Understanding Human Research Ethics

A handbook for researchers

2012–2013

UNIVERSITY OF THE FRASER VALLEY

HREB Member List 2012-2013

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HREB Member List – 2012-2013 continued

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Introduction

The University of the Fraser Valley (UFV) requires and supports the highest ethical standards in conducting research involving human participants, and all researchers at or associated with UFV are required to follow research ethics guidelines to ensure that their participants' rights to privacy and dignity are respected and protected. As such, all research (funded or not) that directly and indirectly involves living human participants requires review and approval by UFV's Human Research Ethics Board (HREB) or the designated Departmental Research Ethics Committee (DREC) that report to it and in accordance with UFV's Human Research Ethics Policy and the Tri-Council Policy Statement (TCPS2) on Research Ethics.

The TCPS2 is the joint research ethics policy statement of the federal research agencies (CIHR, NSERC, and SSHRC) or "the Agencies." It was published in August 1998 and revised in December 2010 to promote the ethical conduct of research involving humans. It outlines standards and procedures for research involving humans and applies to those conducting, participating in, or reviewing human research in institutions funded by the Agencies. The Policy applies to all institutions eligible to receive or administer funding from one or more of the Agencies, and members of those institutions – faculty, staff and students. The requirement to follow the TCPS as a condition of funding is contained in the Memorandum of Understanding signed by the Agencies and these institutions (taken from http://www.pre.ethics.gc.ca/eng/panel-group/faq/tcps-eptc/)

This handbook is designed for all faculty, staff and students who wish to conduct research involving human participants. Contextually, it summarizes the relevant sections of UFV's Human Research Ethics Policy 54, and the related policies on Integrity in Research 53 and Conflict of Interest 142. Practically, it also contains the guidelines explaining how researchers prepare and submit research ethics review requests to either the HREB or their DREC. These procedures are abridged in a convenient *Research Ethics Decision Making Process* chart on page 18 to provide a quick access guide for prospective researchers.

For more information, and the complete text of Policies 54, 53 and 142, go to http://www.ufv.ca/Secretariat/policies.htm.

The Role of the HREB

Ensuring the ethical principles are applied to research involving human participants is the responsibility of the UFV Human Research Ethics Board.

The HREB has two primary roles -- educative and review. In its educative role, the HREB serves the UFV research community as a consultative body and thus, contributes to education in research ethics. In its review role, the HREB has the responsibility for independent, multidisciplinary review of the ethics of research to determine whether the research should be permitted to start or to continue. The HREB is considered a delegation of the President's Office at UFV. The President has the authority to dismiss or appoint HREB members at his or her pleasure. The committee has the authority to approve, reject, propose modifications to, or terminate all proposed or ongoing research involving humans within the institution's jurisdiction based on the ethical considerations as set forth in the Policy.

The HREB is not an inquisition or designed to make life difficult for researchers. It is to help you process your requests as expeditiously as possible, and to ensure that your research accords with the highest ethical standards required by UFV and consistent with the TCPS2. If at any time you are unsure of how to proceed, contact your HREB representative from your department, or the HREB Chair.

For more information on Research Ethics at UFV, visit www.ufv.ca/research/research_ethics or contact one of the members of the HREB on page i and ii

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Tips and Guidelines for Faculty and Students

Because all research on humans takes place in a cultural context, the field of research ethics is in a state of permanent evolution and policies do change. That said, when it comes to actually completing and submitting your request for ethical review, there are some constants. The following bullets below offer some useful hints and advice that apply to all requests for ethical review at UFV.

- Always fill out your *Request for Ethical Review and Ethics Checklist* first. If it appears as a minimal risk project, it could be reviewed through the delegated process.
- Please check the website: http://www.ufv.ca/research/research_ethics for current forms. They will be dated. Most years the forms are revised. Therefore, if you do not submit on the current forms, questions may be mission or revised, and this may delay your review process.
- If the protocol does not meet minimal risk guidelines, then it will go to a full Board review. Therefore, watch your submission timelines. Requests to the UFV HREB must be emailed to Yvette Fairweather in the Research Office on the Wednesday a week prior to the next regular meeting (see *HREB Meeting Schedule* inside back cover). If they are not, they will have to wait for the meeting of the following month. Students submitting to a DREC should check with their department.
- Make sure you submit all documents. At bare minimum, these include:
  - *Request for Ethical Review* and the *Checklist for Minimal Risk (now one document)*
  - letters of consent
  - letters of information
  - all survey instruments (questionnaire, interview script, etc.)
  - ethics approvals from collaborating institutions
  - for thesis projects, the thesis advisory committee's approval is required
  - Biohazards approval (if applicable).

- When filling out requests, complete all boxes. If the box is not relevant, at least record 'N/A'.
- Write your requests and supporting documents in grammatically correct English throughout. Proofread your documents before submission, the HREB does not do this. Requests for ethical review remain confidential, but consent letters, questionnaires, etc. circulate in public.
- Write your request in plain English. While HREB members are familiar with a wide variety of quantitative and qualitative research methodologies, they are less familiar with disciplinary jargon. Special terminology should be used consistently throughout the request and between the request and supporting documents. Spell out acronyms the first time used.
- Handwritten requests will not be accepted. Fill them out electronically and submit directly to the HREB Administrative Assistant, Yvette Fairweather in the Research Office. Faculty will need to submit a separate email attaching all other documents.
- Throughout your request, be especially clear on:
    - the identities of everyone involved in the research, including, but not limited to, the primary and, if any, secondary investigators, and any and all individuals, institutions or collaborating agencies otherwise involved in the research process (e.g., persons distributing questionnaires, intermediaries in recruitment or contact, persons assisting in data management, etc.)
    - the duration of the research (you are allowed one year default so if in doubt, take at least that)
    - your methodology (reviewers do need to know, in plain language, exactly what you are doing and how)
    - whom you are recruiting and how, and the names of who is actually doing the recruitment
    - how you will ensure the principle of free and informed consent, and protect the confidentiality and privacy of your research participants

- exactly what you are going to do with the data, indicating whether it is in primary or aggregate form; who will have access to it and at what stage in the research process; how and where you are going to secure the data; how long you will retain the data; whether or not the data will be used for purposes above and beyond the terms of the research being submitted for review; and that if the data is to be shared with other parties, you have a signed data sharing agreement in place.

