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INFORMED CONSENT GUIDELINES AND TEMPLATE

Legend
Blue Text – Instructions
Black Text – Required Language
Green Text – Sample Wording and/or Examples
Red Text – Language that should not be used

Participant consent must be:

- **voluntarily given;**
- **free from undue influence or coercion;**
- **fully informed with sufficient time for potential participants to consider whether they want to participate and to ask any questions they may have; and**
- **ongoing.**

The Informed Consent Form (ICF) is one part of the overall consent process. It is the responsibility of the researcher to ensure that participants are fully informed and consent throughout the project.

Please note that a well-presented ICF that is in accordance with TCPS2 (2022) standards will facilitate the Research Ethics Board approval process. Please adhere to the following formatting requirements:

1. Spelling, grammar, and formatting must be error free before it is submitted for review.
2. Consent forms should be written at a Grade 6 level of understanding. Use a readability index, such as www.hemingwayapp.com, to confirm the level.
3. If you are using any technical words or jargon, provide a lay definition in brackets beside the technical language. Use non-scientific terminology. Do not include emojis.
4. Avoid unnecessary repetition in the document.
5. The ICF must be written in the second person – 'you will be asked to…'. Use first person pronoun ('I') for only the signature portion of the form.
6. To ensure that the document is easy to read, use at least 12-point font Arial (or a similar font in sans serif). Consider the target audience. Some participant populations may require a larger size font.
7. Avoid relying on acronyms. If they must be used, write out all acronyms in full the first time they appear.
8. Those participating in a research study should always be identified as 'participants' and never as 'subjects'.

9. Use consistent language throughout (e.g. 'Principal Investigator', or 'Lead Researcher', or 'Researcher'; 'research team', 'team members', 'lab members' 'study team'; 'study' or 'project' or 'research project').
10. ICFs must be created/printed on institutional letterhead.
11. All ICFs must include a footer with the version date (dd/mm/yyyy) and page numbers (page x of y").
12. Avoid asking for unnecessary participant identifiers in the ICF. Only the participant's name and signature should appear. If additional identifiers are required, this must be fully justified in the protocol submission and approved by the REB.
13. Headings, small paragraphs, and spaces between the paragraphs are encouraged for easier reading.

NOTE: If any changes to this document are required, you **MUST** seek approval from the REB before implementing those changes.

On Institutional Letterhead

Participant Informed Consent Form

Study Title: Include the title of the study. This should be the same as the Protocol Title listed in RAS.

Principal Investigator: Include name, academic title, department (if applicable), college/faculty, contact information. Note: If the PI is a student, delete this heading and use the Student Principal Investigator title below.

Co-Investigators: (if applicable and where listed in the research personnel table in the protocol). Include name, academic title, department (if applicable), college/faculty, contact information. All co-Investigators must be listed.

Student Principal Investigator (where student is PI for their own project)**:** Include name, level of degree (e.g., Master's Student, PhD Student), department (if applicable), college/faculty, contact information

Student Advisor (where Student Principal Investigator is completed above)**:** Include name, academic title, department, (if applicable), college/faculty, contact information

Funder (or Sponsor if applicable): If the project is funded, identify the name of funding source(s). Do not include fund numbers.

Conflicts of Interest and Undue Influence: if applicable. This section should describe:

- Any real or perceived conflicts of interest as it/they relate to any of the researchers or study staff.
- Any apparent undue influence where prospective participants are recruited by researchers who are in a position of authority. Mitigation strategies/safeguards must be

explained to potential participants.

- Conflicts of interest occur where the researcher could have conflicted motivations. A conflict of interest exists if there is a potential benefit to the researcher(s), or study staff beyond the professional benefit from academic achievement or presentation of results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights.
- A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.

[Name of researcher] is receiving personal financial payment from [source] for [reason for payment]

Or

[Name of researcher] does not have/none of the researchers have any conflicts of interest in this study/research.

[Name of researcher] may have a relationship to you as your [teacher/doctor/supervisor, etc.]. To help prevent this relationship from affecting your decision to participate, the following steps have been taken [include safeguards].

