UNIVERSITY CANADA WEST

PROCEDURE

Policy Number:	**5020p**
Policy Title:	**Research Ethics**
Approved by:	**Academic Council**
Approval date:	**November 9, 2011**
Effective date:	**September 12, 2012**
Review date:	**July 9, 2021**
Next review date:	**July 2025**

1. Submission Guidelines by the Researcher

Before submission of the ethics protocol, the researchers responsible (note that for student research submissions for students, the faculty supervisor is responsible) to confirm that:

1.1 Submissions must be on the UCW REC ethical review application and protocol form, and applications are required to be electronic and addressed to the Academic Department.

1.2 Applications and protocol submissions must be submitted to the REC in a PDF file in the following format:

a. Title the submitted document using only the date (YY-MM-DD) and last name of the researcher, e.g., 21-04-01-Smith.pdf
b. If the submission is a recent mission, title the document as, for example, 21-04-02-Smith-Resubmission.pdf

1.3 Additional documents submitted may be submitted as follows

a. Student submissions must be emailed to the Academic Department by the faculty supervisor with a copy to the student.
b. Faculty research submissions or email directly to the Academic Department by the faculty member.
c. Include the date the researcher completed TCPS2 training (must be within the last 365 days) on the top of their ethical review protocol.
d. All communication with REC must be sent using only UCW email addresses to protect students and faculty confidentiality. Protocols received from or copy to email addresses other than university Canada west will be returned without review.
    i. Submit only a final ethical review protocol for review, not a version showing edits and ensure that version is appropriately presented in a scholarly and professional way.
    ii. When completing a protocol, answer each question thoroughly. Incomplete answers are incomplete or missing attachments as a result of the protocol being returned for resubmission.

2. Scholarly Research Process.

See Appendix A

3. REC Internal Review Procedure.

See Appendix B.

4. Review Procedures and Timelines

Once the REC received the academic department's application, the REC Chair will review the application and assign to a committee member subject matter expert and randomly assign a second reviewer. A minimum of two committee members will review all applications except for an expedited review as described in "Expedited Review" above. Applications assessed at minimal risk by the reviewers will then be sent to the Chair to communicate a decision to the academic department. If the reviewers disagree on the application's status of recommendations, the full application will be sent to REC during a convened meeting for review.

a. Research that involves greater than minimal risk will require review by the full REC during a convened meeting.
b. You may submit a completed application as described above at any time. Applications will be received by the Chair every Monday from the academic department.
c. The Chair will randomly assign minimal risk studies to no less than two committee members.
d. Committee members will review and submit their independent decisions to the Chair by the following Monday.
e. If the committee members disagree on a recommendation/decision, the matter will be referred to the full REC at a scheduled meeting held bi-weekly.
f. Resubmission of applications will be handled in the same way as outlined in Section 10.
g. Decisions of the REC will be communicated to the academic department by the Chair weekly. The academic department will then communicate the decision to the applicant.

5. Outcomes of the REC.

The REC will make one of four (4) decisions:

a. APPROVED:
   REC approval indicates that the reviewer(s) have concluded that the research and consent forms met the criteria for approval. Approvals are granted for one calendar year, and the applicant should submit a request for an extension for up to four additional years as required.
b. MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL:
   The REC provides conditional approval pending submission of revisions and additional information within 3-days. In this situation, the REC provides the Chair with authority to approve and document the minor revisions. The REC provides conditional approval pending submission of minor revisions and additional information. If revisions are not received within 3-days the research is automatically deferred.
c. DEFERRED:
   The REC may withhold approval pending submission of significant revisions and or additional information. For some studies, the REC may appoint one or more board members to consider and discuss the reasons with the principal applicant. Once the applicant has made the revisions, the revised protocol is added to the next REC meeting for review.
d. NOT APPROVED:
   The REC may determine the disapproval have a protocol due to factors related to the risk that may outweigh the benefits to be gained or if the proposed research does not meet federal criteria.

6. Other Guidelines

Reconsiderations. Applicants can request reconsideration of decisions affecting the research project. The REC has an obligation to provide a reasonable opportunity for the researcher to discuss the decision.

6.1 Appeals. Decisions of the REC may be appealed to the Vice President, Academic. The appeal may also be referred to another institution REC as an appeal board, or the Vice President, Academic may appoint a special committee. The appeal decision by the Vice President, Academic is final.

