University of Manitoba | Research Ethics and Compliance

Human Research Ethics - Fort Garry
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Informed Consent Guidelines and Template

For Permission to Contact for Future Studies

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.

Note that a well-presented ICF that is in accordance with TCPS2 (2022) standards will facilitate the Research Ethics Board approval process. Adhere to the following general 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. Small paragraphs, and spaces between the paragraphs are encouraged for easier reading.
14. Headings are preferred.

NOTE: If any changes to your **approved** consent form (s) 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 database or repository. 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.

Co-Investigators (if applicable and as 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.**

You are being asked for permission to be contacted in the future for participation in research studies undertaken by [name of the researcher and/or lab]. 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.

Research in the [name of the lab(s)/group(s)/Centre]

Provide a general description of the type of research or studies typically undertaken in the lab/in your research program.

To help us recruit people for these studies, we are asking for your permission to store your [indicate the data to be collected e.g. name, email address, other personal information] so that we can reach out to you about upcoming research studies. There will be no negative consequences if you choose not to be added to this database/repository. You may still participate in upcoming studies that you may hear about in other ways. If you would like to know more about our future research, you can find information on our website.

It is up to you to decide whether you wish to participate in any of the future studies you may be contacted about. There will be no negative consequences if you choose not to participate in any future study. A consent form similar to this one will be presented to you for each future study you decide to participate in.

Study Risks and Benefits

Provide a general description of risks and benefits to participating in this repository/database.

The risk of including your name in this data is minimal, meaning that the risks are no greater than what you might encounter in your daily life.

While there may be no benefit to you, your information will help researchers to quickly identify individuals who may wish to participate in a particular research study. You may benefit from participating in more studies and learning about research at the University of Manitoba.

Use and Storage of Information

All the personal information you provide to be stored in this database/repository is confidential which means we as the research team must keep it safe. We will do our best, however, it is not possible to guarantee absolute confidentiality.

Describe:

- Where, how, and for how long the various forms of data will be stored
- Who will have access and what type of data they will have access to. Include data that may be shared with people outside UM.
- If applicable, how and when the data will be destroyed (by MM/YY) (e.g. shredding paper copies, erasing electronic copies).

This information should be consistent with the data storage plan in your protocol submission and any agreements you may be required to enter into (e.g. service, data transfer).

Your information will be stored on a secure platform approved by the University of Manitoba. Only people on the research team/lab(s)/group(s)/Centre will see your information. Your information will be destroyed [add the circumstances, ex. after 5 years of not hearing from you, once you turn a specific age]. If you would like to make any changes to your contact information you can notify ….. at any time.

Withdrawing Describe when and how participants may withdraw their personal information from the database and describe what will happen to this information (e.g., it will be deleted from the database/repository and destroyed). Include who they should contact to withdraw and a withdrawal date if/as appropriate.

Your participation in this database/repository is voluntary. You may ask that your personal information be withdrawn from the database/repository for any reason. You do not have to explain why. You will not be penalized in any way. You can ask to withdraw by emailing or calling [insert team member and contact information].

Questions or Concerns

Designated University of Manitoba personnel may check that this information is being kept safely and securely. To do this, they may review the database/repository records.

This database/repository has been reviewed and approved by a Research Ethics Board at the University of Manitoba. However, this does not mean that participation is risk-free. If you have questions about your rights as a research participant, you may contact the Office of Human Research Ethics at humanethics@umanitoba.ca or (204) 474-7122.

If you have any questions, concerns, or complaints about this database/repository, you may contact any members of the research team listed on the first page or the Office of Human Research Ethics.

Consent

By signing this document, I agree that:

- I have read the above information or had it read to me.
- I have had the opportunity to ask and have answered all of my questions.
- I understand what is being asked of me.
- I will be giving permission to have my personal information entered into a database/repository and stored so that I may be contacted to participate in future studies.
- I may freely ask to have my personal information removed permanently from the database/repository at any time.
- I do not waive my legal rights by having my personal information stored in the database/repository.

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

I agree to have my personal information included in the database/repository.	☐**YES** ☐ **NO**

Name of Participant	Participant's Signature	Date