no dissenting vote. Decisions taken with this method should be noted on the agenda and included in the minutes of the next formal meeting.

3.5 Meetings with the Applicant

For purposes of clarification, the VIU REB may require a meeting pertinent to ethical review. The VIU REB shall accommodate reasonable requests from researchers to

participate in discussions about their proposals, but not be present when the REB is making its decision.

3.6 Minutes

Minutes of all VIU REB meetings shall be prepared and maintained by the VIU REB Secretary. The minutes shall clearly document the VIU REB's decisions and any dissents and the reasons for them. Minutes are accessible to authorized representatives of the institution, researchers and funding agencies.

4. Applications for Ethical Review and Submission

4.1 Copies to be Submitted

Those requiring an ethical review of a research project are responsible for submitting their application and any supporting documentation by email or forwarding six printed copies to the Ethics Officer.

4.2 Timing of Submissions

Applications should be submitted to the VIU REB at least two (2) weeks prior to the next scheduled meeting of the VIU REB <http://www.viu.ca/REB/members.asp>. For information regarding approximate review-to-approval timeline(s) for full and expedited reviews, see Sections 5 and 6 below. The VIU REB shall review all Applications as expeditiously as possible, but is under no obligation to act with less than the above notice or during the June 15 to August 15 period.

4.3 Application for Ethical Review

The Application for Ethical Review submitted to the VIU REB must be in a format specified by the VIU REB and presented in language that members of the VIU REB can readily understand. At a minimum, the Application will contain:

4.3.1 The research proposal: either the proposal being submitted for funding, if funding is being sought, or a similar proposal with sufficient details about the investigators, collaborating institutions, and project to make the status, purpose, and procedures of the research (including selection of subjects) clear.

4.3.2 A separate statement, which addresses ethical issues (see Section 4.4).

4.3.3 Copies of the various forms and protocols to be used in the research—e.g., consent forms and questionnaires.

4.3.4 If the proposed research is multi-centered (i.e., involves more than one institution, agency or jurisdiction), the researcher must indicate the ethical review measures being taken at the other participating institutions. The researcher is referred to the TCPS, Sec. 1-G <link: <http://pre.ethics.gc.ca/english/policystatement/section1.cfm#1G>> for ways of

facilitating this review.

- 4.3.5 If the proposed research is to take place in full, or in part, in other jurisdictions or countries the researchers must satisfy the VIU REB that the research shall undergo prospective ethics review both at VIU and in the country or jurisdiction where the research is done. Researchers will be expected to demonstrate cultural sensitivity. Researchers are referred to TCPS, Sec. 1-H <link: <http://pre.ethics.gc.ca/english/policystatement/section1.cfm#1H>>
- 4.3.6 Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the VIU REB.
- 4.3.7 All students are required to complete the TCPS Tutorial (<http://www.pre.ethics.gc.ca/english/tutorial/>), and submit a copy of the Certificate of Completion with each Application.

4.4 Statement(s) on Ethical Issues

The statements on ethical issues included as part of the Application for Ethical Review should address each of the following issues:

- 4.4.1 Informed consent and voluntary participation: Applications must include a full description of the procedures to ensure that participation by subjects is based on informed consent and voluntary.
- a. Procedures for recruiting subjects should be clear and free of coercion. Any rewards or incentives for participants should be clearly presented and proposed.
 - b. An informed consent form, which will be signed by both researcher and participant. Detailed descriptions of the requirement for free and informed consent can be found in the TCPS, Section 2: <http://pre.ethics.gc.ca/english/policystatement/section2.cfm#2A>. All consent forms will address the following issues:
 - i. A description of the study and what will be asked of the subject, including how much time the subject will be asked to dedicate to the study.
 - ii. Voluntary participation – the informed consent form should include statements that outline the subjects’ right to withdraw at any time, for any reason, without an explanation and without a penalty.
 - iii. Anonymity and confidentiality – the guarantees given to participants, details including how data are to be stored, who has access to them, and when and how the raw data will be destroyed.