6.2 Conflict of Interest. In situations when a REC review member ho has a conflict of interest in relation to the submission, the member shall fully disclose the nature of the conflict of interest to the Chair and not be present when the REC is discussing the project or making his decision.

6.3 Monitoring. The research proposal shall include a proposed continuing review or monitoring process appropriate to the proposal. At a minimum, this will consist of an annual report to the REC confirming that research is proceeding as approved and immediately notify REC whenever any deviation to the approval is encountered. The researcher will send a closure form to the academic department after the research.

6.4 Review of Multi-Centered Research. The case of research involving more than one institution the REC will communicate with and coordinate an interview with the appropriate REC of the other institution(s).

6.5 Review of Research in Other jurisdictions or Countries. As in all applications, the REC will ensure appropriate ethical standards and practices are proposed for conducting research regardless of its location. When the research is to be carried out in other jurisdictions, it will be reviewed by the REC and the counterpart organization in the jurisdiction where the research is taking place to ensure safeguards are in place in the host jurisdiction where such an agency exists.

6.6 Record Keeping. Each REC member reviewing projects will follow the UCW review template and forward their decisions to the Department Chair. The Academic Department will maintain a master file on a secure database shared by the academic department. The REC Chair will ensure that committee meetings will have standardized minutes, including decisions, the reasons for them and any dissent.

APPENDIX A – UCW Scholarly Research Process (Faculty & Student)