This consent form, [a copy of which has been given to you] or [a copy of which you can download or print], is only part of the process of informed consent. If you want more details about something mentioned here, or information not included here, feel free to ask any of the people named above. Please take the time to read this document and any accompanying information carefully. It is very important that you understand:

- what is being asked of you,
- what the risks and benefits of participation are, and
- how the information you provide will be used and stored.

Purpose of the Study: Describe in non-technical (lay) terms the purpose and objective(s) of the research. Avoid jargon and theoretical concepts that your participants are unlikely to be familiar with. This section should not be more than a few sentences long. Do not copy and paste from your research proposal.

You are invited to participate in this research study about…. I/We are hoping to learn about…

For student research: I am doing this research for a course/thesis/dissertation/project under the supervision of [Supervisor's name]. This research study is about… We are hoping to learn about…

Study Procedures: Set out the details of data collection activities that participants will be involved in and the estimated duration of each activity, so participants understand what they are being asked to do and the time commitment required of them.

- Describe any equipment that may be used to collect/record data (e.g. audio/video recorder, camera, exercise equipment, technical equipment).
- Describe the location(s) of the research activities. Videoconference platforms should be specified.

- If applicable, describe any member checking activity, such as a transcript review, as part of your procedure. Be sure to include a deadline and instructions for the return of participant comments/revisions and a description of what will happen if the deadline is missed.

Example - Interviews: If you decide to take part in the study, we will meet for a 1- 1.5 hour interview through UM Zoom. With your consent, I will audio and video record our meeting. After your interview, you will have the chance to review the transcript (the document of what you said). You can add, change, or delete information from the transcript as you see fit. I will email you a copy of the transcript and you will have 2 weeks to respond. If I don't hear from you after 2 weeks, I will assume that you are okay with the transcript as is.

Example - Intervention: If you decide to take part in the study, we will meet 3 times for 1 hour each over a six-week period at the Active Living Center at the University of Manitoba, Fort Garry Campus. Meeting 1 will consist of …… Meeting 2 will consist of….etc.

Study Risks: Describe any foreseeable risks, discomforts, and/or side effects from the study participation. Risks might include anxiety, guilt, sadness, anger, physical discomfort, injury, etc. Describe the strategies you will use to minimize or manage these risks for participants. If potential risks or discomforts are anticipated or the research project is of a sensitive nature, include information on the arrangements/availability of counselling, support, healing, medical assistance, or other such services. If the research has the potential to reveal information that is required by law to be communicated to a law enforcement, other agency, or the courts (e.g. child or elder abuse, a subpoena issued by a court), inform participants of your legal obligations in this section.

A potential risk is that you may feel badly, as people sometimes do when they talk about …. If you feel sad or depressed, you can call ….. to talk to someone.

This survey is minimal risk, meaning that the risks are no greater than what you might encounter in your daily life.

A potential risk is injury when exercising. We will follow our first aid procedures….

Study Benefits: State the benefits of this research, stressing that these benefits are not guaranteed. Include benefits that are both broader/societal and personal (where appropriate).

There are no direct benefits to you by participating in this study, but you will learn about study in … at the University of Manitoba.

There are no direct benefits to you by participating in this study, but we hope to learn more about [this issue] so we can develop… in the future/so that we can better understand … FF

Compensation: Describe any compensation that will be offered to participants. Compensation includes honorariums for participation (e.g. cash, gift card, pre-paid cards), gifts, reimbursements for participation (e.g. parking, bus tickets, babysitting). Describe how and when you will deliver the compensation to the participant. If course credit is available to university students, explain the process.

Include the following verbatim if you will be providing honorariums:

We may collect additional personal information from you to record giving you an honorarium. [If you will receive more than $250 over the course of the study, we will ask for your social insurance number to send you a tax receipt]. The researchers will keep this information separate from any research information. This information will be kept in a secure location for 7 years in case the University of Manitoba has to account for the money during a financial audit.

Storage and Use of Data:

Describe:

- Where, how, and for how long the various forms of data will be stored
- who will have access
- how the data will be reported at the end of the study.

This information should be consistent with the data storage plan in your protocol submission.