- iv. Risks and benefits (physical, psychological, social, economic, and legal) of participation.
 - v. Contact numbers of principal investigator as well as contact numbers of resources (when deemed necessary).
- c. Vulnerable Populations: The concept of ‘vulnerability’ as it applies to research participants refers to those factors that may compromise the ability of the individual to make a free and informed choice regarding participation. Factors that affect decision making, such as extreme youth or age, or mental incapacity (permanent or temporarily induced by medication or illness), and circumstances that may impair or limit freedom of a participant’s choice (e.g. incarceration, influential relationships) are the two main sources of vulnerability. Children, adults with mental disability and prisoners are typical examples of vulnerable populations. Others may, however, be vulnerable with respect to the particular circumstances dictated by a given research project (e.g., students may be considered vulnerable with respect to participation in faculty research).
- d. If the research involves vulnerable populations, or others who could reasonably be judged to be less than fully capable of making a free and informed decision in their own interest, the VIU REB will be guided by TCPS, Sec. 2-E, Articles 2.5 and 2.6 <http://www.pre.ethics.gc.ca/english/policystatement/section2.cfm>. In these cases, the statements on ethical issues must include extra details and explanation about the necessity of using these subjects, about the recruitment of subjects and about substitute consent procedures and protection for vulnerable subjects. Substitute consent is in fact the consent of authorized representatives. These procedures and the intended consent form should be included, as well as any statements that outline the subject’s right to withdraw without penalty.
- e. Legally Incompetent Populations: The VIU REB will only approve research with legally incompetent persons if the proposed research questions can only be addressed within the identified group(s) and the proposed research does not expose participants to more than minimal risk without potential for direct benefits. Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject’s dissent will preclude his or her participation.

4.4.2 Anonymity and Confidentiality: The guarantees about anonymity and confidentiality that are to be given to subjects and the ways the confidentiality of individuals in published results is to be maintained. Details should include how data is to be stored, who has access to them, and when and how the raw

data will be destroyed.

- 4.4.3 Risks and Benefits: The risks and benefits (physical, psychological, social, physical, economic, legal) of participating in the research, both immediately and with the publication and use of the results. The extent to which risks have been assessed by specialists and the precautions, which will be taken to minimize risks, should both be explained.
- 4.4.4 Deception: If deception is involved, the VIU REB must be satisfied that significant gains in knowledge could result and that alternative methods are not available. The REB will not sanction withholding any information that could reasonably cause subjects to refuse to participate.
- 4.4.5 Explanation of Results to Subjects: When, and to what extent, the nature, purpose and results of the study will be explained to subjects.
- 4.4.6 Retention of Data: How the data will be stored, who will have access to it, when it will be destroyed and how it will be destroyed.
- 4.4.7 Procedures for Gaining Consent: Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Procedures for gaining consent if the data is to be used in the future for any purpose other than that explicit in the initial signed consent form should also be addressed.
- 4.4.8 Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, researchers must document the procedures used to seek and obtain free and informed consent.
- 4.4.9 The VIU REB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent outlined above, or waive the requirement to obtain informed consent, provided that the VIU REB finds and documents that:
 - a. The research involves minimal risk;
 - b. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration.
 - d. Whenever possible or appropriate, the subjects will be provided with additional pertinent information after participation; and
 - e. The waived or altered consent does not involve a therapeutic intervention.

4.4.10 Other: Discussion of any other pertinent ethical issues.

5. Full Review Process

5.1 Anticipated Timeline for Full Review

Applications requiring full review will be reviewed by all members of the VIU REB during the scheduled monthly meeting. As per section 4.2 above, applications must be received at least two (2) weeks in advance of the scheduled meeting to ensure sufficient time for member review prior to discussion. A list of meeting dates is available via <http://www.viu.ca/REB/members.asp>. For applications requiring no or few revisions, the average timeline for VIU REB approval is 4 weeks from date of submission. For applications requiring multiple revisions, the average timeline for VIU REB approval is 4 to 6 weeks from date of submission.

