THE UNIVERSITY OF WINNIPEG

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1.4 Article 3.1 states that an individual's consent can be withdrawn at any time; and if a participant withdraws consent, the participant can also request the withdrawal of their data."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 securing consent from prospective study participants. The consent process begins with the first contact with prospective study participants and it continues throughout the study.

2.3 In order to secure free and informed consent, the study should be explained in language that can be understood by the prospective participant and/or the legally authorized representative. Prior to giving consent to participate in a study, prospective participants and/or their legally authorized representative should understand:

- the purpose of the research;
- the nature and duration of their participation;
- the risks, if any, of participation;
- the benefits of participation;
- any compensation that the researcher is providing to study participants;
- information on withdrawal from the study;
- how study participants' information will be protected (i.e., confidentiality and anonymity of information);

- how participants can obtain information on the study findings;
- plans for debriefing study participants at the conclusion of the research; and
- the names and contact information of the researcher, and the contact information for the representative of the ethics committee responsible for review (either the ethics officer for UHREB or the Departmental Ethics Committee Chair).

2.4 Individuals should also have an opportunity to ask questions about the study prior to giving consent.

2.5 To obtain written evidence of consent:

- each page of the consent form should be initialed by the participant or the legally acceptable representative;
- the final page of the consent form should summarize important aspects of consent and should be signed and dated by the participant and/or the legally acceptable representative;
- where relevant, a witness or translator is required to sign and date the consent form if the witness or translator has been involved in the informed consent process; and
- the person obtaining consent (the researcher or research staff) must sign and date the form.

2.6 Participants should be provided with a copy of the signed consent form at the time of signing, or alternatively, an information document that outlines the purpose of the research, the nature and scope of the individual's participation, as well as contact details for the researcher conducting the study. A copy of the signed consent form must be provided if requested by the participant.

3.0 When Written Consent is Not Feasible

There are circumstances in which a researcher may need to modify the process for obtaining consent. In all such cases, "it is the responsibility of researchers to justify the need for any alteration to consent requirements to the satisfaction of their REBs" (Article 3.7A).

4.0 Research Involving Children

TCPS 2 (2018) does not identify a specific age when children may be able to provide their consent to participate in research, but the determination of their ability to consent rests on whether they have the capacity to understand the significance of the research and the implications of the risks and benefits to themselves. For more guidance see: https://ethics.gc.ca/eng/policy-politique_interpretations_consent-consentement.html. If the researcher determines consent from a legal guardian is required, the assent of the child should also be sought if possible. The requirements to explain fully the purpose of the research, the nature of the participant's involvement, the risks and benefits of the research are still necessary, and all of this information needs to be communicated in language that can be fully understood by children invited to participate in the research. (A formal script for securing assent verbally should be included in the application to the UHREB if signed assent is not practicable.)

5.0 Research Involving Individuals with Diminished Capacity

When conducting research involving individuals with diminished capacity, the researcher is obliged to ensure that those individuals are able to provide their assent to the fullest extent possible. Legally authorized representatives must participate in the consent process, keeping at

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.

THE UNIVERSITY OF WINNIPEG

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 (page x of y).
- □ The text of the consent form should be written in plain language (aiming for a grade 6 reading level), and avoid jargon, acronyms, and abbreviations.
- □ The text should be written in "the second person" (you/your), except in the signature section where the text should be written in "the first person" (I/me/my).

ABOUT THE RESEARCH

- □ A statement regarding the purpose of the study.
- □ A statement on why individuals are being invited to participate in the study, and how many people are expected to be included in the study.
- □ A description of the study methods and how they relate to the participants (e.g., how many interviews or surveys will be conducted, what observations will be made, etc.)
- □ A statement of the study's duration and how much time that participants can expect to commit to the study.
- □ A statement of any risks associated with the research and steps that are being taken to minimize the risks.
- □ A statement of any benefits associated with participation in the research.

ABOUT STUDY PARTICIPANTS' RIGHTS

- □ A statement that participation is voluntary, and that participants may withdraw from the research at any time without any negative consequences.
- □ A statement regarding if the researcher is providing any honorarium (if relevant) and reimbursement of costs of participation (e.g., parking, public transit), as well as how these forms of compensation are affected by a participant's withdrawal.
- □ A statement regarding what happens to data that has already been collected if an individual withdraws from the study. (Participants should be informed that they may request that data already collected not be used.)

- □ A statement indicating if and how participants can review data collected about them.

ABOUT CONFIDENTIALITY AND ANONYMITY

- □ Indicate how participants' information will be protected. This includes indicating who will have access to the data collected, how information will be stored, and for how long.
- □ Explain how information will be kept confidential to the extent permitted by law.
- □ If research involves the use of audiotaping, videotaping, and/or photography, outline who will have access to the tapes or photographs.
- □ If data is to be anonymized, how will this be done? For example, will results be aggregated?

ABOUT ANY RESEARCHER CONFLICTS OF INTEREST

- □ If a researcher has any conflict of interest, this must be disclosed. The researcher should also indicate how the conflict of interest is being mitigated.

ABOUT FUTURE USE OF DATA

- □ Researchers must inform participants about subsequent uses of data, including any plan to deposit research data in an appropriate repository, the scope of potential future use, as well as any specific limitations (for example, consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry"). For more specific guidance see: https://ethics.gc.ca/eng/depositing_depots.html

ABOUT FUTURE CONTACT BY THE RESEARCHER

- □ If the researcher anticipates that there may be subsequent stages of the research that would necessitate re-contacting participants, this should be indicated on the consent form with the possibility to opt-in or opt-out of future studies.

ABOUT REPORTING THE RESULTS OF THE RESEARCH

- □ Explain how and where the research will be disseminated (i.e., conference presentations, journal publications, plain language documents available in the community, websites, etc.).
- □ State when the results are likely to be available, and how participants can obtain information on the study results (e.g., access on a dedicated website, brochures that will be distributed, etc.).

CONTACT INFORMATION IN THE EVENT OF QUESTIONS OR CONCERNS

- □ Information on who individuals can contact (with contact details) if they have any concerns about the research (usually the Principal Investigator and the Ethics Officer of UHREB). In the case of student researchers, it should be clear that the Principal Investigator is a student. The student's supervisor should also be listed. In the case of Course-Based research or Independent Senior Undergraduate Student Research the Departmental Ethics Committee Chair should be listed as the contact.

THE UNIVERSITY OF WINNIPEG

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.