Table 1.0 Faculty Research Project Funding Process

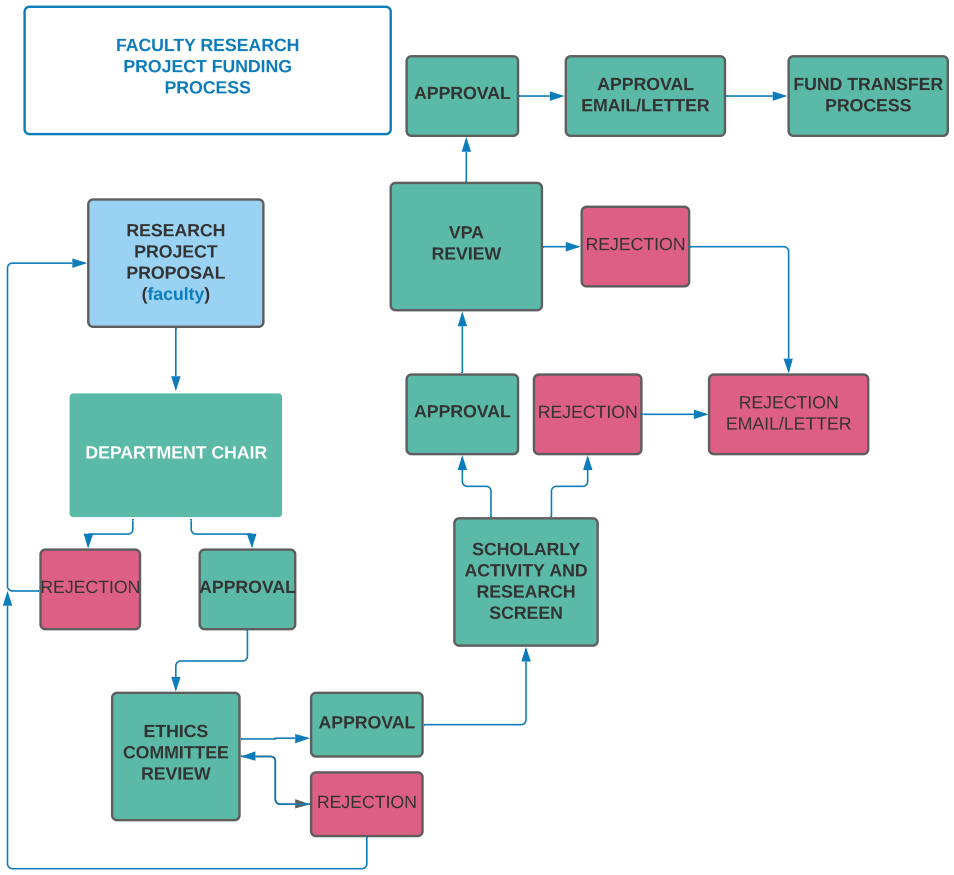
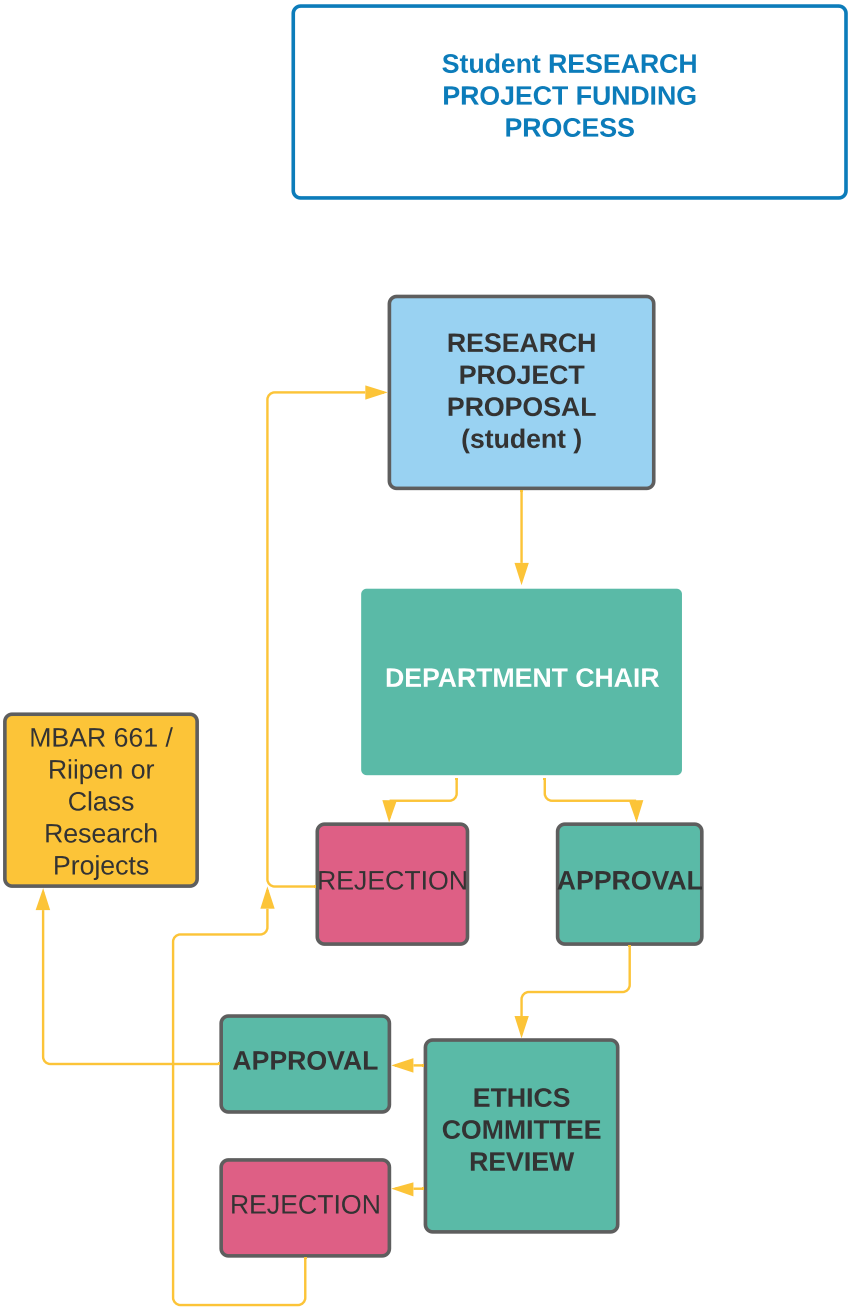