- The principle of free and informed consent lies at the heart of ethical research. Letters of consent must fully disclose all foreseeable risks and benefits of the research. In cases where additional letters of assent are required for adolescents or other individuals under the age of majority, write them in a language that the target population will understand. Letters of consent, assent or information should not be excessively long, but must be clear on:
  - what you are researching and why
  - who the researcher(s) are
  - all reasonably foreseeable possible risks and benefits of a physical, mental, emotional, financial, or other relevant measure
  - how you will ensure your potential participants anonymity and confidentiality
  - what you are going to do with the data, whether in primary or aggregate form, how long and in what form you are going to keep it, any possible future use of the data, and where it will be secured
  - a rider to the effect that participants are free to withdraw from the research at any time without penalty to themselves
  - a rider to the effect that participants having any concern or question about the research can contact Adrienne Chan, Acting Associate Vice-President of Research and Graduate Studies (if other collaborating institutions are involved, this rider should include their relevant offices also). Give Adrienne's phone number (604 557-4074) and e-mail as contact information.

Frequently Asked Questions

How long will it take for an application to be reviewed and approved?
There are a lot of factors involved and it depends on the nature of the project. HREB protocols are reviewed in the order they are received so depending on the time of year there can be anywhere from 1 to 15 protocols in the queue. HREB protocols will take a minimum of 2 weeks to be reviewed and approved and most of the time protocols are sent back for revisions.

Student projects – 1-2 weeks (minimal risk), 2-3 weeks (full board):
Student projects that are minimal risk and have been recommended for approval by the Department Research Ethics Committee (DREC) will usually be approved within a week. If there are revisions to the protocol that the Chair of the HREB is requesting from the student, it will usually be approved within the week after the student has submitted the changes.

If the student project is not minimal risk it needs to be reviewed and approved by the full HREB board at the monthly meeting. The protocol review time is subject to the meeting date – if the student submits before the deadline of the next meeting then it will be reviewed and revisions will be requested within the month. If the student misses the deadline the protocol will have to wait until the next month's meeting.

If there are multiple student DREC protocols from an instructor and a class assignment, the review time will be at least two weeks. Please allow enough time for your students to receive approval of their project.

Faculty projects (2-3 weeks):
Faculty protocols will be put in the queue for review by the chair and vice chair of the HREB. The researcher will usually hear back from the ethics administrator within a few days if it is minimal risk or if it needs a full review. Minimal risk submissions will take at least 2 weeks to be reviewed and for revisions to be sent. Once revisions are received, approval is usually given within a week unless further revisions are required.

Protocols that need to be reviewed by the HREB are subject to the meeting date. After the protocol is reviewed at the ethics board meeting (1-5 week wait depending on when the protocol was submitted), the protocol will follow the same time frame it would as if it were minimal risk unless major revisions are required.
Graduate student submissions are considered under the faculty projects guidelines. Graduate students complete the HREB faculty form.

What is the difference between a full and a delegated review?
A full board review requires that the submitted protocol be reviewed at the monthly meeting (UFV meeting week 4, Thursdays. See the last page for the meeting schedule). If a protocol is NOT minimal risk, it will be reviewed by the full board. If a study involves minors it automatically goes to the full board. A course designation also automatically goes to the full board.

A delegated review is a protocol that is minimal risk and can be reviewed and approved by the Chair and Vice-Chair of the HREB. It does not go to the full board review at the monthly meeting nor does it have to wait for the meeting date to be reviewed which is why the process is an delegated one.

What is a course designation?
A course designation is when a course is designed to be a research course and has a research assignment, but it can also be a non-research course with a research assignment. If the assignment will be an ongoing one and involves having the student doing some form of research, please get in touch with the Chair of the HREB to see if the course can be designated as a research course. Course designations are given a three year approval instead of the typical one year approval and make it much easier for students to get their assignments done.

I'm not sure if I'll run the course assignment more than once. Do I still need a course designation?
If you are doing a trial run of a research assignment before implementing it into your course outline and curriculum, you can apply for a student request for ethical review on behalf of all your students and attach a class list. This approval will be given for one year but only for the students on the class list.

I think my project falls in the professional education and skill development category. Can I proceed without ethics review?
You should always check with the HREB first if you think your project might be exempt from ethics review.

My project has changed. Do I need to submit a new request?
No – if your project has changed minimally, such as hiring a new research assistant, expanding into another school to get more participants, or simply needing an extension for another 6 months to finish collecting the data, a request for amendment can be sought. If the changes are significant (such as changing the use of the data) then the HREB will notify the researcher and ask for a new protocol.

