**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

**TEMPLATE**

**GENERAL INSTRUCTIONS**

* The consent form template was designed to meet current regulatory and ethical standards. These documents provide headings and sample text to assist you. The REB recommends that study teams use the template whenever possible and customize it to be accessible and appropriate for your participant groups.
* Please consult the accompanying guidance document for additional information.

**How to Use this Template**

* Headings in **bold black font** and subheadings in *italicized black font* denote sections which should be used and should not be altered or removed.
* Text in black font should be included.
* Instructions are indicated in green font. Sections where investigators need to provide content are denoted by [Insert…].
* Sample text/examples are provided in blue/teal font and may be adapted to the study or omitted if they are not relevant to the specific study.
* The instructions (green font) and options not applicable to your study in blue/teal font should be deleted from the consent form prior to submission to the REB.
* Pointers to sections in the main application form or consent form guidance document where relevant information should be found are provided in *orange italicized font*.
* Sample language for your particular study may not be provided in the guidance document or template. If there is no template language for your specific situation, please create your own.

**Informed Consent Form DOs**

* Use plain (lay) language throughout that is easy to understand and is accessible to the study population.
* Information should be provided at an eighth grade reading level. Use the [Flesch-Kincaid Grade Level score](https://support.microsoft.com/en-us/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2) to ensure readability.
* Write in the second person (“You/Your”).
* Whenever possible, avoid using technical/medical terms, acronyms and abbreviations. However, when required, they should be clearly defined at first use.
* Consult the [TCPS 2](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html) to ensure compliance with regulations/guidelines.
* Consult the Guidance Document for descriptions of information to be included in the Consent Form.
* Use a size and font of text that is consistent and easy to read (size 11 or larger of Arial or Times New Roman is recommended).
* Use the headings provided in the template document.
* Ensure that the final form is properly formatted and free of spelling or grammatical errors. **Use spell-check.**
* After all edits have been made, all text should be black.
* Delete these instructions prior to submission.

**Informed Consent Form DON’Ts**

* Do not provide the full inclusion and exclusion criteria.
* Do not include the participant’s unique study identifier on the consent form.
* Do not request the participant to initial every page.
* Do not include any logos.
* Do not state that the CMCC Research Ethics Board has “approved” the study since this may appear to offer a guarantee of safety.
* Do not provide duplicate information.
* Do not leave blank spots to be filled in later (i.e., investigator name).
* Do not change the paragraph spacing in the form.

**REMINDER**

**The signing of the informed consent form is only a component of the informed consent process. In most cases, researchers should have a consent discussion with potential participants, and respond to any questions they may raise before a consent form is signed.** Consent is an ongoing process throughout the conduct of the study to ensure consent for participation is maintained.

For queries related to the consent form guidance document and/or template, please contact the Office of Research Administration (ora@cmcc.ca).

**Informed Consent Form for Participation in a Research Study**

**Title of Research Study**

[Insert study title as it appears on the REB application form]

**Investigators**

*Principal Investigator*

[Insert full name]

[Insert affiliation]

[Insert CMCC phone number]

[Insert CMCC email address]

*Co-Investigator(s)*

[Insert full name]

[Insert affiliation]

[Insert email address]

**Funder/Sponsor (if applicable)**

[Insert name of organization(s)/agency(ies) that have provided financial support for this project]

[Include the grant/funding number if known]

 **Introduction**

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study’s procedures, risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. **You should ask the Principal Investigator (PI) or study team to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form.** Before you make your decision, feel free to talk about this study with anyone you wish including your friends and family. Participation in this study is voluntary.

This study has been reviewed by the Canadian Memorial Chiropractic College Research Ethics Board [Insert assigned REB#] on [Insert date on REB certificate].

**Purpose and Procedure**

*Purpose*

You have been invited to participate in this study because [Insert the main features of the population to which the research applies].

[Insert relevant background information and the purpose of the study]

*Please refer to the Guidance Document for information about what to include.*

*Procedures*

[Insert brief details on the study procedures and data collection methods]

*Please refer to the Guidance Document for information about what to include.*

**Potential Benefits**

[Insert direct benefits to the participants, if applicable]

*Please refer to the section in the application form that is titled Risks and Benefits.*

If there are no direct benefits, state: There are no direct benefits to you from participating in this study.

**Potential Risks, Discomforts, and Associated Safeguards**

[Insert information about risks associated with the study procedures]

*Please refer to the section in the application form that is titled Risks and Benefits.*

If there are no known risks, state: There are no known or anticipated risks to you from participating in this study.

**Use and Storage of Data**

If your study does not collect personal information that directly identifies a person (i.e., anonymous data), state: This is an anonymous study. This means that no information that could be used to identify you is being accessed or collected as part of this study and we will not be using or analyzing your data in a way that could identify you.