Table 2.0 Student Research Project Funding Process



Appendix B – Research Ethics Committee Decisions Tree

Table 3.0 Decision Chart – Applications Full Review

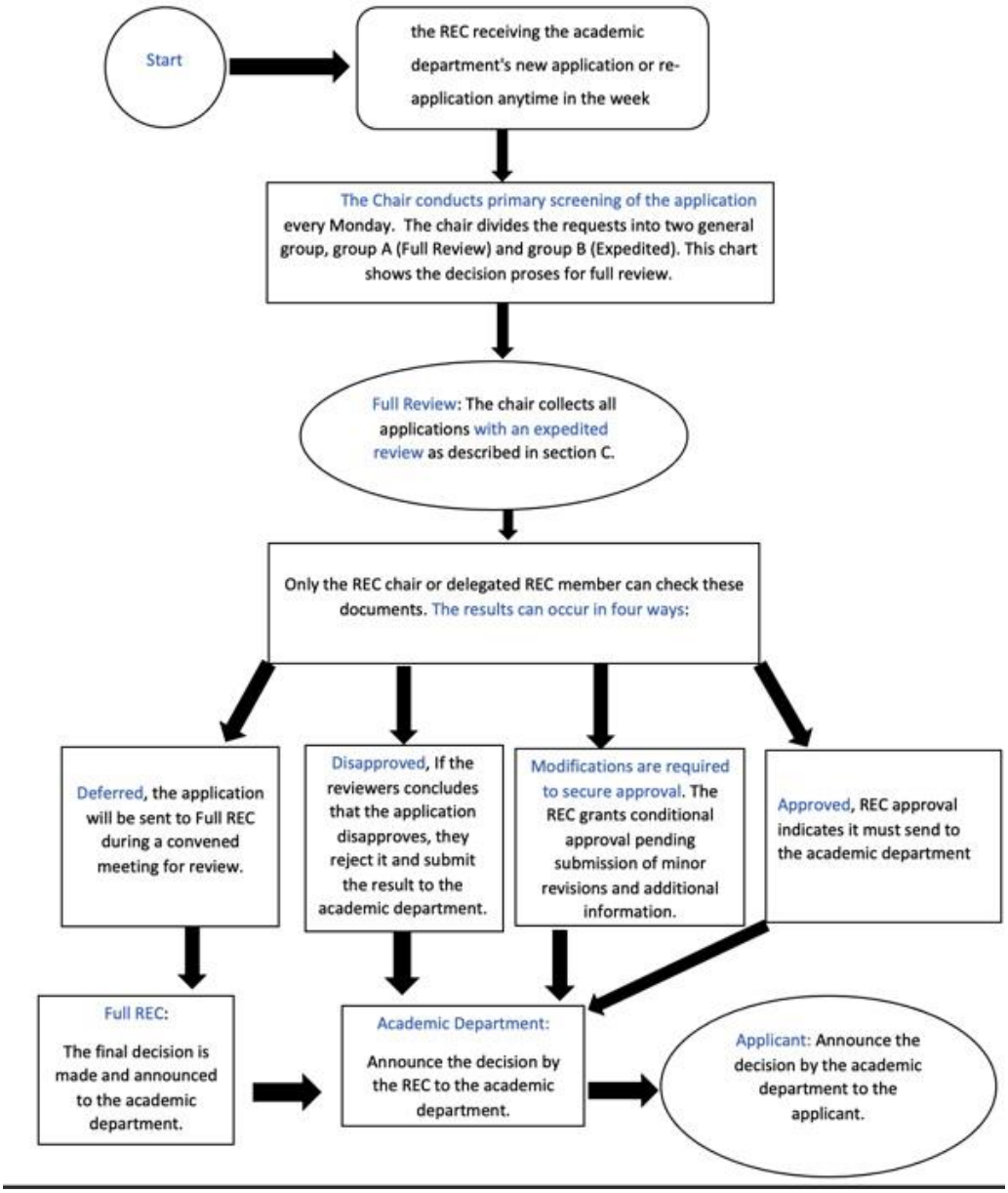
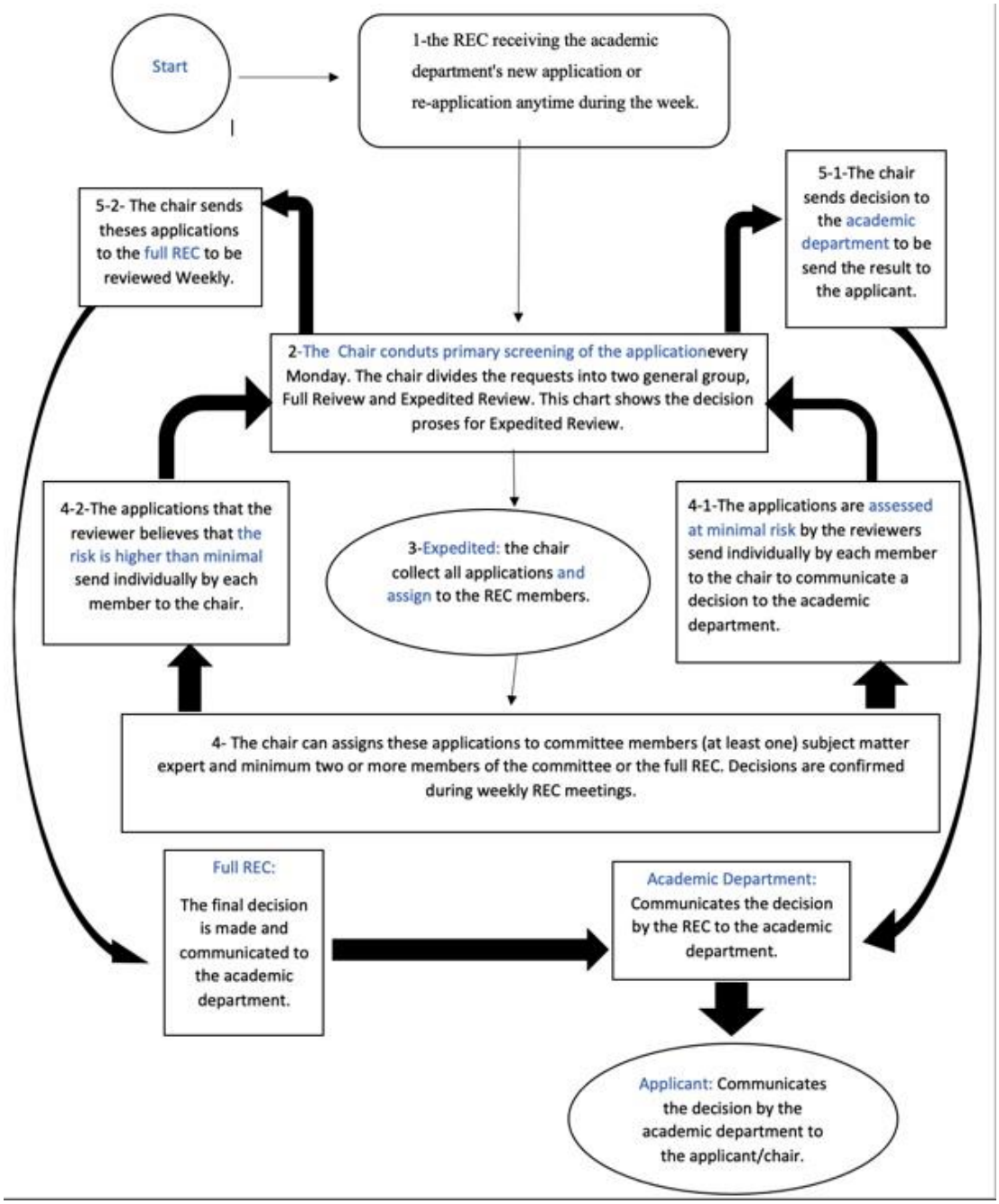