For confidential/anonymous data: All the information you provide as part of this study is confidential. This means that only members of the research team will see your information. For safety, your information will be kept on a UM-approved secure platform.

Example - For anonymous data: Any information you share will not identify you. This means the only people who will know you participated are members of research team. When we share the results of this study, we will combine everybody's responses. This means other people won't see your answers. We may keep your information indefinitely.

At the end of this document, you will have a chance to tell us whether you will allow your information to be sent outside of the University of Manitoba. Your information may be [sent to other researchers; sent to other organizations; made publicly available]. The information is being shared [for further analysis or testing; as part of the research study; because it is required by a funder or journal].

Example - For anonymous data with compensation: Any research information will be collected through a different link than your compensation information. We will not be able to link the personal information you share with us for compensation with the research information you shared. We may keep your research information indefinitely. Only people on the research team will see your personal information. We will destroy any information that identifies you (name, email address) by MMYY.

At the end of this document, you will have a chance to tell us whether you will allow your information to be sent outside of the University of Manitoba. Your information may be [sent to other researchers; sent to other organizations; made publicly available]. The information is being shared [for further analysis or testing; as part of the research study; because it is required by a funder or journal].

Example - For coded data: We will have a file that links your name to your information using a code. We will keep the file with your name, contact information, and code separate from the research information you share with us. When we share the results of this study, we will

combine everybody's responses. This means no one will see your answers, name, or contact information.

Only people on the research team will see your contact information and/or responses. We will destroy any information that identifies you (name, email address) by MMYY. The rest of the information may be kept indefinitely.

At the end of this document, you will have a chance to tell us whether you will allow your information to be sent outside of the University of Manitoba. Your information may be [sent to other researchers; sent to other organizations; made publicly available]. The information is being shared [for further analysis or testing; as part of the research study; because it is required by a funder or journal]. It will not include your name or any information that could identify you.

Where participants choose to waive confidentiality: All the information you provide as part of this study is confidential unless you choose to identify yourself and the information you share. For safety, your information will still be kept on a UM-approved secure platform.

Example - For coded data when waiving confidentiality: We will have a file that links your name to your information using a code. We will keep the file with your name, contact information, and code separate from the research information you share with us. When we share the results of this study, we will combine everybody's responses. This means no one will see your answers, name, or contact information.

At the end of this document, you will have a chance to tell us whether you would like your real name to be used when we share the study results. We will not use your name or contact information when we share the study results unless you say it is okay. If you do not agree, we will destroy any information that identifies you (name, email address) by MMYY. The rest of the information may be kept indefinitely.

At the end of this document, you will have a chance to tell us whether you will allow your information to be sent outside of the University of Manitoba. Your information may be [sent to other researchers; sent to other organizations; made publicly available]. The information is being shared [for further analysis or testing; as part of the research study; because it is required by a funder or journal]. It will not include your name or any information that could identify you unless you agree.

We will do our best to keep your personal information safe. However, it is not possible to guarantee confidentiality. We will only share your personal information if the law requires us to.

Describe how the data will be used (e.g., thesis, articles, report to an agency or community). If direct quotations will be reported, or if personally identifying information will be included in the report, this needs to be clearly stated; if the data will be reported anonymously in an aggregated or summarized form, this should also be stated.

The study results will be shared through 1) the publication of a master's thesis; 2) journal publications and presentations in relevant academic fields; and 3) a summarized report of the study results to be sent to interested participants.

Withdrawing: Describe when and how participants may withdraw from the study and describe what will happen to their data (e.g., data will be deleted from the research study and destroyed). Include who they should contact to withdraw and a withdrawal date if/as appropriate. If there is a point at which they can no longer withdraw, describe whether and how their data might be used and what will happen to it.

Example – For studies where participants **can** withdraw: Your participation in this research study is voluntary. You can choose to do only the activities and/or answer only the questions that you are comfortable with. You may withdraw from the study for any reason. You do not have to explain why. You will not be penalized in any way. You may withdraw from the study until MMYY. Should you withdraw, all gathered responses will be destroyed. After this date, we will start to analyze the information so it may not be possible to withdraw your information. To withdraw, please contact [insert team member] at the phone number or email above.