My project will definitely take longer than a year to complete. Do I have to submit a new request every year?
If you are sure your project will take longer than a year make sure you indicate the project length on the request for ethical review. When approval is given the certificate will still only be valid for a year, but the HREB will extend the certificate for another year upon receiving an annual report of the project. The annual report form can be found at http://www.ufv.ca/Research/Forms.htm

What is the TCP2S?
The second version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is a document created by the three major granting agencies in Canada: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). This document provides guidelines for researchers using human participants in their research and covers everything from the ethics review to privacy and confidentiality to clinical trials. The TCPS also provides a tutorial for researchers to educate them on the ethics process and ethical concerns. **It is highly recommended that everyone doing this type of research complete the tutorial**. The tutorial can be found at: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

What do I do if my research involves multiple institutions?
We do our best to make sure the process is not onerous when doing research at multiple sites. You will need approval from each site. You should submit your application to the primary institution for ethics review (generally the PI's home institution) first. When you receive ethics approval from there you will then send all your documents to our HREB for review (the application form and all supporting documents). The HREB will review the application on the other institutions forms and will either approve the ethics for UFV or request extra information. The UFV HREB will need a copy of the ethics approval from each institution.

I want to survey teachers or have children in school as participants in my study. What is the process?
Before the HREB can approve a protocol that involves anyone in any school district, we need written consent from the school district and/or the principals at the schools. Consent letters need to be given to the parents with enough time for them to make an informed decision (at least three business days). Although the HREB does not require a criminal record check, it is recommended that you have one on file if you will be working with children.

What are the guidelines for storing and destroying data?
Raw data needs to be stored in a secure area/way until it is destroyed. For example, if you have hard copy surveys they need to be in a locked cabinet or office. If you have online data it needs to be on a password protected computer or password protected USB drive.

Who should I send my request to?
Faculty should send their projects to Yvette Fairweather. Students should submit their project to their appropriate DREC first unless they know it is not minimal risk – then they can send it to Yvette Fairweather. Graduate students are treated like faculty and should submit their protocols directly to Yvette Fairweather.

My question isn't here. Who can I contact?
For general research ethics questions please contact Yvette Fairweather (yvette.fairweather@ufv.ca). For more specific questions regarding the details of the protocol or questions on course designations or professional education/skill development please contact the Chair of the HREB, Kathy Keiver (Kathy.Keiver@ufv.ca).

Guidelines For
Course-Based Student Research Projects
Involving Human Participants

Introduction

The guidelines and procedures in this document apply to research projects involving human participants and conducted by an entire class or individual students or small groups within a class. Such projects are generally of two types:

- projects designed by a student or group of students and in which the student(s) have some freedom in designating the participant pool and/or methodology of the research
- projects designed by the instructor which share a common methodology and/or participant pool, and assigned to the entire class as a regular course component.

Defining student research

A student research project is defined as any research program that:

- has students conducting interviews in individual or focus group sessions, or engaging in various kinds of monitoring or participant observation
- has students designing and/or administering tests, questionnaires, and/or analyzing primary data
- has students obtaining and/or analyzing secondary data
- has students engage in any other activities which would be considered research in the disciplinary tradition of the course being taught.

These guidelines do not apply to students assisting faculty or faculty-directed research outside of class, or to students engaged in independent research for honors essays, theses or dissertations. Any such research projects must be submitted to either the Departmental Research Ethics Committee (DREC) or the UFV Human Research Ethics Board (HREB) as outlined in the UFV Research Ethics Policy 54.

These guidelines do not apply to any activities designed by the instructor solely for professional education or skill development purposes and not embedded in a research framework as outlined in UFV Policy 54. Such projects are not subject to either university or departmental review so long as they align with appropriate professional standards, codes of conduct or review processes required by the relevant faculty.

Please refer to the chart on page 18 for an overview.

Distinguishing research from professional education and skill development

Distinguishing projects classified as research from those classified as information gathering for professional education or skill development purposes is as follows:

1. data recording and collecting activities qualify as research when any of the following apply:
    - the intent is to educate students on research processes used to explore and expand existing theories, paradigms, or concepts
    - students compare new techniques, practices or programs with standard approaches in order to determine methodological effectiveness
    - the results or findings are written in a format that would be acceptable for a research journal or academic conference presentation.
2. data recording and collecting activities qualify as professional education or skill development when any of the following apply:
    - the intent is to use information to provide diagnosis, identification of appropriate interventions, or general advice for a client
    - the intent is to develop skills which are considered standard practice within a profession (e.g., interview skills, presentation skills, observation, assessment, intervention, evaluation, auditing, etc.)

- the information gathering process is part of the normal relationship between student and participant (e.g., classroom teacher and student interaction, nurse and patient, social worker and client, etc.)
- the data collected or conclusions to be drawn are disseminated in private, either within the class or with the client(s)
- the student is communicating or interviewing other students or their advisor/supervisor for feedback in a course (e.g. an TESL practicum)
- Personal communication (e.g., a student on a field trip speaking with a tour guide). This communication may be used in a term paper without ethics approval only if the communication was happenstance and is not being used for any research purposes (e.g., data collection, analyzing, publishing, etc.).

Instructors who are uncertain as to how to properly classify any research, learning or skill development project should contact either the relevant DREC or the UFV HREB.

General principles governing ethical reviews

These guidelines meet all the requirements of University of the Fraser Valley's (UFV) Human Research Ethics Policy 54 and the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*.

As such, the UFV HREB and the DRECs all utilize a proportionate approach based on the general principle that the more invasive the research the greater should be the care in assessing it.

Potential harms to, or infringements on participants and their rights to privacy are usually identified and evaluated as risks, which are defined in terms of the magnitude of possible harm to the participant(s) and the probability of its occurrence. Risks can range from minimal to significant to substantial and are evaluated primarily from the viewpoint of the potential participant(s).

In all instances, the UFV HREB and DRECs evaluate potential harms from a baseline of the concept of minimal risk, which is defined by the Tri-

Council policy as that level of risk that accrues "if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her life that relate to the research."