Table 4.0 Decision Chart – Applications Expedited Review (Student/Classroom)



Appendix C – REC Submission Step by Step Instructions

Prepare your Ethical Review Protocol for Submission

How to Successfully Prepare your Ethical Review Protocol for Submission: Step-by-Step Guide

Step 1: Register in the Research Ethics Training course (TCPS2)

UCW Ethics Training registration is requested for student researchers by faculty advisors or course instructors who will send an email request that includes the student's UCW email address to the Academic Department. Faculty researchers directly send an email request to be registered in the Research Ethics Training.

Step 2: Complete the Ethics Training with a minimum 70% passing grade.

Upon achieving the minimal passing grade of 70%, an email Confirmation of Completion of Research Ethics Training will be sent. Students are responsible for forwarding the confirmation email to their respective faculty advisor or course instructor. A failing grade of less than 70 % requires the student to notify their course instructor or faculty advisor to get permission for a retest. The academic department will email the individual for Research Ethics Training modules reset.

Step 3. Review the UCW Research Ethics Policies and Procedure Handbook see REC web page.

Step 4. Download the Ethical Review Protocol Form from the REC web page.

In order to enter content accurately into the form,

1. download the form to your personal computer,
2. save the form to your personal computer,
3. open the saved form from your personal computer, and
4. enter your content.

