Appendix (A)

Human Participants Research Protocol

(Non-funded AND at Minimal Risk)

(Revised on November 20, 2012)

Human Participants Research Protocol

(Not Funded AND at 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 at **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 is not funded and at minimal risk *, submit the following documentations 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. York University Graduate Student Human Participants Research Protocol Form (**Form TD2 in this Appendix**);
5. Informed Consent Document Checklist for Researchers (**Form TD3 in this Appendix**);
6. Informed Consent Statement (written or verbal script); (refer to **p. 8 in this Appendix for a sample**)
7. Sample questionnaire and guiding interview questions, if needed.

This material will be reviewed by the Graduate Program's Ethics Review Committee. Reviews will take no more than 2 weeks from the date of submission.

* 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, 5th Floor of York Research Tower or on the web at

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

FORM TD2

YORK UNIVERSITY GRADUATE STUDENT
HUMAN PARTICIPANTS RESEARCH PROTOCOL
(Please print)

Student Name: **Date:**

E-mail: **Phone Number**:

Program: **Degree:**

Title of Thesis, Dissertation, Major Research Paper, or Course:

Name of Supervisor (Thesis, Dissertation or MRP) or Course Director:

A. **Is the research you are conducting funded?**

No_____ Yes_____

The definition of "funded" does not include funding in the form of student OGS scholarships, SSHRC fellowships, NSERC scholarships, or CIHR studentships. These awards are intended to support students through their studies and do not require reports from students on the specific research activities conducted. The definition of "funded" does apply to grants awarded for specific research projects, whether those projects be the student's own research projects or research being conducted as part of a faculty member's funded research project. Typically, for funded research, granting agencies require reports of the research conducted.

B. **Are the risks to participants more than minimum risk?**

No_____ Yes_____

The Human Participants Research Committee uses the definition of minimal risk as outlined in the SSHRC/NSERC/CIHR *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. 1.5). An expanded version of this definition is available from the Office of Research Ethics (5th Floor of York Research Tower) upon request.

If you answered "Yes" to either question A or B, please note the following:

Students are required to follow an alternate ethics approval process to be carried by the Human Participants Review Sub-Committee (HRPC) through the Office of Research Ethics (ORE),5th Floor of York Research Tower. MRP Supervisor is required to first contact the Chair of the Graduate Program/Department Ethics Review Committee to establish and follow through the approval process.

I. Please answer the following questions regarding ***Research Information***:

(1) Project Description and Rationale: In layperson's terms, please provide a general and very brief description of the research and rationale (e.g., hypotheses, goals and objectives etc.) **PLEASE DO NOT SUBMIT YOUR MRP PROPOSAL TO THE OFFICE OF RESEARCH ETHICS (ORE).**

(2) Participants:

a. State who the participants will be:

b. How will the participants be recruited?

c. Will inducements be offered?

d. What will be required of the participants?

(3) Risks and Benefits: What risks to, and benefits for, if any, are there for the participants?

II. Please answer the following questions on the ***informed consent*** of research participants:

(1) Will you provide a full explanation of the research to the participants prior to their participation?

Yes_____ No_____ (If **no**, please elaborate below.)

(2) Is substitute consent involved (e.g., for children, youths under 16, incompetent adults)?

Yes_____ (If **yes**, please elaborate below.) No_____

(3) Is deception involved?

Yes_____ No_____
(If **yes**, please elaborate below. Please comment on debriefing, if applicable.)

(4) Will individuals remain anonymous?

Yes_____ No_____
(If **no**, please elaborate below. Please note that it is expected that participants remain anonymous unless they have given their prior written consent.)

(5) Will the data be kept confidential?

Yes_____ No_____
(If **no**, please elaborate below. Please note that it is expected that the data will be kept confidential unless the participants have given their prior written consent. Please also note that if you advise participants that the data will be confidential, you should state that confidentiality will be ensured, within the limits of the law.)

(6) How will informed consent be obtained? (Check one)

_____ Written Informed Consent Document **(Attach copy)**

_____ Oral Informed Consent Document (Permissible only in extenuating circumstances, where written communication is not feasible; **script of oral informed consent must be provided**)

NOTE:	The **Form TD3 in this package** provides a checklist for the content of the Informed Consent Document.

STUDENT DECLARATION

I hereby certify that all information on this form and all statements in the attached documentation are correct and complete. I understand that all human participants in the research must have signed a written consent form or have provided oral consent for their participation in the research. I understand that should there be any change in the research methodology or any increased anticipated risks to human participants, I will advise the Faculty of Graduate Studies; if these changes are not minor, my research proposal may be required to undergo a further ethics review. I understand that any misrepresentation in the proposal or attached documentation may lead to a charge of breach of academic honesty. I also understand that I must retain Consent Forms for two years following the completion of the research.

_____ _____

Student's Signature Date

SUPERVISOR DECLARATION

I hereby certify that all information on this form and all statements in the attached documentation are correct and complete. I have advised the student that, as specified in Item 6 above and in attached documentation, all human participants in the research must have signed a written consent form or have provided oral consent for their participation in the research. I have advised the student that the Faculty of Graduate Studies will be advised of any changes in research methodology or any increased anticipated risks to human participants and that a further ethics review may be required as a result of such changes. I have advised the student that Consent Forms must be retained for two years following the completion of the research.

☐ **Course work or MRP only; A TCPS tutorial certificate dated within the past 2 years is in the student's file.**

_____ _____

Signature of supervisor (of Thesis, Dissertation, or MRP) or Course Director

Date

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 Health Graduate Program Office 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 proposal has been reviewed and approved by the Health Graduate Program's Ethics Review Committee in compliance with the standards of the Canadian Tri-Council Research Ethics guidelines?
		----	Have you provided contact information for participants should they have questions (including a contact phone number and email address for *your Principal Supervisor and Graduate Program Office*)?
		----	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)**

Ethics Committee Member's Approval: _____

Ethics Committee Member's Approval _____

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 the Ethics Review Committee of Health Graduate Program 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 the Health Graduate Program Office (Tel: 416-736-2100 extension 44494; Email: gradcds@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	