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| **HUMAN RESEARCH ETHICS BOARD CONSENT FORM TEMPLATE**  **How to Use this Template**   * **Delete this instructional page**. * *Red italicized text* indicates instructions to the consent form authors (you). Delete this from the final draft. * Blue text indicates information required from your study. Replace with the details from your study in regular black font. * **Black** text is standard wording to be used in your final consent form. * Supply the information requested under the bolded headings (e.g., **Summary of the Study**). Do not modify these headings unless you have HREB’s permission to do so. * Add details relevant to your study. * Suggested text/examples are provided throughout the template. Any suggestions that are not relevant to your study should be removed. * Please check the correctness of your spelling and grammar. * Each page footer must include the Ethics ID# and be formatted as ‘Page X of Y’. * Change all text to **black font** before submitting the final consent form for review.   **Writing Guidelines**   * Participants can only provide truly informed consent if the study details are clearly explained (see TCPS2 2022, Article 3.2). * Write the consent form in:   + age-appropriate plain language (non-technical and jargon-free),   + using active voice, and   + first or second person (“I” or “you”). * Adjust the language to suit the participants’ education and fluency. For adults, aim for grade 8 (age ~13) reading level, generally, and no more than grade 10 (age ~15) in any circumstance. * Define all acronyms and abbreviations when they first appear. * Use readability tools like Microsoft Word or [read-able.com](http://read-able.com). * When referring to participant data, the term “**coded**” is recommended as it effectively communicates that steps have been taken to reduce the risk of re-identification but there also remains a small residual risk of re-identification. * Researchers are discouraged from replacing the term coded with alternative terms such as “de-identified” when seeking consent to share data as it may suggest that the data carries no residual risk of participant re-identification. In addition, the term coded is defined in TCPS2 and commonly understood across research contexts. |

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|  | **CONSENT TO PARTICIPATE IN RESEARCH** |

**title:**[Insert the full title of the research]

**HREB Number:** [Insert number]

**Study primary Investigator:** [Insert name, department, telephone number/email address]

**Co-Investigators:** [Insert names as relevant]

**Supervisor:** [Insert the supervisor’s name and contact information here if the researcher is a student (undergraduate or graduate)]. *Delete this section if the researcher is not a student.*

**Sponsor:** [The name of the sponsor appears here]. *A sponsor is the individual or entity responsible for overseeing the study. If no sponsor, delete*

**Funder:** [Put the name of the organization/company providing funds, human resources, and/or equipment here]. *For example, if the study is funded by a Tri-Agency grant held at MRU, then Mount Royal University would be considered the sponsor, and the specific Tri-Agency would be considered the Funder. If the funder and the sponsor are the same entity (for example, an internal research grant), then remove the Funder section and only include the Sponsor.*

You are being invited to participate in a research project, as described in this consent form. Please note that this consent form gives you a summary of the research and explains what you will be asked to do. It is only one part of the consent process. Please take the time to read this carefully and to understand any accompanying information. If you have any questions, please ask for help. You will receive a copy of this form. *Researchers shall provide participants with a copy of the consent form or other documentation of consent, unless the HREB agrees that this is not appropriate or practicable. If consent is conducted online, indicate how participants can receive a copy of the consent form.*

**Summary of the study**

[Clearly outline what this study proposes to do, its purpose, the goals of the study, how, where, when, and why, including your eligibility criteria.] *Use plain language that will be easily understood by the participants. Avoid jargon and technical terms.* *No more than a paragraph of text is necessary.*

**What will I be asked to do?**

If you volunteer to participate in this study, the researcher will ask you to do the following:

[Clearly outline and describe the activities of the participant using plain language free of jargon in a **step-by-step manner** as it will be experienced by the research participant]

* *Include the frequency and duration of what the participant will be asked to do*
* *Specify the location of study activities.*
* *Describe types of data collection (e.g., if using questionnaires/surveys or interviews, provide an example question).*
* *Indicate if any sensitive questions will be included.*
* *If you are requesting to video or audio record participants, state this intention clearly in the consent form and provide the rationale.*
* *If there will be follow up (e.g., a second part to the study), indicate how this will be accomplished (e.g., how will participants be contacted). Affirm that participation in follow up is completely voluntary.*
* ***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.”*

**How long will I be in this study?**

*Explain the duration of the study or how long the study will last. This will help participants decide if they have the time to participate.*

Participation in this study will take a total of about [specify time and duration].