Example – For studies where participants **cannot** withdraw: Your participation in this research study is voluntary. You can choose to do only the activities and/or answer only the questions that you are comfortable with. You may withdraw from the study for any reason up until you submit your responses. You can do this by exiting the browser. You do not have to explain why. You will not be penalized in any way. Should you withdraw, all of your responses will be destroyed. Due to the nature of the study, once you submit your responses, we will not be able to remove your information as it cannot be linked back to you.

Example – For studies where participants **cannot** withdraw but have compensation: Your participation in this research study is voluntary. You can choose to do only the activities and/or answer only the questions that you are comfortable with. You may withdraw from the study for any reason. You do not have to explain why. You will not be penalized in any way. However, to receive your honorarium you must click through to the end of the study. Due to the nature of the study, once you submit your responses, we will not be able to remove your information.

Questions or Concerns: A designated University of Manitoba auditor may check that this study is being done safely and properly. To do this, they may visit the study site or review the research records. We will tell you if someone outside the research team will be there while you are participating. If this makes you uncomfortable, please tell the Principal Investigator, who will ask the auditor to return at another time.

This study has been reviewed and approved by the [insert full name of appropriate REB]. However, this does not mean that participation is risk-free. If you have any questions, concerns, or complaints about this study, you may contact any members of the research team listed on the first page or the Office of Human Research Ethics at humanethics@umanitoba.ca or (204) 474-7122.

Consent:

By signing this document, I have read the above information and have had the opportunity to ask and have answered any questions I may have.

I understand that:

- I will be taking part in a research study.
- I may freely leave the research study activities at any time.
- I do not waive my legal rights by participating in the study.

Please review the following statements. For each statement, please check if you agree or do not agree.

I agree to participate in this study.	☐**YES** ☐ **NO**

I agree to be audio-recorded in this study.	☐**YES** ☐ **NO**
I agree to be video-recorded in this study.	☐**YES** ☐ **NO**

I agree to have (check one):

☐ a general descriptor used instead of my name when results are shared for this study.
☐ my first name used when the results are shared for this study.
☐ my full name used when the results are shared for this study.
☐ a pseudonym (fake name) used when the results are shared for this study.

I would like my pseudonym to be _____

I agree that the information I provided to the research team can be used for future research purposes by members of this study's research team and/or their students.	☐**YES** ☐ **NO**
I agree that the information I provided to the research team can be sent to or used by other researchers, funders, research or community organizations, journals, or other third parties for any future research purposes **only if anonymized**.	☐**YES** ☐ **NO**

I agree to be contacted by a member of this research team for future phases related to this research study. If yes, please provide an email address: _____ *By agreeing to be contacted, you are not required to participate in any future phases. If you wish to withdraw your name from this list, please contact [insert].*	☐**YES** ☐ **NO**

If I choose to withdraw partway through the study, I agree that the research team may still include the responses I have completed in their analysis.	☐YES ☐ NO

I agree that the research team can use photos and videos I have produced for this study when they share the study results.	☐YES ☐ NO

Name of Participant	Participant's Signature	Date

For oral consent:

I read and explained all of the information in this consent form to the participant before receiving the participant's consent, and the participant had knowledge of its contents and appeared to understand it.

Name of Participant	Researcher's Signature	Date

Summary of Results: Describe how people can receive a summary of results or their individual results. Formats may be mail, email, website etc…

Please provide an email address below if you would like to be sent a summary of the study results and/or my individual results.

Email address: _____

A summary of the study will be available on our website…. when the study has finished.

Notice Regarding Collection, Use, and Disclosure of Personal Information

Your personal information is being collected under the authority of *The University of Manitoba Act*. The University of Manitoba is committed to preserving your right to privacy. The information you provide will be used by the University to support our research. Your personal information will not be used or disclosed for other purposes, unless permitted by *The Freedom of Information and Protection of Privacy Act* or *The Personal Health Information Act*. If you have any questions about the collection of personal information: Ph: 204-474-9462 or Email: fippa@umanitoba.ca