5.2 Outcome(s) of a Full Review

5.2.1 Upon full review and discussion of the application, if no revisions and/or clarifications are requested by the VIU REB members, the VIU REB grants approval. The Ethics Officer notifies the researcher that the research may begin.

5.2.2 If revisions and/or clarifications are necessary prior to VIU REB approval, the Ethics Officer synthesizes VIU REB member comments for communication to the researcher. Upon receipt of the requested revisions and/or clarifications, the Ethics Officer circulates the revised application to VIU REB members for reconsideration. If the revisions satisfy VIU REB member concerns, the VIU REB grants approval. The Ethics Officer notifies the research that the research may begin.

Alternately, if VIU REB members are not satisfied with the revised application, the Ethics Officer will reinitiate the application revision process by relaying outstanding revisions and/or clarifications to the researcher. This review process will continue until all VIU REB members are satisfied with the application for ethical review. If multiple revisions and/or clarifications are necessary after the first resubmission of the application, the VIU REB may invite the researcher to the next monthly meeting to address VIU REB concerns. At any point during the review process, a researcher has the right to request, and the VIU REB have the obligation to provide, reconsideration of decisions affecting a research project.

5.2.3 If after multiple reconsiderations, whether VIU REB or researcher-initiated, the VIU REB deems the proposed research unethical, the VIU REB shall provide the researcher with a comprehensive record of member concerns and give the researcher an opportunity to reply before the VIU REB makes a final decision.

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

6. Expedited Review Process

6.1 Anticipated Timeline for Expedited Review

A sub-committee of the VIU REB that includes the Ethics Officer and a member of VIU REB who has the necessary knowledge and expertise will determine whether the Application meets the criteria for an expedited review. The expectation is that the expedited review sub-committee will respond to a complete Application within two (2) weeks.

6.2 Outcome(s) of an Expedited Review

6.2.1 Upon expedited review, if no revisions and/or clarifications are requested by the VIU REB sub-committee members, the VIU REB grants approval. The Ethics Officer notifies the researcher that the research may begin.

6.2.2 If revisions and/or clarifications are necessary prior to VIU REB approval, the Ethics Officer synthesizes the sub-committee comments for communication to the researcher. Upon receipt of the requested revisions and/or clarifications, the Ethics Officer circulates the revised application to the sub-committee for reconsideration. If the revisions satisfy sub-committee concerns, the VIU REB grants approval. The Ethics Officer notifies the research that the research may begin.

Alternately, if the sub-committee is not satisfied with the revised application, the Ethics Officer will reinitiate the application revision process by relaying outstanding revisions and/or clarifications to the researcher. This review process will continue until the sub-committee is satisfied with the application for ethical review. If multiple revisions and/or clarifications are necessary after the resubmission of the application, the sub-committee may forward the application for full review by the VIU REB (see Outcomes of a Full Review, Section 6.2). At any point during the review process, the researcher has the right, and the VIU REB have the obligation to provide, reconsideration of decisions affecting a research project.

6.3 Reporting to the VIU REB of Expedited Review Approvals

The sub-committee will convey the outcome of its deliberations to the researcher and to the Chair of VIU REB. At the regular monthly meeting of VIU REB the Ethics Officer presents for VIU REB review a summary of those Applications in the past month that have been subject to an expedited review.

7. Undergraduate¹ Student Projects

7.1 Approval of Undergraduate Student Projects

The general obligations of Policy 31.03 on Research Involving Human Subjects apply to students as well as other members of the University community. However, the ethical review of undergraduate student projects conducted under faculty supervision as part of an approved University course is handled in two different ways (See Sections 7.2 and 7.3 below), depending on the type of project and the existence of approved departmental or faculty procedures.

7.2 Departmental Review Process

A department or faculty with procedures approved by the VIU REB for Research on Human Subjects (see sec. 1.2(b) above) can use its own procedures to approve undergraduate student research projects, provided these projects:

- i. are part of an undergraduate course in the department or faculty,
- ii. do not involve deception, and
- iii. are of 'minimal risk'. (TCPS, Section 1
<http://www.pre.ethics.gc.ca/english/policystatement/section1.cfm#1C1>>.

