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1. **Who Must Apply for Ethics Approval or Approval for a Waiver?**

1.1 **General Requirement**

All University of Victoria (UVic) faculty, students and staff require either ethics approval or a waiver approval from the Human Research Ethics Board (HREB) if their research involves human participants, remains, cadavers, tissues, biological fluids, embryos or foetuses, and DNA/RNA or fragments of DNA/RNA. HREB approval must be obtained before recruitment or data collection begins.

In a few specific instances, researchers may be granted a waiver from the requirement of full ethical review. Further information on waivers can be found in Section 3.2 Waiver from Full Ethics Review.

1.1.2 **Undergraduate Honours and Graduate Students**

Undergraduate honours and graduate students must submit the Ethics Application Form or the Waiver Form to procure their own Certificate of Approval for their individual honours thesis or graduate research project or dissertation. For more details on waivers and student research, see Section 3.2 Waiver from Full Ethics Review below.

1.1.3 **Exceptions to the General Policy**

There are three exceptions to the general policy on who must apply for HREB ethics approval or waiver approval:

1. If a professor and student are co-investigators, the student is not required to submit an individual Ethics Application Form, however both the professor and the student must be named as co-investigators in the professor’s Ethics Application Form and on the Certificate of Approval.

2. When research is conducted by faculty and staff as an Outside Professional Activity\(^1\) an ethics application is not required only if:

   (a) No aspect of the research, from proposal to completion is undertaken by asserting connection or affiliation with the University of Victoria (e.g., university title, the university logo, letterhead, nor name are used);

   (b) The research is not conducted at the University of Victoria and does not use the University’s resources; and

   (c) The results disseminated in the public domain do not indicate association with the university.

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\(^1\) Typically this would apply to a university member who is acting in her/his capacity as a private contractor, whether incorporated or not.
3. Students conducting research outside the auspices of the University of Victoria and/or its academic programs (e.g., students on work terms or Co-op terms) are not required to obtain HREB approval provided:

(a) The research is entirely under the control of an outside agency that has no research affiliation with the University of Victoria;
(b) The research is not directly supervised by University of Victoria faculty or staff;
(c) The research conforms to the three criteria stated above in No. 2 for faculty and staff; and
(d) The student does not plan to use the research project or data for academic credit (e.g., a thesis or major project).

2. Guiding Ethical Principles - The Tri-Council Policy Statement (TCPS)

In 1998, The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) was adopted by the Social Sciences and Humanities Research Council (SSHRC), the Natural Sciences and Engineering Research Council (NSERC), and the Canadian Institutes of Health Research (CIHR). The TCPS sets the minimal standard required for ethics review of research that involves human participants. Below are the TCPS Guiding Ethical Principles to be used as a guide when completing your Ethics Application Form. Researchers should also be familiar with the full TCPS document.

2.1 TCPS Guiding Ethical Principles

Respect for Human Dignity: The cardinal principle of modern research ethics is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person — from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons — to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. Standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity.
**Respect for Justice and Inclusiveness:** Justice connotes fairness and equity. No segment of the population should be unfairly burdened with the harms of research, nor should those who may benefit from advances in research be neglected or discriminated against.

**Balancing Harms and Benefits:** The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance — that is, that the foreseeable harms should not outweigh anticipated benefits.

**Minimizing Harm:** A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects.

**Maximizing Benefit:** The principle of beneficence is also related to harms and benefits and imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

### 3 Types of Applications

There are several types of applications and forms used by the HREB to review and monitor research protocols. Please read this section to determine which type of application is appropriate for your research project and which forms need to be filed during the course of your research. All application forms and guidelines are available on the Office of Research Services (ORS) website.

#### 3.1 Application for Ethics Approval

The majority of research involving human participants requires ethics review using the full application. The Annotated Guidelines for Completing the Human Research Ethics Board Application for Ethics Approval for Human Participant Research are available in a companion document on the ORS website.

#### 3.2 Waiver from Full Ethics Review

It is important to note that a waiver from the requirement of a full ethical review is only permitted in very limited circumstances and such a waiver does not release researchers from any other applicable legal obligations such as protecting a person’s right to privacy, fulfilling copyright requirements, etc. If your study does not meet one of the requirements below, you will be required to submit the full Application for Ethics Approval.
Five categories of research may qualify for a waiver from full HREB ethical review:

1. Research that is limited to secondary analyses of anonymized data. “Anonymized” means that the data cannot identify, or be linked to the individuals who provided it. All forms of data (usually databases) must be supplied to the researcher in completely anonymous formats. The anonymized data may be in the public domain (e.g., Statistics Canada) or not (e.g., collected by a professor who decides who may have access to the data).