Above this threshold of minimal risk, the research will warrant a higher degree of scrutiny and greater provision for the protection of the interests of the participant. The concept of minimal risk also applies to the level or kind of inducements or offers intended to excessively encourage participation in a particular research project.

As a general rule, a research project will qualify as minimal risk provided the following conditions apply:

- participants are competent adults
- there is no physical, emotional, psychological, sociological, or economic risk
- topics discussed and questions asked can be handled in ways which cause little or no discomfort or distress
- methodologies are non-invasive
- neither deception nor partial disclosure is involved
- participants do not experience any excessive inducement to participate.

If the activity qualifies as professional education or skill development as defined above, no further action is required.

Application for Designation as a HREB Approved Course

Category 1 - Research Course – Full Course Review

If the research project is designed by the instructor, shares a common methodology and/or participant pool, and is assigned to the entire class as a regular course component, the instructor should apply direct to the UFV HREB for a Designation of Course as a Research Ethics Approved Course.

These requests are reviewed and evaluated in the same way as any faculty based research project as specified in the UFV Research Ethics Policy 54. Once approved, such courses are authorized for three (3)

academic years from date of issuance of the Certificate of Approval so long as there are no subsequent changes to the participant pool, research methodology, or level of instructor supervision of projects.

Category 2 - Non-Research Course – Full Course Review

There are some courses that are not designed to be research courses but may have an assignment in which the students need to do a form of research to learn how to manipulate or analyze data (e.g. statistics). Students may or may not choose to use human participants. The instructor should apply directly to the UFV HREB for a Course Designation as a Research Ethics Approved Course if:

a) The research assignment is part of the regular course instruction and may involve human participants (participant pool, interviewing students in the cafeteria, etc.). This research assignment is not a one-time only project and can be expected to be completed again in another term.
b) The research is instructor monitored
c) Students conduct a research assignment
d) Projects have similar parameters and expectations

Having a course designation for a non-research course in which a research assignment is completed every term is a smoother process for both the instructor and the student. Otherwise every time the assignment is given, each student would need to fill out all applicable forms (student request for ethical review, checklist for minimal risk) and submit supporting documents (consent forms, scripts, etc.).

These requests are reviewed and evaluated in the same way as any faculty based research project as specified in the UFV Research Ethics Policy 54. Once approved, such courses are authorized for three (3) academic years from date of issuance of the Certificate of Approval so long as there are no subsequent changes to the participant pool, research methodology, or level of instructor supervision of projects.

Application for Student Research Assignment
Category 3 - Research Course - Assignment Only

If the research project is designed by a student or group of students and there is some freedom in designing the participant pool and/or methodology of the research, the student should apply to the relevant DREC.

Category 4 - Non-Research Course With Research Assignment

If the research project is a small assignment in a non-research course the student should apply to the appropriate DREC.

1. Students should begin their application for ethical review by completing and signing the *Student Request for Ethical Review and Checklist for Minimal Risk.* Students are advised to seek the assistance of the course instructor in order to ensure that the project is within the range of minimal risk.

2. If the project is deemed minimal risk the student will submit his/her application to the DREC and must include all of the following:
   a) a completed *Student Request for Ethical Review Form* and *Checklist for Minimal Risk* (one form).
   b) all questionnaires, interview forms, or other survey instruments used
   c) consent form (if applicable)
   d) any supporting documentation from partner organizations (if applicable)
   e) any supporting documentation from client organizations (if applicable).

   Students should ensure that while all elements of an ethics review application are clear, this is especially the case with informed consent, which must be in a plain and simple language that all potential participants will understand. It is understood that the process for obtaining consent may vary according to the research setting (i.e., telephone, questionnaire, interview, etc.) or the culture of the participants(s) (i.e., international, Aboriginal, etc.).

At minimum, the consent form (or equivalent) must include the elements identified on the checklist on the Student Request for Ethical Review form, question 43.

3. The DREC will review the project application in either a face-to-face meeting or electronic meeting, including all the forms, and determine whether or not the research is within the range of minimal risk. If the application is not within the range of minimal risk as determined by the *Checklist for Minimal Risk*, then the DREC must forward the application and supporting documents directly to the UFV HREB.

4. If it is within range of minimal risk, the DREC may respond in one of the following ways:

   a) by determining that the project requires no revisions, in which case the project may proceed to the HREB for final approval
   b) by requiring minor revisions, in which case the researcher should effect the required changes and resubmit to the DREC
   c) by requiring major revisions, in which case the research is not approved, and the researcher must substantially revise and resubmit to the DREC.

   The UFV HREB recognizes that as students sometimes develop an understanding of research methods interactively over time, it may not be possible or desirable for them to submit all components of an ethics review application prior to the start of the research. The DREC is authorized to review requests consisting of only the *Checklist for Minimal Risk* and Student Request for Ethical Review Form provided all survey instruments and consent and/or other forms are reviewed as they become available and before being incorporated into the research program.

5. The chair of the DREC sends the application and supporting documents, minutes of the DREC meeting (or ***complete*** email thread of electronic meeting), and recommendation of approval to the chair of the UFV HREB. The DREC will forward only complete requests to the HREB for final approval prior to data collection.

6. The UFV HREB Chair will review the application and recommendation and may either:

    a) approve the application and send a Certificate of Approval to the student (cc the DREC)
    b) not approve the application, and redirect it to the DREC outlining its reasons for not approving it and any modifications required in order to meet approval if and when it is resubmitted.