Student projects so approved have the same status as those approved by the VIU REB itself.

7.3 Undergraduate Student Projects Requiring VIU REB Review

The following undergraduate student projects always require ethical review by the VIU REB. Students should submit the projects under their own name, listing their faculty member as supervisor. The supervisor must have signed the Application, acknowledging that she/he has carefully reviewed the Application and considers it ready for submission to the VIU REB. Applications submitted via email should be sent by the supervisor to fulfill the signature requirement.

- i. All projects for courses in departments, which do not have departmental review procedures approved by the VIU REB.
- ii. All projects involving deception or the risk of harm.
- iii. All projects not directly connected with course requirements.

8. Requirements for Reporting and Review

8.1 Status Report

At the time of approval the VIU REB will specify requirements for reporting the status of ongoing research. The minimum period for reporting shall be yearly. Status reports shall include:

¹ An 'undergraduate' student is any student who is not in a graduate level program, including students in degree, diploma, certificate, or other programs.

- i. the progress that has been made in the research project;
- ii. any changes to procedures that have been carried out or are proposed; and
- iii. any changes to the risks and benefits statement.

Upon receiving a status report, the VIU REB will decide if a new approval process is needed and will inform the researcher of the decision.

9. Imposition of Penalties

9.1 Penalties Imposed on Students

Penalties imposed on students for the violation of policy and procedures when projects are covered under Section 7.2 are the responsibility of the Dean. Penalties when projects are directly approved by the VIU REB under Sections 5 and 6 are the responsibility of the Dean after consultation with the VIU REB. All penalties imposed on students can be appealed through the normal channels available to students for the appeal of grades and other penalties.

9.2 Penalties Imposed on Faculty

Penalties imposed on faculty for the violation of policy and procedures are the responsibility of the President. The President will consult with the faculty member and his or her Dean. Penalties imposed on faculty can be grieved through the normal channels provided by the applicable collective agreement.

10. Appeals

10.1 Submission/Review/Reconsideration Process Prior to Recourse to Appeals Process

Applicants who have had all or part of their project rejected by the VIU REB and are unable to reach an agreement with the VIU REB by which they can proceed, have access to an appeal process. Because ethics review and the observance of research ethics at VIU is based on the collegial relations between the VIU REB and researchers, a request for appeal should be the last resort.

As per the outlined application submission process for both full and expedited review (see Sections 5 and 6), the VIU REB will communicate to the researcher(s) any requests for revisions should the proposed research not meet VIU REB and Tri-Council Policy Statement standards. Upon submission of requested revisions to the application, the VIU REB reviews the requested revisions and may approve the application for ethical review and/or request additional revisions. In the event that the VIU REB or researcher(s) feel that a face-to-face meeting would benefit both parties, the VIU REB will invite the researcher(s) to attend the next scheduled meeting of the VIU REB in an effort to mediate the application process prior to a VIU REB negative decision and subsequent recourse to the outlined appeals process.

10.2 Appointment of Appeal Committee

The Appeals Committee, as of January 3, 2009, for a term of three years, will be The Research Ethics-Human Subjects Committee at Thompson Rivers University.

10.3 Notification of Appeal

Applicants who wish to appeal a final VIU REB decision should send a notice of appeal to the Vice-President, Academic. The notice of appeal should specify the decision being appealed and the reasons for the appeal. The Vice-President, Academic will refer the research in question to the Appeal Committee. Copies of the proposal, any revisions and all documentation and correspondence shall be made available to the Appeal Committee.

10.4 Meetings

The Appeal Committee will meet as per the Research Ethics-Human Subjects Committee at Thompson Rivers University has regularly scheduled.

10.5 Decisions

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

10.6 Appeal Committee Members

The Appeals Committee shall consist of members of The Research Ethics – Human Subjects Committee at Thompson Rivers University.

FORMS:

Forms available via <http://www.viu.ca/REB/forms.asp>.