* *When appropriate, include estimates of the different aspects of the study and state, if applicable, that the study will involve long-term follow-up and specify time frames.*

**What type of information will be collected?**

If you volunteer to participate in this study, the research team will collect: *[provide the following information, as applicable]*:

* [Participant information collected] *List all information that will be collected about participants, including all personal information that will be collected. Provide a description if that could improve the participant’s understanding of what they are agreeing to (e.g., gender, name, ethnicity, education level, etc.).*
* [How personal information is collected] *List all modes of collecting personal information (i.e., interview, video recorded interview, audio recorded interview, questionnaire, survey, focus group, etc.).*
* *For data collected or stored using web-based tools (e.g., Survey Monkey, Google Meet, Google Drive etc.), participants must be informed of the location where the data is stored and about any limits to confidentiality that may exist. The following statement must be included:* Your information will be [collected or stored]using[software name and company location]*.* The information you submit may be subject to laws in force outside of Canada. As with any information transmitted via the internet, there is some risk that data may be intercepted by unauthorized parties and, therefore, privacy cannot be guaranteed.
* [Number of Participants recruited] *Describe approximately how many people will take part in this study. This will help the participant understand how identifiable personal information will appear within the larger study context.*
* [How personal information will be used and shared] *Explain how personal information will be used or shared. For example, in aggregate for large data sets or if the participant will be video recorded or audio recorded, explain whether the recordings will ever be shown in public.*

*Note -* ***If no personal identifying information*** *is to be collected (personal identifying information includes, but is not limited to, names, email addresses, student ID numbers, social insurance numbers, IP addresses, in-person conversation, etc.), and the participant will be anonymous (as outlined in TCPS2 Chapter 5), use the following statement:* No personal identifying information will be collected in this study, and all participants shall remain anonymous.

*Note: TCPS2 Chapter 5 defines anonymous very specifically*

* ***Anonymous data****: Information that never had any identifiers associated with it.*
* ***Anonymized data****: Information from which identifiers have been removed irreversibly and no code exists to re-link data to individuals.*
* ***Coded data****: Originally identifiable data where direct identifiers were removed and replaced with a code—re-identification may still be possible, depending on access to the code.*

**How will information about me and my participation be kept confidential?**

*Inform participants of the extent to which the researchers intend to maintain the confidentiality of records that identify participants.*

* [Efforts to maintain confidentiality] *What methods are in place to code or anonymize information (see definition above)?*
* [Data storage] *How will data or records be stored? (Physical copies in 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.).*
* [Who has access] *List all individuals and roles that will have access to the data collected. Is the sponsor or community partner going to have access to the data? In what form? Specify whether the individuals will be able to identify participants (through demographic or personal data collected) or not. If applicable, indicate research assistant(s) access, but specific names of RAs are not required.*
* [If applicable, details of data repository] *If consent will be requested to deposit data in a repository, describe which data will be deposited and the type of access that will be applied (e.g. public, closed, restricted).*

*Advise participants if you believe that the fact of their participation will be known (e.g. if they are doing an interview on work time) but you will keep all information they provide confidential.*

**Are there potential risks if I participate?**

[List and describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be managed.]

***Example -***

*Performance of the tests described above can lead to muscular fatigue or muscle soreness, which should dissipate over a few minutes, and should not be greater than the muscular fatigue or soreness you experience during regular exercise. There may be some redness associated with the electrodes, which should subside in a few minutes following the testing session.*

*Participants will be encouraged to report any symptoms of pain or fatigue to the investigator(s) administering the tests. The investigators are experienced in this methodology and all relevant measures will be taken to ensure participants' risks are minimized.*

**Are there potential benefits if I participate?**

[Describe any potential direct benefits to the participant first, followed by potential general benefits.] *Benefits could be for a group to which the participant belongs or overall knowledge in an area.*

***Example***

*There will be no direct benefit to you from participating in this study. However, this study may help researchers learn more about how students learn in a flipped classroom.*

**Compensation**

[Inform participants what compensation, if any, will be provided for their involvement in the study. This includes incentives or reimbursement for participation-related expenses.]

***Example - No payment or reimbursement***

*You will not be compensated for your time or efforts in the study.*

***Example - Reimbursement for out-of-pocket expenses***

*A $10 gift card for parking will be issued upon completion of involvement.*

**Voluntary participation and withdrawal of consent:**

You are under no obligation to participate in this research study. You can decide to stop at any time, and you are free to withdraw [Provide participants with a deadline for requesting withdrawal of their data. If data is collected anonymously (information that never had any identifiers associated with it) then it must be clear that withdrawing cannot occur once the data collection is completed.] without penalty or loss of benefits. You will not suffer any disadvantage or reprisal for withdrawing.