Human Research Ethics Decision Making Process

Course-Based Student Research With Human Participants

See *Guidelines for Course-based Student Research Projects* on pg. 10 for more information

Is it minimal risk?	Category	Description	Action Required
No			**Full UFV HREB review (see meeting dates on page 38)**
Yes	Professional Education & Skill Development	• Primarily for professional education and/or skill development (see examples on page 11) • Instructor guided	No action required. Proceed according to accepted standards of professional conduct
Yes	1. Research Course Full Course Review	• Primarily for conducting research or experimenting with method and/or participant pool • Instructor driven • Whole course • Uniformity of projects	**Full UFV HREB review**. Request for designation of course as an **HREB Approved Course** for three a (3) year term
Yes	2. Non Research course Full course review	• Research assignment is part of the regular course instruction and involves human participants (participant pool) • Instructor monitored • Students conduct a research assignment • Uniformity of projects	**Full UFV HREB review** Request for designation of course as an **HREB Approved Course** for a three (3) year term
Yes	3. Research Course Assignment Only	• Individual student research projects within a course • Directed studies	**DREC** review for individual projects. DREC recommendations go to HREB Chair for final approval. DREC sends minutes, protocols and all accompanying materials to the HREB Chair.
Yes	4. Non-Research Course withResearch Assignment	• Research assignment (assignment is one time only, or student generated)	

Faculty / Graduate Student / Institutional Research *

See *Guidelines for Faculty-based Research Projects* for more information

Is it minimal risk?	Category	Description	Action Required
No			**Full UFV HREB review (See meetings dates on page 38)**
Yes			**Delegated Review** by HREB Chair and Vice-Chair

** Research conducted by students for faculty is considered faculty research and must follow the procedures for faculty as per UFV HREB Policy 54*

HREB – Human Research Ethics Board

DREC – Departmental Research Ethics Committee

DREC Terms of Reference

Definition and Scope

All minimal risk student-directed undergraduate research proposals that qualify as research as defined in the UFV Research Ethics Policy 54 must be subjected to the review of a standing Departmental Research Ethics Committee (DREC) as provided in Section 1 B(1) - Article 1.2; D(1.1); and D(4) Article 1.10 of Policy 54.

Please refer to the Guidelines for Course-based Student Research Projects on pg. 10 for more detailed information on DREC operations.

Membership

The composition of the DREC is at the discretion of the department, so long as:

- the department maintains a written policy for the composition and procedures of its DREC and provides copies of same to the UFV HREB
- the DREC includes at least three members, at least one of whom must have experience in research and ethical review of research proposals, or in the alternate is able to consult with the UFV HREB in setting general guidelines or handling contentious decisions
- the DREC review decision is made by a committee of at least two members of the DREC, but does not include the instructor of the course under consideration
- in the event that the department cannot provide at least two members over and above the instructor of the course under consideration, then it must enlist a member from another DREC.

Research Evaluation Procedures

Departmental procedures may vary to suit any needs unique to the relevant department so long as the DREC makes provision for:

- students obtaining informed consent from all research participants
- students providing for adequate protection of all participants with regards to privacy and confidentiality
- students fully informing their participants if the data are to be made public
- securing of all consent forms and information gathered for three years, or any other period of time that may be required as a matter of law, whichever is the greater
- ensuring that any and all research conducted by, for, or in the department, and involving human participants be subjected to ethical review.

Record Keeping

DRECs are to provide the Chair of the HREB with the following documentation for approval prior to data collection:

- minutes of the face-to-face DREC meeting or complete email thread of electronic meeting
- complete Student Request for Ethical Review and all supporting documents (consent form, checklist for minimal risk, agreement letters, etc.)
- recommendation of approval to the HREB.

The current DREC for each department is listed on the Research Ethics webpage at: http://www.ufv.ca/Research/Research_Ethics/Department_Research_Ethics_Committees.htm. If a department contact is missing the default member is the current department head.

In the fall semester, representatives of the HREB (usually the Chair and Vice-Chair of the REB) run a training workshop on how to review a protocol, which types of research need review, what minimal risk is, and anything else that DREC's may want to learn about. If you are interested in taking this workshop please contact Yvette Fairweather or look for a campus-wide announcement.

UFV Research Ethics Policy - 54 – Synopsis

The following section synthesizes the Articles in the UFV Research Ethics Policy 54 relevant to the procedures UFV faculty, staff and students must follow when conducting research on human participants. Please note that these Articles appear here in summary form only. For the full text, please refer to Policy 54 at http://www.ufv.ca/secretariat/policies.htm.

Definitions

1. Research

By definition, research refers to any activity that involves a systematic investigation to establish facts, principles or general knowledge. However, there is a distinction between activities directed at the acquisition of data for research in the pure sense and those designed for professional education or skill development. For more on this distinction, see *Guidelines for Course-Based Student Research Projects*.

2. Researcher

A researcher is defined as any person associated with UFV who undertakes to conduct research as defined above. This includes faculty, staff, and students, as well as any individuals from the community who are associated with a UFV generated research project.
It also includes anyone who enlists UFV faculty, staff, students, or departments as participants.

3. Research Participants

Under TCPS policy, a research participant refers to any living individual or groups of living individuals about or from whom a researcher either obtains data through some kind of methodological intervention or interaction with the individual or group, or uses or accesses data either containing, or that can be traced to, identifiable private information.

PROCEDURES AND GUIDELINES

A. Research Requiring Ethical Review

Article 1.1

a) All research directly or indirectly involving human participants requires review and approval by the HREB or its designate in accordance with this policy and the TCPS before the research is started.

b) However, research about a living individual clearly in the public domain (such as a politician, artist or performer), provided it is based on publicly available information, documents, works or performances and not on interviews or access to private papers, is not subject to ethical review.

c) Similarly, research directed at program evaluation or professional education or skill development, or based on archival or public information data bases, is not subject to ethical review. However, research based on list-mining of certain electronic websites (e.g., blogs, chatrooms, social networks, etc.) is subject to ethical review.