   **Linked Data**
   Researchers undertaking projects that involve linking databases are required to submit the full Application for Ethics Approval. Researchers who are being supplied anonymous data that has already been linked may submit a waiver form. However, in this latter case, if further information is required, the HREB may require the researcher to submit an Application for Ethics Approval. Researchers using linked data are encouraged to contact the Human Research Ethics Coordinator (hrethics@uvic.ca) prior to submitting a waiver form.

2. Research that involves a living individual in the public arena, or is about an artist, based exclusively on publicly available information, documents, records, works, performances, or archival materials.

3. Research that involves observation of participants who are seeking public visibility such as speakers at public political demonstrations, public meetings, etc.

4. Research that involves observations that: do not allow for the identification of the participants; do not involve staging or manipulating the setting or circumstances; and is conducted in an open public setting (e.g., parking lot or public park). If the study meets the above requirements, but is conducted in a public space that involves observing children under the age of 13, researchers are required to put in place a plan to address potential concerns that may arise about an adult watching young children.

5. Student research which does not deviate from the professor’s UVic HREB-approved project that is active (e.g., ethics approval has not expired). This category refers only to students who will not be undertaking any of their own research outside of the professor’s study (that is, the students will only use work completed for the professor’s project for their own student project/thesis/dissertation).

### 3.3 When Researchers are not Required to Complete an Application Form

No application form is required for the following categories of research:

Research limited to the use of materials that are in the public domain and for which all applicable copyright, patent, or other legal requirements and approvals have been either fulfilled or received.
Research limited to Ethical Assessment of the Institutional Quality of Program and Services, as outlined in the University of Victoria’s Policy 3850. (*Please Note* that this policy applies to internal quality assurance, performance review or testing within the University of Victoria only.)

The University conducts a wide range of activities at the institutional and departmental level that can be described as quality assessments of academic and non-academic providers, programs and services. These types of assessments are specifically excluded from the TCPS.

For activities that border on, or may include elements of research, ethical approval from the HREB may be required. Determination of whether a quality assessment activity requires HREB approval will be made through consultation with the Chair of the HREB and the Director of Institutional Analysis.

### 3.4 Course-Based Research Projects

As part of their teaching strategies related to research, many instructors assign class projects and activities in which students must collect data from human participants. These projects may be carried out by individual students, small groups, or as a single class project. Course-based research assignments vary in scope, but all include gathering data from human participants for the purpose of class presentations or reports or other activities considered research within the discipline in which the course is taught. Please see the Application for Ethical Review of Course-Based Research and the corresponding Guidelines for Course-Based Research on the ORS website.

### 3.5 Joint UVic/VIHA

Researchers who intend to conduct research that involves any agency under the auspice of the Vancouver Island Health Authority (VIHA), and whose study qualifies as minimal risk, are required to apply to the UVic/VIHA Joint Research Ethics Subcommittee. Researchers conducting above minimal risk research will need to submit separate ethics applications to both UVic and VIHA. If you are unsure as to which form(s) to use, contact the Human Research Ethics office ([ethics@uvic.ca](mailto:ethics@uvic.ca), 250-472-4545) to clarify. The UVic/VIHA Joint Application can be found on the ORS website.

### 4. The Ethics Application Review Process

Before filling out your application, ensure that you have read and are familiar with the University Regulations for Research Involving Humans and the Annotated Guidelines for Completing the Human Research Ethics Board Application for Ethics Approval for Human Participant Research.

#### 4.1 Complete and Submit the Application for Ethics Approval

An Ethics Application Form must be completed for each research project. Carefully complete all sections of the application form, attach all required documents and appendices, and ensure that
all required signatures are included. Incomplete applications will be returned and will delay the process of review. The original signed application and two photocopies are submitted to the Human Research Ethics Office (in the Office of Research Services).

If possible, deliver the application in person to avoid mail delays. The application will be date-stamped the day the office receives it and the review process period of four to six weeks will commence the day the application is received.

