HREB Informed Consent Form Checklist

As noted in the TCPS2, "Respect for persons implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible" (p. 27). In line with this, research participants have the right to be treated with respect and dignity in every phase of the research and to be fully and clearly informed of all aspects of the research prior to becoming involved in a research project. Suggested wording is provided below to assist you in creating information/consent documents.

General Considerations for your Consent Form:

☐ The consent form is written in age appropriate language**.** Attention must be paid to the participants' level of education and/or fluency in English, or another language, in which the consent is written. Appropriate language and reading level needs to be considered when considering certain populations (e.g., children, the elderly, populations with compromised literacy, populations with unique cultural considerations, etc.). **HREB encourages researchers to assess readability of their consent form using WORD or** http://read-able.com/

☐ MUST be written in lay terms where appropriate (i.e., non-technical and jargon-free)

☐ Use the active voice whenever possible

☐ Use the first or second person where possible (e.g., *I* or *you* rather than *the subject* or *participants*)

☐ A statement that the study has received ethics clearance from HREB. The following statement can be used and is typically placed after the signature block at the end of the consent form: "The Human Research Ethics Board of Mount Royal University has approved this research study."

☐ A statement indicating that the participant is being provided with a copy of the consent form. The following statement can be used and is typically placed after the signature block at the end of the consent form: "A copy of this consent form has been provided to you for your records and reference." (Note: in some cases this is not required, e.g., an online study using implied consent).

The following headings map onto the blank consent template that is available on the HREB website. Under each heading below is information that must be included on consent forms as well as information that researchers should include if applicable to their specific project:

Project Title:

☐ A title that is descriptive of the project is provided is included.

Investigators:

☐ The name of the PI followed by co-investigators and affiliations (e.g.,MRU/U of Calgary and specify which Faculty/Department) are included.

Contact Information of Researchers:

☐ List PI's telephone, e-mail and address followed by all co-investigator's telephone, e-mail and address, if applicable. Note: List all researchers.

Sponsor:

☐Name all funders. (If you have no funders/or community sponsors remove this heading).

Summary of the Study:

☐The following statement must be included:
"You are being invited to participate in a research project, as described above and in this consent form. Please note this consent form serves to provide an overview of what the research in question is about and what your participation would entail; it is only one part of the consent process. Read this consent form carefully. You should understand the accompanying information. If you have any questions, please ask for help. You will receive a copy of this form."

Note: the above statement will need to be modified for studies proposing implied consent and in which a copy of the consent form is not provided to participants.

☐Clearly (in plain language appropriate to your audience) outline what this study proposes to do, its **purpose**, the goals of the study, how, where, when and why, including your eligibility criteria.

Participant's Involvement/ What would my involvement entail?

Outline specifically what the role of the participant will be; feel free to use bullet form or flow charts. The following information would normally be included and should be phrased in terms of a step-by-step description of the research as it will be experienced by the research participant:

☐Nature of participation and responsibilities of participant - What will they be asked to do and how many times throughout the duration of the study (surveys, questionnaires, interviews, focus groups, follow-up etc.).
☐Describe the research procedures
☐How much of their time will be required? (Duration of the study)
☐How long will they be asked to remain in the study (longitudinal study or not)?
☐ If applicable, describe the procedures in place to allow participants to review their transcripts and/or to review the quotations that will appear in the final report. For example, "After your interview, and prior to the data being included in the final report, you will be given the opportunity to review the transcript of your interview, and to add, alter, or delete information from the transcripts as you see fit."

Collection of Information, including Personal Information/ What sort of information, including personal information, would be collected and how?

☐List all information that will be collected about participants, including all personal information that will be collected. Provide a description of it if needed (e.g., gender, name, age, ethnicity, contact information, educational level, etc.).
☐List all modes of collecting information (i.e., interview, videotaped interview, audio taped interview, questionnaire, survey, focus group, etc.).
☐List all individuals and roles that will have access to the data collected. Specify whether the individuals will be able to identify participants (through demographic or personal data collected) or not.

- ☐Is the sponsor or community partner going to have access to the data? In what form?
- ☐Do the participants get a copy of their data to review (e.g., to review interview transcripts)?

☐Describe the anticipated uses of the data.
☐Specify how information, including personal information, will be reported (i.e., will participants be given a code or pseudonym? Will data be reported in aggregate?)
☐Describe how the information will be securely stored (examples: locked filing cabinets, location of computers containing data away from public areas, development and enforcement of organizational rules about who has access to personal information about participants, computer passwords, firewalls, anti-virus software, encryption, etc.).
☐ If applicable, for data collected using an on-line survey company (e.g., Survey Monkey), participants must be informed of the location where the data is stored and about any limits to confidentiality that may exit.
☐If applicable, if the Consent Form and/or data are returned to you in a way that potentially identifies the participant (i.e., questionnaires are returned by fax, email or mail), participants must be informed about this potential loss of anonymity, and you must describe the procedures that will be implemented in order to minimize this risk.

