Human Research Ethics Board (HERB)

- Main Page:
  - http://www.uvic.ca/research/conduct/home/regapproval/humanethics/
- HERB Guidelines and Application forms available on the Office of Research Services (ORS) website

Contacts at HERB:

Human Research Ethics
Office of Research Services
University of Victoria
Administrative Services Building (ASB),
Room B202
PO Box 1700 STN CSC
3800 Finnerty Road
Victoria, BC V8W 2Y2
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TRI-COUNCIL POLICY (1 of 2)

- UVic has adopted the **Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS)**
- Tri-Council is made up of:
  - **SSHRC** (Social Science and Humanities Research Council)
  - **NSERC** (Natural Sciences and Engineering Research Council)
  - **CIHR** (Canadian Institute of Health Research)

TRI-COUNCIL POLICY (2 of 2)

- **Ethical Principles**:
  - Respect for Human **Dignity**
  - Respect for Free and Informed **Consent**
  - Respect for Vulnerable Persons
  - Respect for Privacy and **Confidentiality**
  - Respect for Justice and Inclusiveness
  - Balancing **Harms** and **Benefits**
- Found at:
  - http://www.uvic.ca/research/conduct/home/regapproval/humanethics/# (click on Guidance Tools)

TCPS Definition of Minimal Risk

- Potential participants can reasonably expect to regard the possible harms implied by participation to be **no greater than those encountered by the participant in those aspects of his/her everyday life that relate to the research**

Application Review Process

- Risk is assessed (TCPS definition)
- Review process assigned
  - Minimal risk:
    - Expedited – Chair and the Coordinator only
    - Slightly Complex - Chair, Coordinator and two designated reviewers from HREB
  - Not minimal risk:
    - Full HREB review at next monthly meeting

Recruitment

- Participants have the right to know why they are being asked to participate and how you obtained their names.
- If third parties or organizations assist with recruitment, it must be done in ways that conform to privacy regulations.

Consent

- Consent is a process, not just a form
- Full disclosure (unless need to use deception, which we won't!)
- Time to consider and ask questions
- Voluntary and able to withdraw at any time

Recording Consent

- Signed (e.g. consent form)
- Verbal – recorded (e.g. telephone interview)
- Implied (e.g. anonymous survey)

Risks

- Participants have a right to be informed of any risks associated with their involvement in the study including:
  - **Psychological/emotional**: e.g., increased sadness, anxiety, fear, depression, loss of privacy and re-traumatization
  - **Social:** e.g., loss of status, respect, alienation, social stigma
  - **Physical:** e.g., pain, scarring, infection
  - **Economic:** e.g., threats of job
- Create measures to prevent/minimize risks and respond to harms

Anonymity

- Anonymity means that the researcher has no knowledge of who the participants in the study are, and cannot ever link the data to the participants.
- Whether researchers offer anonymity to participants depends on the study.

Confidentiality

- Protection of the participants' identity (anonymity) and the protection, access, control and security of his or her data and personal information during recruitment, data collection, dissemination of data and findings and data storage.

Limits to Confidentiality

- Participants must be made aware of limits to anonymity and confidentiality in the consent process.
- Confidentiality may be breached when:
  - the law requires it (e.g., disclosure of child abuse) or
  - there is a reasonable expectation of harm occurring to the participant or others

What to think about…

- Users/Participants
  - How will you recruit them?
  - How are you going to be interacting with them (interviews, observation, survey, etc..)?
- Attachments
  - Recruitment materials, e.g., script(s), letter(s)
  - Consent form(s)
  - Research instruments
  - Approval from external organization
- **Submit Ethics and Consent forms to me: mstorey@uvic.ca before you recruit or collect data from users!**

Minimal Risk (only!)

- Participants are competent adults, youth or children;
- Participants live freely in the community (i.e., are not captive, e.g., in prison or hospital);
- The topics are non-controversial and carry little or no risk to the participants;
- The methods are non-invasive, such as the use of questionnaires or interviews;
- The projects do not involve deception.

What you need to do!