4.2  The Review Process

Newly received applications are pre-reviewed and routed by the Ethics Coordinator for review using several criteria. If the project is determined to be minimal risk research, it will be assigned to one of two streams of review. Straightforward applications will be reviewed by the HREB Chair and the Ethics Coordinator or Ethics Facilitator only. Applications that present more complex issues will be reviewed by the Chair, the Coordinator or Facilitator and two designated reviewers from the HREB. If the research project is determined to be greater than minimal risk or if there are special protections needed, the application may be forwarded to the entire HREB for full review at their next monthly meeting.

In all cases, if the application is approved as submitted (i.e., revisions are not required), the researcher (and if applicable the graduate supervisor and departmental graduate secretary) will receive an email Notice of Ethical Approval from the HRE Assistant indicating that the application has been approved and research may commence. The research protocol number will be included in the email and a Certificate of Approval will be sent via regular mail.

If the application is not approved as submitted and revisions are required, a Notice of Ethical Review will be sent by email by the HRE Assistant to the researcher (and if applicable, the graduate supervisor). The Notice of Ethical Review will include detailed feedback on the requested revisions.

The revised application and attachments, including all requested revisions, are to be emailed according to the directions found in the Notice of Ethical Review. The revisions will be acknowledged upon receipt. The revisions will be reviewed and if they comply with the Notice of Ethical Review, the researcher (and if applicable the graduate supervisor and departmental graduate secretary) will receive an email Notice of Ethical Approval from the HRE Assistant indicating that the application has been approved and the research may commence. The research protocol number will be included in the email and a Certificate of Approval will be sent via regular mail.

If the revisions are incomplete, a second set of revisions may be required. In this case, the HRE Assistant will email a 2nd Notice of Ethical Review. Once revisions that comply with all points made in the 2nd Notice have been received, ethical approval will be granted.

Please note: Revisions must be emailed within four months of receiving the Notice of Ethical Review. If a response is not received within four months, you will be notified that your file will be closed. After the file is closed, if you wish to receive ethics approval, you will need to reapply with a full application.
4.3 Length of Time for the HREB Review Process

Depending on the volume of applications in process, if no revisions or only minor revisions are needed, the review process usually takes between four and six weeks from submission to e-mail notification of approval. This depends in part, on how quickly the researcher completes the required revisions (if applicable). If significant changes are required, there may be two rounds of revisions and the process will take longer.

4.4 Term of Approval and Ongoing Monitoring of Approved Protocols

Beginning in 2008, as per federal regulations, ethics protocols are approved for a one-year period. If recruitment and data collection have not been completed within the year, an application for annual renewal will be need to be submitted. (See Section 4.7 below.)

4.5 Modifications

If recruitment and data collection have not been completed by the end date on the Certificate of Approval, a Request for Modification form needs to be submitted to Human Research Ethics at least one month prior to the expiry date. The approximate time needed to complete the project needs to be stated on the Application for Continuation of, or Revisions to, Ethical Review, along with a brief description of the remaining work to be done.

Before modifying an approved protocol (e.g., revising a recruitment strategy, making substantive changes to the research methods or instruments), researchers must first submit a Request for Modification and receive approval for the proposed changes.

4.6 Annual Renewals

The HREB requires approved protocols to be renewed on an annual basis, including longitudinal studies, if the researcher is still recruiting participants or collecting data. The Request for Annual Renewal form must be completed and submitted to Human Research Ethics each year until recruitment and data collection are completed.

4.7 Adding or Removing Research Team Members

If research team members are added or removed, the principal investigator must notify the Human Research Ethics by sending an email to ethics@uvic.ca indicating the name and role of the person(s). If the principal investigator changes, or co-principal investigators are added to the project, a Request for Modification form is required. The university is sometimes contacted by the public regarding the legitimacy of a project, thus having accurate information about all individuals involved in the project is required.
4.8 Retention of Ethics Files

An ethics file is closed once a researcher submits the Project Completion Form indicating that all recruitment and data collection has been completed or if the researcher’s approval period expires (if no Request for Annual Renewal was received and granted). The application file is normally maintained in the Human Research Ethics office for a three-year period. For specific approved applications, if longer retention periods are required by external bodies, the documents will be maintained beyond the three-year period. The Tri-Council (SSHRC, NSERC and CIHR) and other research funding or ethics review bodies will be provided access to the files if necessary for reporting and auditing purposes.