Consent Form Template – Fort Garry

Sample Consent Form to be on Institutional Letterhead

(Please contact your faculty/department for a digital or hard copy of letterhead)

Note: Bolded sections normally must be included verbatim on the consent form.

Research Project Title: _____

Principal Investigator, academic rank, and contact information: _____

Research Supervisor (if applicable), academic rank, and contact information: _____

Sponsor (if applicable): _____

---------- Include the Following Verbatim:----------

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

----------Researcher to Supply the Following:----------

The researcher(s) should supply the following information in ordinary language, avoiding jargon and explaining crucial terms. This is a sample consent form so, if any item is not applicable, it need not be included:

1. A brief description of the purpose of the research.

2. A description of the procedures involving the participant, including their nature, frequency, duration, and the total time involved.

3. A description of any recording devices to be used.

4. A description of the benefits, if any, directly to the participant.

5. A description of the potential risk, if any, to the participant. If the risk of harm is more than minimal, (i.e., harm greater than that which one might experience in the normal conduct of one's everyday life), an explanation of how participants who actually experience harm will be helped. If appropriate, a list of helping resources should be provided.

6. An indication of whether the data will be anonymous (contain no personal identifiers) or confidential (contain personal identifiers). If the latter, a description is required of the steps the researcher will take to protect the confidentiality of participants. Explain who will have

access to information collected, as well as specifically where and how it will be stored. If neither anonymity nor confidentiality can be guaranteed, participants should be made aware of possible consequences.

7. A description of any form of credit or remuneration for participating, including when and how it will be provided.

8. A description of how the participant may withdraw from the research, without negative consequences.

9. A description of the debriefing, if any, that will be provided to the participant immediately after data collection. Such debriefing is normally required.

10. A description of how and to whom research results will be disseminated.

11. A description of how and approximately when (MMYY) a brief (1-3 pages) summary of results will be provided to the participant. Normally, participants should be given a choice of mechanisms (e.g., mail, email) in which to receive a summary.

12. A description of how and approximately when (MMYY) confidential data (if any) will be destroyed. Anonymous data may be kept indefinitely.

---------- Include the Following Verbatim:----------

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time, and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

The University of Manitoba may look at your research records to see that the research is being done in a safe and proper way.

This research has been approved by the Research Ethics Board at the University of Manitoba, Fort Garry campus. If you have any concerns or complaints about this project, you may contact any of the above-named persons or the Human Ethics Officer at 204-474-7122 or HumanEthics@umanitoba.ca. **A copy of this consent form has been given to you to keep for your records and reference.**

---------- Provide for Signatures as Required: ----------

Participant's Signature: _____ Date: _____

Researcher and/or Delegate's Signature: _____ Date: _____

Updated: June 29, 2023

For studies involving health research, the following addition is suggested:

Medical / research records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba (PHIA). All records will be kept in a locked secure area and only those persons identified as requiring access to your records will have opportunity to review or copy your medical / research records.

Certain authorized organizations may inspect and/or copy your medical / research records for quality assurance and data analysis purposes. These organizations may include representatives of the study sponsor or funding agencies, any national or international (foreign) regulatory agencies who may have oversight responsibilities for the study, The Health Products and Food Branch Inspectorate / Health Canada, the National Cancer Institute, or the Food and Drug Administration (FDA) of the United States.

The University of Manitoba may look at the research records to see that the research is being done in a safe and proper way.

If any of your medical / research records need to be copied and provided to any such organization, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the institution. You have a right to review your medical records and to request corrections to your personal information.

Specific to Health Canada regulations:

Clinical trial research records are to be securely retained for 25 years. It is important to note that even upon withdrawal from a clinical trial, information obtained during your participation in the study will be maintained (not destroyed) as per applicable regulations or guidelines governing the study.

[If necessary:] please specify who will be accessing records containing personal health information and which records (i.e. medical records, if so, at which site; research study records, physician's office records, etc.) so that the individuals participating in the research are informed as to specifically who may be accessing any of their personal health information].[If applicable:] Indicate what data will be entered into the computer and transmitted electronically. Specify the agencies that will receive this electronic data and how the identifying information will be kept confidential.

By signing this consent form, you agree to the described collection, review, use and storage of your medical / research records.

In Studies Involving Vulnerable Populations:

For research with persons who are unable to give valid, informed consent for reasons of age, disability, or other vulnerability, the signed informed consent of a substitute decision-maker should be obtained. The consent form should indicate the legal relationship by which power to consent has been delegated. In addition, the researcher shall, as much as possible, explain to such prospective subjects the research and involvement being requested, and seek their cooperation (i.e., assent) both at the outset of and throughout the project. The researcher should also remain vigilant and be prepared to discontinue the research immediately if there are any indications that continued participation is becoming distressing and/or harmful to such persons.