B. Human Research Ethics Board (HREB)

Article 1.2

a) All research as defined above falls under the jurisdiction of the Human Research Ethics Board (HREB). It is constituted under the Office of the President, and has the authority to approve, reject, propose modifications to, or terminate all proposed or ongoing research involving human participants. The HREB is also charged with the education of, and consultation with, the UFV research community.

b) As spelled out in the *Guidelines for Course-Based Student Research Projects*, certain kinds of undergraduate student

research can be recommended for approval by a designated Departmental Ethics Review Committee (DREC), but is at all times still subject to full disclosure to, and final approval by, the Chair of the HREB.

C. Analysis, Balance and Distribution of Risks and Benefits

Article 1.6

a) In accordance with TCPS, the HREB is charged with utilizing a proportionate approach based on the general principle that the more invasive the research, the greater degree of scrutiny or care in assessing it.

b) In practical terms, this means that the HREB must satisfy itself that the design of a research project that poses more than 'minimal risk' is capable of addressing the questions being asked in the research. In the biomedical sciences, research that does not involve more than minimal risk will depend on the type of research. In the social sciences and humanities, research that does not involve more than minimal risk shall not normally require peer review. The HREB has the authority to seek expert advice when deliberating on any and all research in the natural or social sciences.

c) At all times, and within the limitations noted above, the HREB shall always weigh the possible harms and risks against the overall value of the research. Put alternately, the HREB cannot reject a research proposal on the basis of bias, unfamiliarity, or because it poses controversial questions.

D. Review of Procedures

Article 1.7

a) In accordance with the TCPS, a proportionate approach to ethics review is based on whether or not the potential harms or risks of the research fall below or above the threshold of minimal risk, which is defined as that level of risk which accrues if

potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of their everyday lives that relate to the research.

b) According to UFV policy, and the principle of minimal risk outlined above, research on human participants falls under either of four general categories:

   i) research conducted by faculty or graduate students (in which case requests below the threshold of minimal risk may be delegated, but above to the full HREB)

   ii) research conducted by undergraduate students (in which case requests below the threshold are submitted to the DREC, but above to the full HREB)

   iii) courses designed primarily for research purposes (in which case requests go to the full HREB).

   iv) multi-jurisdictional research

c) As such, and within the general guidelines of the TCPS, the procedures that researchers must follow, including the forms that must be filled out in a research ethics application and whether or not the research proposal is submitted to the HREB or the DREC, please refer to the *Research Ethics Decision Making Process* and the *Guidelines for Course-Based Student Research Projects*.

d) Researchers who are still unclear as to how to classify their research, how to file an application for ethical review, or anything else related to their proposed research on human participants, should contact the Chair of the HREB.

Articles 1.8 and 1.9

These articles deal with matters relating to HREB meetings and attendance. For details, please refer to Policy 54.

Article 1.10

a) The HREB meets face-to-face, on a regular monthly basis, except during July and August, when meetings will be held as required. Meeting dates are listed by academic year at the back of this manual.

b) Although there are exceptions, research requests that are checked off by faculty or graduate students as minimal risk will typically qualify for delegated review, and can be approved by the Chair and Vice-Chair. Requests from undergraduate students that check as minimal risk should be submitted to the relevant DREC. Research requests that are above the threshold of minimal risk must go to the full HREB.

c) The HREB, and in the case of delegated reviews the Chair and Vice-Chair, will function in a fair and impartial manner and accommodate and/or invite researchers to the meeting at which their requests are being heard. Researchers may freely enter into discussion with the HREB and be assured that those discussions will be recorded in the minutes. However, researchers may not be present when the HREB renders its decision.

d) HREB decisions can fall under any one of the following four categories:

- **Approved** - approval of proposed research activity as originally submitted
- **Minor Revisions -** application returned to the researcher for minor revisions, in which case the researcher makes the necessary changes and then resubmits to only the Chair and Vice-Chair for final approval

- **Major Revisions -** application returned to the researcher for major revisions, in which case the researcher makes the necessary changes and then resubmits to the full HREB
- **Not Approved -** rejection of the proposed research activity

d) The HREB will render its initial decisions in a timely manner. However, the time between initial application for ethical review and final approval will depend on a range of factors, including when the application is first filed; whether it is a student application; whether or not the research proposal is minimal risk and/or can be delegated; and the nature of any minor or major revisions requested.

Articles 1.11 and 1.12

a) Researchers have the right to request, and the HREB has an obligation to provide in a timely manner, reconsideration of decisions affecting a research proposal. Such reconsideration will be guided by the principles of natural justice and a fair opportunity for researchers to be heard.

b) In cases where researchers and the HREB cannot reach agreement through the process of reconsideration, the researcher may seek an appeal to the UFV Research Ethics Appeal Board (REAB), a body constituted under the Office of the President, but whose membership is not the same as the HREB.

Articles 1.13 and 1.14

These articles deal with the potential conflict of interest applicable to HREB members, review procedures for ongoing or longitudinal research and review of research in other countries. For details, please refer to Policy 54. See also the summary of the UFV Conflict of Interest Policy 520.03.