Step 5. Before submitting your Ethical Review Protocol/Application for REC Review, validate the following items are complete

1. Check spelling and grammar.
2. Attach only the approved UCW Informed Consent Forms directly from the REC web page.
3. If you are storing research data on an external drive (laptop/usb/flashdrive) *you are required to both password protected and encrypt the data.*
4. If you are storing your research data on a personal desktop PC, then the research data is must be password protected. You must also describe in your application, your agreement to destroy the primary data 3 years after the data you close your research project.
5. Faculty advisors are required to sign the Ethical Review Protocols submitted by their students.

Appendix D – Relevant Law

Legislation has been created by both BC and the Canadian federal governments to protect personal information within their respective jurisdictions. Depending on the research, one or more statutes may need to be considered. The following are the statutes for their relevant jurisdictions:

a. **Public sector** (e.g. government, government agencies, BC universities & colleges):
   - Canada: Privacy Act
   - BC: Freedom of Information and Protection of Privacy (FOIPPA)

b. **Private sector** (e.g. business, not-for-profits):
   - Canada: Personal Information Protection & Electronic Documents Act (PIPEDA)
   - BC: Personal Information Protection Act (PIPA)

The BC Freedom of Information and Protection of Privacy Act regulates how personal information is collected, used or disclosed by public bodies, which includes UCW and its researchers. The following definitions are important in understanding what information is protected and what is not.

c. **Personal information** - "means recorded information about an identifiable individual other than contact information" (Schedule 1)
d. **Contact information** - "means information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual" (Schedule 1)
e. **Collection, retention, use & disclosure** - FOIPPA sets out requirements regarding the collection, retention, use and disclosure of personal information by public bodies. The following provides some brief information. (Refer to FOIPPA, Part 3 for more information).

   - **Collection**:
     - Collecting personal information is only permitted where it is authorized under an Act, for law enforcement, or where it relates directly to and necessary for operating program or activity of public body (s. 26).
     - Personal information must be collected directly from the individual (with some exceptions) and the person collecting it must inform the individual of the purpose & authority for collecting the personal information (s. 27).
   - **Retention** - Personal information must be kept for at least one year if it was used to make a decision that directly affects the individual (s. 31).
   - **Use** - Personal information may only be used for the following purposes (s. 32):
     - for which it was collected or a consistent purpose,
     - with informed consented, in writing (& Reg. s. 6), or
     - a purpose for which the information may be disclosed to that public body under ss. 33-36, which includes "research purposes". Important FOIPPA provisions in section 35 must be considered when disclosure is for research purposes (see "Disclosure for research" below for more information).
   - **Disclosure** - circumstances where disclosure of personal information is permitted are set out in sections 33-36.

- s. 33.1 - FOIPPA was amended to protect personal information from being disclosed outside of Canada. This section list the circumstances where personal information may be disclosed inside or outside Canada, such as when a person requests access to their own information, where there is written consent, as permitted under an Act, or for health & safety reasons (see FOIPPA for details).
- s. 33.2 - This section lists the circumstances when personal information may be disclosed inside Canada, such as for law enforcement, for a purpose consistent with the purpose for which it was originally collected, or in accordance with s. 35 as set out next.
    - Disclosure for research or statistical purposes (without the individual's consent, for example) is only permitted where all of the following conditions are met (s. 35):
        - the research cannot be accomplished unless in individually identifiable form (or the researcher has consent of the Commissioner)
        - the personal information will not be used to contact person to participate in research
        - any record linkage is not harmful to an individual and the benefits are clearly in the public interest
        - the head of the institution has approved conditions regarding security/confidentiality, removal of identifiers as soon as possible, prohibition of subsequent use, and
        - the researcher has signed agreement to comply with agreement and any policies of institution re confidentiality.

The BC Personal Information Protection Act regulates how personal information is collected, used or disclosed by private organizations, such as clinics. The federal Personal Information Protection and Electronic Documents Act (PIPEDA) regulates private organizations under federal jurisdiction and personal information that is communicated between provinces. Researchers will need to consider private sector legislation when they are involved with a private organization in a way that deals with personal information. For example, if the researcher is collecting personal information from a Counseling Centre, they must ensure that the personal information disclosure by the organization complies with PIPA. The following provides:

a. Personal information - "means information about an identifiable individual and includes employee personal information but does not include (a) contact information, or (b) work product information" (s. 1)
b. Contact information - "means information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual" (s. 1)
c. Consent - The rules regarding collection, use and disclosure of personal information under PIPA are much more restrictive than under FOIPPA. It is a consent-based approach. Consent may be express or implied.

Resources:

Office of the Information & Privacy Commissioner