Appendix (B)

Human Participants Research Protocol

(Funded OR Not Minimal Risk)

(revised on November 20, 2012)

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(Funded OR Not Minimal Risk)

Students who conduct a research study using human participants must complete the Tri-Council Policy Statement (TCPS) tutorial, available online at **www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel**, and obtain a research ethics clearance **prior to the conduct of research.** If the research is not approved prior to the start of research, the research will not have received research ethics clearance and will be deemed unacceptable for submission as a component of this course. Information regarding the use of human participants in research studies may be found on the Faculty of Graduate Studies webpage **www.yorku.ca/grads/policies_procedures/research_ethics.html**

Students are advised that all human participants in the research must have either signed a written consent form or have provided oral consent for their participation in the research. **Students also are advised that the consent forms will be retained by the Principal Investigator (i.e. the student) for 2 years following the completion of the research.**

IF the research being conducted is associated with a faculty member's existing research project, which has already been approved by the Human Participants Review Sub-Committee (HRPC) through the Office of Research Services (ORS), students will submit the following documentation to the Graduate Program Office.

1. MRP Proposal;
2. Ethics Approval Form (**in the MRP guidelines**);
3. TCPS tutorial completion certificate dated within the past 2 years prior to the submission of MRP Proposal; (Note that the certificate is issued on-line upon the completion of tutorial.)
4. Statement of Relationship Between Proposal and an Existing HPRC Approved Research/Facilities Form (**Form TD4 in this Appendix**) plus attachment(s) as outlined in the Form.

Otherwise, students are required to follow an alternate ethics approval process to be carried out by the Human Participants Review Sub-Committee (HRPC) through the Office of Research Ethics (ORE). The MRP Supervisor is required to first contact the Chair of the Graduate Programme's Ethics Review Committee to establish and follow through the approval process.

Students will submit an **original copy and 6 photocopies of the HPRC Protocol Form** posted on the ORE website at **www.yorku.ca/research/documents/HPRCProtocolForm.doc** plus attachment(s) as outlined in the Form to the ORE, located on 5th Floor of York Research Tower.

To assist students in completing this HPRC Protocol Form, the following "tools" are enclosed with this appendix.

(1) Informed Consent Document Checklist for Researchers (**refer to Form TD3 in this Appendix**)
(2) Informed Consent Statement Sample; (**refer to p. 6 in this Appendix**)

In addition, students will submit the following documentation to the Graduate Program Office.

1. MRP Proposal;
2. Ethics Approval Form (**in the MRP guidelines**);
3. TCPS tutorial completion certificate dated within the past 2 years prior to the submission of MRP Proposal; (Note that the certificate is issued on-line upon the completion of tutorial.)
4. A photocopy of the HPRC Protocol Form plus attachment(s) outlined in the Form as stated above.

* The **definition of minimal risk** being used is the one given in the SSHRC/NSERC/MRC *Tri-Council Policy Statement "Ethical Conduct for Research involving Humans*" (August, 1998):

> **"If potential subjects 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 subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk." (p. 15)**

Graduate students doing Major Research Papers, Theses, or Dissertations in which research involving human participants occurs are required to be familiar with York University's policies about the use of human participants and should be familiar with the SSHRC/NSERC/MRC *Tri-Council Policy Statement "Ethical Conduct for Research involving Humans*" (August, 1998). These can be found at the Office of Research Ethics (ORE), 5th Floor of York Research Tower or on the web at

www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

TD4 Form
Statement of Relationship between Proposal and Existing Approved Research / Facilities

Student: _____
(please print)

Graduate Program: _____**Critical Disability Studies** _____

Proposal Title:

_____

_____

Please check appropriate box:

☐ **Research Involving Human Participants**
The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Human Participants Review Committee (HPRC). All the procedures, the methods for participant recruitment and methods for obtaining informed consent within this proposal were included in the *HPRC* application of the full project and have not changed. The informed consent form has not changed.

☐ **Research Involving Animals**
The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Animal Care Committee (ACC). All the procedures for animal care and use within this proposal were included in the *Animal Use and Care Protocol* application of the full project and have not changed.

☐ **Research Involving Biohazards**
The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Advisory Committee on Biological Safety (ACBS). All the procedures relating to the use of biological hazards within this proposal were included in the *Biosafety Certificate (Research)* application of the full project and have not changed.

