THE UNIVERSITY OF WINNIPEG | Vice-President, Research and Innovation

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. All of these requirements are outlined in TCPS2 Chapter 3, Article 3.13.

This checklist is adapted from a checklist developed by the Ontario Shores Research Ethics Board, which can be found here.

General Requirements

- ☐ The consent form is on letterhead of The University of Winnipeg. (UWinnipeg Logos can be found here: https://www.uwinnipeg.ca/branding/logos.html
- ☐ 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, 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).

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 participants will be expected to commit to the study.
- ☐ A statement of any risks associated with the research, and any steps that are being taken to minimize the risks.
- ☐ A statement of any benefits associated with participation in the research.

Study Participant's 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.

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?

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.

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

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.

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 – ethics@uwinnipeg.ca). 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.

Consent Signature

- [ ] This section should be written in the first person singular (I/me/my).

- [ ] Include a statement that by consenting to participate, the individual:
    1. 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;
    2. has read the consent form; and
    3. 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.