*Specify how to withdraw (i.e. who to contact, contact information via telephone, e-mail, mail, etc.). Explain what will happen to the participant’s 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 statement should be included when applicable.* 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.

***Example***

*You are free to withdraw at any time during the time of data collection without penalty or loss of benefits. Notify one of the study investigators listed at the top of this form, either in person, by phone or by email within 24 hours of data collection. While your personal data will be coded once it is collected, you may choose to have all data collected prior to your withdrawal destroyed.*

**What happens to the information I provide?**

[Include information regarding the measures to be undertaken for the dissemination of research results and whether participants will be identified directly or indirectly.]

* *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.*
* *If data will be accessible for secondary use via a repository, anticipated uses should include those that reflect the nature of the repository and access (i.e. unanticipated uses if publicly accessible, further research if restricted).*

***Example***

*This research will be published in a peer-reviewed scientific journal and presented at National and International conferences. Coded data may be requested by journal-repositories as a requirement for publication. No identifiable individual data will be included in these publications.*

**Use of data for Future Research**

*If data may be used by members of the research team in future studies, describe the nature of the potential research and data access. Participants should be given an opportunity to express their preferences regarding their data being used for future research. Delete if not applicable.*

We would like to ask for your consent to use your coded study data in controlled access.

“**Coded**” means that information that directly identifies you (e.g., your name, your civic address, and contact information) will be removed and replaced with a unique, random code. “**Controlled access**” means making data available to authorized members of the research team through the principal investigators secure database for further research studies.

Sharing your coded study data may contribute to other research projects and their results could benefit others in the future.

If you agree, your coded study data will be held securely by the principal investigator. Researchers that wish to use it will be required to agree to respect restrictions on its use. They will be authorized to download and analyze it as part of a study, for a specified time, so long as they continue to use it responsibly.

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|  | Please initial |
| ❑ YES, share my coded research data in an open-access database. |  |
| ❑ NO, do NOT share my coded research data in an open-access database. |

**Use of data for Open Access**

*If data may be posted in an open repository, describe the nature of the potential research and data access. Participants should be given an opportunity to express their preferences regarding their data being used for future research. Delete if not applicable.*

We would like to ask for your consent to share your coded study data in open access.

“**Coded**” means that information that directly identifies you (e.g., your name, your civic address, and contact information) will be removed and replaced with a unique, random code. “**Open access**” means making data available through a public website for anyone around the world to freely access and use.

Sharing your coded study data may contribute to many different research projects and their results could help benefit individuals in the future.

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|  | Please initial |
| ❑ YES, share my coded research data in an open-access database. |  |
| ❑ NO, do NOT share my coded research data in an open-access database. |

**Contact for future research**

*If you wish to invite participants to be contacted in the future research, describe the nature of the potential research contact. Participants should be given an opportunity to express their preferences regarding being contacted for future research. Delete if not applicable.*

The research team may contact me in the future to ask me to take part in other research studies, with the understanding that I can always decline the request.

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|  | Please initial |
| ❑ YES, I am willing to be contacted to take part in future research. |  |
| ❑ NO, I do NOT want to be contacted to take part in future research. |

**Questions or Concerns?**

If you have further questions or want clarification regarding this research, please contact [Provide PI’s name and e-mail address] *and the supervisor's name, department/faculty telephone number, and email, if applicable.*

If you have any questions about your rights as a research participant, or if you have any concerns about your treatment during the study, please contact the Research Compliance Officer at Mount Royal University at 403-440-8470 or by email at hreb@mtroyal.ca.

**Signature (written consent):**

*For written consent, ensure that the signature block is on a page that includes text from the consent form.*

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.

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| Participant’s Name |  | Signature and Date |
|  |  |  |

Principal Investigator/Delegate’s Name Signature and Date

**Online consent:**

*For studies using digital consent, such as online survey data collection, replace the Participant’s Name and Signature fields with the options.*

Selecting YES 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.

❑ Yes, I consent to participate in this research study.

❑ No, I do not wish to participate in this research study. *(Ensure that this second option routes the participant to a page that is not the survey and does not collect data.)*

The Human Research Ethics Board of Mount Royal University has approved this research study.

*Researchers shall provide participants with a copy of the consent form or other documentation of consent, unless the HREB agrees that this is not appropriate or practicable. Include the following sentence.*

A copy of this consent form has been provided to you for your records and reference. The investigator has kept a copy of the consent form. *If consent is conducted online, indicate how participants can receive a copy of the consent form.*

***Before submitting your consent form****, please check it over (or have it checked) for grammar, spelling, and typing errors.*