Article 1.15

Research to be performed outside the jurisdiction or country of the institution which employs the researcher shall undergo

prospective ethics review both (a) by the HREB within the researcher's institution; and (b) by the HREB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

Free and Informed Consent

A. Requirement for Free and Informed Consent

Article 2.1

a) The principle of free and informed consent lies at the heart of research ethics. In practical terms, this means that research governed by this policy may begin only when prospective participants, or authorized third parties that represent them, have received the opportunity to give free and informed consent about their participation, and that this is maintained throughout the entire research process.

b) Evidence of free and informed consent shall normally be obtained in writing. Where written consent is culturally unacceptable, or there are good reasons for not securing consent in writing, the procedures used to seek free and informed consent will be documented.

c) The HREB may approve a consent procedure which alters the principles of (a) above, provided the HREB concludes that the research falls below the threshold of minimal risk; that the alteration is unlikely to adversely affect the rights of the participant; that the research could not be carried out without the alteration; that participant will be provided with additional pertinent information after participation is secured; and that the alteration does not involve a therapeutic intervention.

d) In the context of free and informed consent, researchers should also familiarize themselves with the contents of UFV Integrity in

Research and Scholarship Policy 210.09. A synopsis of the relevant sections of this policy is included in this manual, below.

B. Voluntariness

Article 2.2

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

C. Naturalistic Observation

Article 2.3

Although there may be exceptions (such as in the case of political rallies, demonstrations or public meetings in which participants are deliberately seeking public visibility), research involving naturalistic observation is subject to HREB review.

D. Informing Potential Participants

a) Researchers must provide to prospective participants, or their authorized representatives, full disclosure of all information relevant to free and informed consent. Put alternately, researchers must ensure that potential participants are given adequate opportunity to consider their participation.

b) In practical terms, this means researchers must, at minimum, provide prospective participants with information that the individual is being invited to participate in a research project; a comprehensible statement of research purpose; the identities of the researcher(s); and the expected duration and nature of the research and scope of their participation.

c) Researchers must provide a description of all reasonably foreseeable harms and benefits that could arise from their participation; an assurance that prospective participants are free not to participate and have a right to withdraw at any time without prejudice to pre-existing entitlements; the possibility of any commercialization of research findings; and any actual or

perceived conflict of interest on the part of the researcher(s), institutions or sponsors.

E. Competence

Article 2.5

Subject to any legal requirements, individuals who are not legally competent to give free and informed consent can only be asked to become research participants when the research project can only be carried out using individuals in the identified group(s); free and informed consent will be sought from their authorized representatives; and the research does not expose them to more than minimal risk.

Article 2.6

For research involving incompetent individuals, researchers must demonstrate to the HREB how free and informed consent will be sought from the authorized representative (not including the researcher or any member of the research team) and the continued free and informed consent of the authorized representative so long as the participant remains legally incompetent. In the event that the participant becomes competent during the research, his or her free and informed consent will be sought as condition of continuing participation.

Article 2.7

This article deals with research in emergency health situations. For details, please refer to Policy 54.

Article 2.8

Subject to all applicable legislative and regulatory requirements, researchers shall report any adverse events that occur during the course of conducting research. An adverse event is considered to be any undesirable experience or response that was not expected and not stated in the informed consent and original protocol. This includes anything emotional, psychological or physiological.

Privacy and Confidentiality

A. Accessing Private Information: Personal Interviews

Article 3.1

Subject to exceptions outlined in Article 1.1 above, researchers intending to conduct interviews to secure identifiable personal information shall secure HREB approval for the interview procedure and script, and the free and informed consent of interviewees as required in Article 2.4 above.

B. Accessing Private Information: Surveys and Questionnaires

Article 3.2

a) Subject to Article 3.1 above, researchers shall secure HREB approval for obtaining identifiable information and must include such considerations as the type of data to be collected; the purpose for which the data will be used; any limits on the use, disclosure and retention of the data; and appropriate safeguards for security and confidentiality of the data.

b) Researchers must disclose to participants all modes of observation or data gathering (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that might allow identification of particular participants.

c) Researchers must notify participants of any anticipated secondary use of identifiable data; any anticipated linkage of data gathered in the research with other data about participants; and provisions of confidentiality resulting from the research.

C. Secondary Use of Data

Article 3.3

HREB approval is required if researchers wish to access secondary data containing identifiable information. In practical terms, researchers need to demonstrate that identifying information is necessary for the research; that they will take the steps necessary to protect individual privacy; and that individuals to who the data refer have not objected to secondary use.

Article 3.4

The HREB may also require that a researcher's access to secondary data involving identifiable information depend upon the informed consent of those who contributed the data; contain an appropriate strategy for informing the participants; and, involve consultation with representatives of those who contributed the data.

Article 3.5

Unless already secured through the process of free and informed consent, researchers wishing to contact individuals to whom secondary data refer shall first seek authorization by the HREB.

D. Data Linkage

Article 3.6

Any implications of approved data linkage in which research participants may be identifiable must be approved by the HREB.

Conflict of Interest for Researchers

Article 4.1

Researchers must disclose actual, perceived or potential conflicts of interest to the HREB. In such cases, researchers are also directed to familiarize themselves with UFV Conflict of Interest Policy 520.03. A synopsis of the relevant sections of this policy is included in this manual.

Inclusion in Research

Articles 5.1, 5.2 and 5.3

Except in situations where specific cohorts are being targeted in a research proposal, researchers shall not exclude prospective or actual participants on the basis of culture, ethnicity, race, gender, sexual orientation, religion, or disability. For details, please refer to Policy 54.

Article 5.4 – Research with Indigenous, and First Nations Inuit, and Métis People.

Please read this section of the policy if you are considering conductiong research with Indigenous Peoples.

Clinical Trials, Genetics, and Research on Human Tissues

Articles 6.1 through 6.4, 7.1 through 7.7, 8.1 through 8.5, and 9.1 through 9.3

While these kinds of research typically do not occur at UFV, the articles in these sections govern a range of research in pharmaceuticals, clinical trials and non-therapeutic interventions, genetic counseling, alteration and banking, and the use or manipulation of human embryos, gametes and tissues. For details, please refer to Policy 54.