- Each team needs to complete the "*Application for Ethical Approval of Human Participant Research*"
- *See http://www.uvic.ca/research/conduct/home/regapproval/humanethics/##templates (scroll down, click on Forms tab, I also put a copy of this on GitHub)*
- *Make sure you add all team members to the ethics form (as co-investigators, grad(s) will be the primary investigator)*
- *Note: you may be able to apply for a waiver, see http://www.uvic.ca/research/conduct/home/regapproval/humanethics/# (last bullet point)*

Template for Consent Form

- You also need to complete one of these!
- There is one on GitHub
- Also some at the Uvic Research site: http://www.uvic.ca/research/conduct/home/regapproval/humanethics/##templates (scroll down click on Forms tab, scroll down to see the templates)

Please don't!

- Use deception
- Have excessive inducements for people to participate (needs to be voluntary)
- Introduce any risk to participants (psychological or physical)
- Ask any questions about intimate or sensitive aspects of participants' behaviour or life history (e.g., abuse of any kind)

You **cannot** interact with any participants until I give you ethics approval...

Do this step by next week!

Checklist (part 1)

Students must provide the instructor with information pertaining to each of the following:

☐ A copy of the informed consent form, that will be read and signed by the participants (see the template on the ORS website or the checklist in the Course-based application form);

☐ A brief description of the project in lay language that can be understood by the participants and that clearly identifies that this is a course-based project and includes the course name and number, and the instructor's name and telephone number;

☐ A full description of all data collection procedures and instruments, as well as expectations regarding the amount of time required for participation (copies of any questionnaires must be provided for the instructor's approval);

- ☐ Whether any risks or benefits are likely to arise

Checklist (part 2)

☐ Whether any risks or benefits are likely to arise from participation in the project (these must be minimal risk research projects);

☐ The names of all persons involved in collecting data for the project;

☐ Details of any compensation offered to subjects (if applicable);

☐ An explanation to participants that will ensure they understand that participation is entirely voluntary and that they can withdraw at any time, without explanation or consequences (i.e., that participation, nonparticipation, nor withdrawal will have any effect on, for example, grades, class standing, or employment - as applicable);

☐ The means by which participants' anonymity will be protected;

- ☐ The means by which the data will be kept

Checklist (part 3)

☐ The means by which the data will be kept confidential, including details of secure storage, who will have access;

☐ Permission to audio tape or video tape the participants (if applicable);

☐ How the raw data, including tapes, notes and other types of data will be disposed of at the end of the project;

☐ The way in which the results will be presented and/or dissemination;

☐ A Reminder: All students must provide written evidence from outside agencies (e.g., school boards, VIHA) granting approval to carry out research that involve such agencies. A copy must be sent to the ORS and will be kept on file with the instructor's application.

Appendix

- Notes for me...

Instructor role… Part 1

- Explaining the nature and purpose of the research project to participants.
- ✓ ☞Recommending recruitment strategies (e.g., by letter; through an organisation; presentation to a group; etc.), and safeguards to ensure that no coercion is used if there is the potential of a relationship between the students and the participants.
- ✓ ☞Obtaining free and informed consent from participants.
- ✓ ☞Explaining the voluntary nature of participation and the participants' right to withdraw at any time without consequences.
- ✓ ☞Describing compensation offered to subjects (if applicable).

My role… Part 2

- ✓ ☞Assessing any potential risks and/or benefits related to the study and explaining them to participants (research assignments must be minimal risk).
- ✓ ☞Addressing anonymity with participants (i.e., protection of the identity of participants along a continuum, from complete to no protection, as appropriate and as agreed to by participants).
- ✓ ☞Addressing confidentiality issues with participants (i.e., identity as well as data, including secure storage of, and controlled access to the data and personal information).

My role… Part 3

- ✓ ☞Explaining how the results will be reported.
- ✓ ☞Explaining how and when the data will be destroyed.
- ✓ ☞Making it clear that permission must be obtained from all outside agencies that will be involved in the study (e.g., companies; community agencies; School Districts; VIHA; Aboriginal Governments, etc.) prior to undertaking the research.
- ✓ ☞Explaining any other procedures relevant