CONSENT

1.0 TCPS2 (2018) describes the consent process as one in which the researcher demonstrates respect for study participants by ensuring that individuals' rights are protected and they are able to make a free and informed decision to participate in research.

1.1 Researchers are expected to respect the dignity and autonomy of individuals, seek voluntary participation of individuals, and not apply undue influence or pressure in securing consent.

1.2 Informed consent requires "full disclosure of information necessary for making an informed decision to participate in a research project" (Article 3.2).

1.3 Although it is sometimes thought that consent is limited to the beginning of the research, the TCPS2 refers to the consent process as ongoing throughout the research. This means that researchers are obliged to maintain open and ongoing disclosure of information to participants so that their consent to participate remains free and informed.

1.4 Article 3.1 states that an individual's consent can be withdrawn at any time; and if a participant withdraws consent, the participant can also request the withdrawal of their data."

A checklist on the necessary components of a consent form is included at the end of this document.

2.0 The Process for Obtaining Consent

2.1 Informed consent must be obtained from the participant or, if the participant is not able to give consent, from the participant's legally acceptable representative (e.g., a parent, guardian or designated other) prior to involvement in any research-related activity. Normally, written evidence of informed consent should be obtained. If a written consent is not possible, the researcher may use an alternative method to document consent, and the reasons for using a modified method of obtaining must be explained in the application to the UHREB.

2.2 Someone trained and knowledgeable in all aspects of the study and the informed consent procedures should be responsible for

the forefront the best interests of the potential participant.

6.0 Research with Non-English Speaking Participants

The researcher must ensure that non-English speaking participants are provided with a consent form and associated study documents in the most appropriate language or that an appropriate translator is present during the informed consent process.

7.0 Implied or *de facto* Consent

Especially in survey research (conducted on paper or online), the researcher is still obligated to obtain participants' consent. Typically, this is accomplished by providing an information page containing the various elements of consent outlined earlier in this document. The researcher would then include wording such as the following: "By returning or submitting this survey, it will be understood that you have consented to participate."

8.0 When a Waiver of Consent is Necessary

Sometimes, it may be impractical or impossible to obtain written consent. For example, in some observational studies, the consent process may need to be modified or waived altogether. Whenever, the researcher deems that a waiver of the consent process is indicated, the reasons for waiving consent must be fully explained and justified in the application to the UHREB. A request for a waiver of consent should include the following information:

- why such a waiver is necessary for the conduct of the research;
- how the requirement to obtain consent would constitute an unreasonable barrier;
- that the research presents no risks to the participants; and
- that the participants will not be identifiable from the data collected.

9.0 Consent Form Examples

See the Consent Templates and Examples section of the Resources page of the Human Ethics website.

INFORMED CONSENT CHECKLIST

This checklist has been developed to assist researchers in preparing an Informed Consent document. It itemizes the form and content that should be included, although Consent documents may vary depending on the nature of the research and involvement of participants.

GENERAL REQUIREMENTS

- The consent form is on letterhead of The University of Winnipeg.
- The first page of the consent document includes the full title of the study and the name of the Principal Investigator and Co-Investigators.
- The pages are numbered sequentially in a footer

CONSENT AND SIGNATURE

- This section should be written in the first person singular (I/me/my).
- Include a statement that by consenting to participate, the individual

  has read the study information and understands the purpose of the research, the nature of their participation, any risks and the anticipated benefits of participation;
  has read the consent form; and
  agrees to participate.

- A place on each page (usually in a footer) where the individual initials the document (this would indicate that the page has been read).
- A signature block that includes the participant's name (printed), signature, and the date.
- A signature block for the person obtaining the consent that includes the name (printed), signature, and the date.
- If relevant, place for the inclusion of a legally authorized representative's name and signature, or a translator's or a witness's name and signature.

OTHER

- The individual is provided a copy of the consent form.

This checklist is adapted from a checklist developed by the Ontario Shores Research Ethics Board.