UFV Conflict of Interest - Policy 142 – Synopsis

The following section synthesizes the Articles in UFV's Policy 142 governing conflict of interest, and fundamental to the conduct of ethical research under Policy 54, summarized above. Please note these Articles appear here in summary form only. For the full text, please refer to Policy 142.

Policy and Definitions

In accordance with the principle of adhering to the highest ethical standards in research, this policy defines conflict of interest, the process by which members of the UFV community avoid situations in which they may be in conflict, and disciplinary procedures in the event that a breach occurs. For details on procedures, please refer to Policy 142.

By definition, a conflict of interest exists when a member of the UFV community, defined as any employee, volunteer, student, or alumnus, has an interest sufficient to cause a reasonable person to question whether the person could be compromised in the impartial discharge of his or her duties. In practical terms, this means members of the community must remove themselves from situations where conflict of interest may arise.

Conflicts of Interest

A conflict of interest exists when a member of the UFV community obtains or gains an advantage to the member or the member's family or business; when it causes an adverse effect on UFV interests; or when a relationship affects a member's capacity to exercise due care, skill and judgment on behalf of UFV and in the performance of the individual's duties. Common situations might include, but are not be limited to:

a) participating in any decision where the member has a pecuniary interest, as in the member's capacity as proprietor, partner, shareholder in an organization or corporation, whether private or public, profit or non-profit

b) making an investment in any situation in anticipation of UFV taking a material interest therein, or resulting from facts not known by or available to the general public
c) participating in the appointment, promotion, discipline or performance review affecting a relative or partner
d) participating in decisions regarding grades, financial aid, awards, academic program or thesis or paper, providing references to a relative or partner.

A conflict of interest could arise if gifts, gratuities or favours of any kind are exchanged between a member and any individual or company whose relationship with UFV entails the member's sphere of opportunities. So long as they are reported to the immediate supervisor, the policy does not prohibit common business courtesies such as receiving a meal or gift of nominal value, or restrict the recognition of donors to UFV.

UFV Integrity in Research - Policy 53 – Synopsis

The following section synthesizes the Articles in UFV's Policy 53 governing integrity of research and scholarship, and fundamental to the conduct of ethical research under Policy 54, summarized above. Please note these Articles appear here in summary form only. For the full text, please refer to Policy 53.

Purpose, Intent and Policy

In accordance with the principle of adhering to the highest ethical standards in research, the obligation of maintaining integrity in research and scholarship rests primarily on faculty, staff and students conducting research as defined in 54 above. Professional misconduct in research, including the failure to comply with the terms of Policy 54, is an offence which, depending on its severity, can be subject to a range of disciplinary measures, including dismissal. For the full text on the procedures governing the determination of, and response to, allegations of misconduct, please refer to Policy 53.

Principles

Maintaining integrity in research and scholarship rests on:

a) using disciplinary and scientific rigor in acquiring, analyzing, using and storing data; not fabricating or falsifying data or results; allowing all collaborators access to the data; and ensuring original records are retained for five years or as long as there is a reasonable possibility that the data could be required
b) recognizing the substantive contributions of all collaborators in research, whether published or not
c) ensuring that authorship of published work includes all those, and only those, who contributed materially to the conception, design, interpretation, execution and reporting the results of the research
d) obtaining written approval for the use of all new information, concepts or data acquired from original manuscripts, training or applications for research funding

e) seeking and obtaining approval from the Human Research Ethics Board before engaging in any research involving human participants or participants
f) seeking and obtaining approval from the Animal Care Committee before engaging in any research involving animals
g) seeking and obtaining approval from the Biosafety Officer or the Radiation Safety Officer before engaging in any research involving biohazards or ionizing radiation
h) complying with external grant regulations as they relate to the operational or financial aspects of research grants and awards
i) revealing to UFV in writing any financial or other interest in any company that contracts research with UFV; material financial interest includes ownership, major stock holdings, directorships, and significant honoraria or consulting fees
j) revealing to UFV in writing any potential conflict of interest, financial or other as spelled out in Policy 142

Websites to Visit

Tri Council Policy Statement - http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

TCPS2 Tutorial - http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

> The Tutorial for the Tri Council Policy Statement for ethical conduct of research involving human participants helps to educate the research community about the TCPS2. It also facilitates the use, interpretation and implementation of the TCPS2.

UFV Human Research Ethics Board - http://www.ufv.ca/Research/Research_Ethics.htm

UFV Policies -

http://www.ufv.ca/Secretariat/policies.htm

HREB Meeting Schedule

2012-2013

Meeting Date Thursday	Time	Place	Deadline for Submission 12:00 noon Wednesday
September 27, 2012	4:00 pm	B133	September 19, 2012
October 25	4:00 pm	B133	October 17
November 22	4:00 pm	B133	November 14
December 13*	4:00 pm	B133	December 5*
January 31, 2013	4:00 pm	B133	January 23, 2013
Feb 28	4:00 pm	B133	February 20
March 28	4:00 pm	B133	March 20
April 25	4:00 pm	B133	April 17
May 23	4:00 pm	B133	May 15
June 20	4:00 pm	B133	June 12

Generally, the HREB meets Week 4 Thursdays of the UFV meeting schedule, from 4 – 7 pm.

Requests for Ethical Review must be received by the Human Research Ethics Board (c/o Research Services & Industry Liaison Office, Yvette.Fairweather@ufv.ca) **by noon on Wednesday, one week prior** to the meeting. Late submissions will not be accepted.

Researchers will be invited to attend a portion of the meeting in order to answer questions or concerns.

* Meeting date has been changed due to holidays.