Supervisor's Name: _____

Supervisor's Signature: _____

Date: _____

Form effective March 2005

Form TD3
INFORMED CONSENT DOCUMENT CHECKLIST FOR RESEARCHERS

YES	NO	N/A	DESCRIPTION
		----	Have you included a brief description of the purpose/rationale of the study?
		----	Have your included a brief description of the study design?
			If the research involves a questionnaire or a survey, have you provided the questionnaire or survey?
		----	Have you indicated the time commitment required of participants?
		----	Have you indicated whether and what incentives are offered to participants and why?
		----	Have you included a brief description of risks/benefits and mitigation methods?
			If the study involves any type of physiological assessment or procedure (such as those studies undertaken by Kinesiology and/or psychology researchers), have you provided the following information in the Informed Consent Document?: i. Information about the expertise of the researchers conducting the study (i.e., if it involves giving an injection, that the researcher is competent to do so) ii. Notification to participants that are being taken to safeguard their person iii. Notification to participants of any potential risks and/or impacts to their person due to their participation iv. Information for participants on any anticipated circumstances arising from their participation in the study v. Notification to participants of any benefits vi. Contact information for participants regarding resources available to them should any concerns arise at a later date
		----	Have your described the methods by which confidentiality and anonymity will be attained and maintained?
		----	Have you included statements of the following (as applicable)? i. Participants have the right not to answer questions ii. Participants have the right to withdraw at any time iii. Should a participant withdraw from the study, all data generated as a consequence of their participation shall be destroyed iv. Participants shall address any ethical concerns regarding the research to the Manager of Office of Research Ethics v. How the research will be presented or reported
		----	Have you described the storage method, length of retention and disposal method of all data gathered during the study?
		----	Have you included a statement indicating that the research has been reviewed and approved for compliance to research ethics protocols by the Human Participants Review Subcommittee (HPRC) of York University?
		----	Have you provided contact information for participants should they have questions (a contact phone number for *your Graduate Program Office* and contact information for the *Manager of Research Ethics for the University at the Office of Research Ethics, 5th floor of York Research Tower, phone 416-736-5914*)
		----	Have you provided contact information for yourself as the Principal Investigator (your name, your campus address, your status--i.e., Graduate Student)
			If the study involves the use of a minor, have you included: i. A separate information letter to the parents of the minor ii. A separate parental permission letter which is to be attached to the minor's letter of "assent" iii. A line for the Parent or Guardian to indicate their relationship to the minor iv. A signature line for the parent/guardian of the minor.
		----	Have you included a signature line and a date line for participants?
		----	Have you included a signature and a date line for yourself as Principal Investigator?
		----	If you intend to publish or present your findings, include a relevant statement. i.e. It is possible that the results of this study will be disseminated through publication and/or presentation. Anonymity will be maintained.
		----	Have you requested participants to provide a "fake name" in the informed consent letter/form?

Student's Name and Signature: _____

(Print Name) **(Signature)**

Supervisor's Name and Signature: _____

(Print Name) **(Signature)**

SAMPLE INFORMED CONSENT FORM

Date:

Study Name:

Researcher:

Sponsor(s): York University and

Purpose of the Research:

What You Will Be Asked to Do in the Research:
[Include a statement regarding the estimated time commitment for the participant].

Risks and Discomforts:
We do not foresee any risks or discomfort from your participation in the research. [*If there is a possibility of harm, it needs to be described]*

Benefits of the Research and Benefits to You:

Voluntary Participation:
Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the *[treatment you may be receiving] [nature of the ongoing relationship you may have with the researchers or study staff]* nature of your relationship with York University either now, or in the future.

Withdrawal from the Study:
You can stop participating in the study at any time, for any reason, if you so decide. If you decide to stop participating, you will still be eligible to receive the promised pay for agreeing to be in the project. Your decision to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, York University, or any other group associated with this project. In the event you withdraw from the study, all associated data collected will be immediately destroyed.

Confidentiality:
[*Unless you choose otherwise*] [*Indicate if the interviewing or recording of the participant will be associated with identifying information]* All information you supply during the research will be held in confidence and unless you specifically indicate your consent, your name will not appear in any report or publication of the research. *[Indicate how the data will be collected, e.g. handwritten notes, video/audio tapes, digital device.]* Your data will be safely stored in a locked facility *[or indicate how the data will be securely stored]* and only research staff will have access to this information. *[Indicate how long the data will be stored and whether it will be destroyed after the study (and how) or will the data will be archived (and if so, where).* Confidentiality will be provided to the fullest extent possible by law.

Questions About the Research?
If you have questions about the research in general or about your role in the study, please feel free to contact myself (telephone and/or email address) or my Principal Supervisor, Professor XXXXXX (telephone and/or e-mail address). The proposal of this research has been reviewed and approved by York University's Human Participants Review Sub-Committee (HRPC) through the Office of Research Ethics (ORE) and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact Alison Collins-Mrakas, Manager of Office of Research Ethics (Tel: 416-736-5914; Email: acollins@yorku.ca).

Legal Rights and Signatures:

I *(fill in your name here)*, consent to participate in *(insert study name here)* conducted by *(insert investigator name here)*. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form; however, I understand that unless I provide a "fake name" as below, I am waiving the right to be anonymous in any report or publication of the research. My signature below indicates my consent.

To be filled out by the Participant:	**To be filled out by the Principal Investigator:**
Name of Participant	Name of Principal Investigator
Signature of Participant	Signature of Principal Investigator
Participant's "fake name" (please print)	Date
Date	