HUMBER
Research Ethics Board

Consent Form Guidelines

For consent to be considered valid, it must be ***informed*** consent. Respect for Persons implies the participant must be given an adequate explanation about the nature of the proposed investigation, its anticipated outcome, as well as the significant risks involved. For informed consent to be valid the person concerned must be competent to make a decision, and the consent must be voluntary. For those who lack the capacity to decide for themselves, an authorized third party acting on behalf of the individual's behalf may decide whether participation is appropriate.

Informed consent is an on-going process that starts with the researcher's first contact with a participant and continues until the study is complete or the participant withdraws. Any discussion of informed consent with the participant, the written informed consent form, and any other written information given to participants should provide adequate information for the participant to make an informed decision about his/her participation.

The obligation to obtain informed consent always rests with the primary investigator conducting the research. This duty may be delegated as needed (to research assistants, students, etc.), assuming those individuals have the knowledge to be able to provide adequate explanations to potential participants on behalf of the Principal Investigator. The Principal Investigator must ensure that consent is not obtained in a manner where undue influence, coercion, of incentives for participation undermine the voluntariness of a participants' consent to participate.

Consent forms should be written on official letterhead in a direct style, using terms and language that potential participants can easily understand. Consent forms should be dated and signed, and the participant should receive a copy of the consent form for his or her own reference.

Consent can be withdrawn at any time, and the participant can request withdrawal of their data. Participants should be made aware if there is a specific point in the study at which their data cannot be withdrawn, and why (ex. Data has been anonymized).

A comprehensive Consent Form should include:

- Title of research project
- The name of the researcher(s)
- A statement regarding the participant's right to refuse to participate/withdraw from the study at any time without penalty
- Verification that the participant has received and read the provided information letter
- Contact information for the researcher(s) conducting the research
- Contact information for the Research Ethics Board (Dr. Lydia Boyko, Lydia.boyko@humber.ca, 416-675-6622 ext. 79322)

For more information about informed consent, including obtaining consent from minors, see Chapter 3: The Consent Process of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2).*

A consent form template is included below and must accompany a detailed Information Letter. The below makes the assumption that at the necessary details of the study and participation are included in the Information Letter.

Template

[Place on Humber Letterhead]

[Contact information for Principal Investigator (Name, telephone number, e-mail)

[Date]

[Project Title]

[Document Title] Consent Form

I, (please print) _____, have carefully read and understood the Information Letter for the project [insert project title], led by [Principle Investigator name]. A member of the research team has explained the project to me and has answered all of my questions. I understand that if I have additional questions about the project, I can contact [Principle Investigator name] at any time during the project.

I understand that my participation is voluntary and give my consent freely. I also understand that I may decline or withdraw from participation at any time, without any penalty or any explanation.

In understand that I can verify the ethical approval of this study, or raise any concerns I may have by contacting the Humber Research Ethics Board (Dr. Lydia Boyko, REB Chair, 416-675-6622 ext. 79322, lydia.boyko@humber.ca), or [Principle Investigator name and contact information].

[Note: If participant has the option of participating in one, or more than one, activities in the research project, the Consent Form should list them clearly. Each activity should have a Yes/No option so that the participant knows they have a choice in which activity they are consenting to participate in.]

My signature below verifies that I have received a copy of the Information Letter, and that I consent to participate in this study:

_____	_____	_____
Participant's Name (printed)	Participant's Signature	Date