☐Describe when the data will be destroyed, if appropriate. Include the sentence below pertaining to destruction of data and or identifying factors if suitable:

"All identifying electronic (and/or paper, if applicable) records will be deleted before (specify a date)" . (Note: if data is collected anonymously, then that should be noted above, and hence no need to delete anonymous data).

☐If data may be used for future research and/or posted in a repository, describe the nature of the potential research and data access. If this is the case, then participants should also be given an opportunity to express their preferences regarding their data being used for future research and the following should then be included:

"_____ : I give consent for the data I contribute to this study, once anonymized, to be
(initial) used for future research (or deposited in a repository, if applicable)."

☐The following will normally be included on your consent form:

"Subject to the exceptions noted on this consent form, efforts will be made by the institution and the researchers to keep the information confidential. Such efforts include: *[list efforts, examples: require researchers to sign confidentiality agreements, anonymizing or coding data, institutional policies regarding confidentiality, etc.]"*

The following items may need to be considered and articulated on the consent form for some research projects if disclosing personal/confidential information is a foreseeable/anticipated risk:

☐If required by law, including but not limited to a legislative provision, search warrant or other court order.
☐With your consent (i.e., consent of the participant).
☐List who may have a duty to disclose information collected and to whom such disclosures could be made. Examples:

- ☐are you subject to obligations to report information to authorities to protect the health, life or safety of a participant?
- ☐are you subject to professional code of conduct or other ethical code that would compel disclosure?
- ☐do specific laws apply that would compel disclosure of information obtained (for example: those requiring the reporting of children in need of protection, in situations where you have a reason to believe there is an imminent risk of serious harm or death to an identifiable person or group, reporting illnesses, contagious diseases or communicable diseases to health authorities, etc.)?

☐For studies collecting any identifying information (including just a name on a consent form) the following heading and statement must be included:

FOIP Notification

The personal information that you provide to Mount Royal University is collected under the authority of the *Post-Secondary Learning Act* and the Alberta *Freedom of Information and Protection of Privacy* (FOIP) Act – Section 33(c). The information will be used for the purpose of conducting the research project. Collected personal information is protected from unauthorized access, collection, use, and disclosure in accordance with the FOIP Act and can be reviewed or corrected, where appropriate, on request. Questions regarding the collection of personal information can be directed to:
Your Title –Your Name – Your Department – Mount Royal University 4825 Mount Royal Gate SW Calgary, AB T3E 6K6 – Phone - Email
[Note: in order to use personal information in a subsequent research project, you must inform the participants that their personal information is being used for a different purpose and they must provide their consent]

Study Risks or Benefits for Participants/What are the risks or benefits involved in my participation?

☐List all potential risks (specify level of severity) and inconveniences involved including the likelihood of their occurrence during participation.

☐List all potential direct and indirect benefits involved arising from participation (do not overstate or exaggerate the benefits).

Voluntary Participation and Withdrawal of Consent:

☐The following must be included on the consent form:

"You are under no obligation to participate in this research study.
You are free to withdraw ***(specify a date after which withdrawl is not possible or if data is collected anonymously then it must be clear above that withdrawing cannot occur once the data collection is completed)*** without prejudice to pre-existing entitlements. You will not suffer any disadvantage or reprisal for withdrawing."
Note: Specify how to withdraw (i.e. contact PI via telephone, e-mail, mail, etc.). Explain what will happen to the participants collected data if they decide to withdraw. Explain further that the researcher can withdraw a participant from the study and include reasons for such an occurrence.

☐The following must be included on the consent form:

"You will be given, in a timely manner throughout the course of the research project, information that is relevant to your decision to continue or withdraw from participation."

What will happen to the results of this research project?

☐If applicable, insert information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, the institutions or the research sponsors.
☐Include information regarding the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly.
☐Insert name and contact information for a qualified designated representative who can explain scientific or scholarly aspects of the research to participants (this will normally be the PI).

Who should I contact if I have concerns regarding ethical issues related to this research project?

☐The following statement must be included:
"If you have any questions concerning your rights as a possible participant in this research, please contact the Research Ethics Officer, at Mount Royal University, 403-440-8470, hreb@mtroyal.ca."

Compensation: (do not include this heading if not applicable to your study)

☐If applicable, inform the participants of what compensation, if any, will be provided for their involvement in study (e.g.: "You will not be compensated for your time or efforts in the study.'

Or ‘A $10 gift card for parking will be issued upon completion of involvement.”). Included in this: incentives, payments, reimbursement for participation – related expenses.

Signature (written consent): *[note: always ensure that the signature block (see below) is on a page with other text]*

☐ The following information must be included:

Your signature on this form indicates that you:

- are voluntarily consenting to participate in this research project,
- understand to your satisfaction the information regarding your participation in the research project and your agreement to participate,
- have not yet commenced participation in the research project – your participation will only begin once you have provided your consent, and
- have been given adequate time and opportunity to:
  - consider the information provided,
  - pose any questions you may have, and
  - discuss and consider whether you will participate.

If you have further questions concerning matters related to this research, please contact: *Provide PI’s name, Department, Faculty, telephone and e-mail address.*

Participant’s Name	Signature and Date
Principal Investigator/Delegate’s Name	Signature and Date