Otherwise, state: Personally identifying information will not be released or published at any time. Names and identifying details will not be included during data analysis. All data collected for research purposes will be labelled with a unique study identifier instead of any of your personally identifying information. The [Study personnel who has access to the linking code] are in control of the key that links your study identifier to you personally and will keep it stored separately from the study data. Personally identifying information will be retained for a period of [Insert duration for retaining identifying information] after [study stage (e.g., publication, completion of data analysis, project closure], after which it will be destroyed.

[Describe how data will be deidentified, stored, and destroyed throughout the research, including during collection, use, dissemination, and retention]

*Please refer to the section in the application form that is titled Privacy and Confidentiality to complete information that should be inserted.*

[Describe personally identifying information that will be collected, how it will be collected, and why it will be collected]

*Please refer to the section in the application form that is titled Privacy and Confidentiality to complete information that should be inserted.*

It is expected that the information collected during this study will be published/presented to the scientific community and meetings and in journals. If the results of this study are published, shared, or presented at scientific meetings, your identity will remain confidential. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

**Incidental Findings (if applicable)**

If information gathered during this study indicates a serious risk of harm to yourself or other people, we have to tell somebody about it. We will do this to protect you or another person. If we feel that you need help right away, we will work with the appropriate health professionals to get you the help you need.

**Confidentiality**

Your privacy shall be respected. No information about your identity will be shared or published without your permission, unless required by law. Confidentiality will be provided to the fullest extent possible by law, professional practice, and ethical codes of conduct. Please note that confidentiality cannot be guaranteed while data is in transit over the Internet

The study team will make every effort to keep your personally identifying information private and confidential in accordance with all applicable privacy legislation.

[Insert description of procedures to safeguard confidentiality of participants]

*Please refer to the section in the application form that is titled Privacy and Confidentiality.*

If demographic data is collected, state: This research study includes the collection of demographic data which will be aggregated (not individually presented) in an effort to protect your anonymity. Despite best efforts it is possible that your identity can be determined even when data is aggregated.

If email communication is used, state: Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed

OR

Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive information via e-mail.

If study uses online surveys implemented in REDCap, state: The online survey is hosted by REDCap (Research Electronic Data Capture, Vanderbilt University, Nashville, United States), a secure data-management web application for building and managing online surveys. Data collected through REDCap is held within a secure, limited-access data centre at CMCC, which is compliant with the Freedom of Information and Protection of Privacy Act (FIPPA). The surveys and survey data are only accessible by members of the research team at CMCC using two-factor authentication. **The previous text should be adapted if a different online survey platform will be used.**

**Voluntary Participation**

Your participation in this study is voluntary and you may partake in only those aspects of the study in which you feel comfortable. You may also decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your [Choose the most applicable: employment status, academic standing, medical care, relationship with the institution, access to services, grades in a course, payment, research credit, etc.]. You will be given information that is relevant to your decision to continue or withdraw from participation. Such information will need to be subsequently provided.

If applicable, insert: You may refuse to answer any question you do not want to answer, or not answer an interview question by saying, ‘pass’.

The investigators have an interest in completing this study. Their interests should not influence your decision to participate.

**Right to Withdraw**

You may stop data collection or withdraw your participation from the study at any time without reason and without penalty.

[Insert process for withdrawing from the study]

*Please refer to the section in the application form that is titled Withdrawal Process.*

If there are no limits on withdrawal, include: If you withdraw from the research project at any time, you may request without reason that any data or human biological materials that you have contributed will be removed from the study.

If there are limits on withdrawal, include: In some research projects, the withdrawal of data or human biological materials may not be feasible (e.g., when personal information has been anonymized and added to a data pool).

**Secondary Use of Data**

If data will be made available for secondary use, state: We would also like to ask that you consider allowing us to store your study data for use in the future. Sometimes, data collected for a study may be useful for answering other research questions. This is called secondary use and may comprise projects initiated by one of the investigators named on this project or investigators from outside the team. While we do not currently know what types of future research may be conducted with this study data, we anticipate that the study data will contribute to research in a similar field of study. Only de-identified data from this study will be shared/used for secondary purposes. You do not need to agree to the secondary use of your data in order to take part in this study. You will be given the ability to consent to the optional secondary use of your data in the consent form.

If data will not be made available for secondary use, state: Sometimes, data collected for a study may be useful for answering other research questions. This is called secondary use and may comprise projects initiated by one of the investigators named on this project or investigators from outside the team. Data collected for this study will not be used for secondary purposes.

**Conflict of Interest**

[Insert details on any conflicts of interest]

*Please refer to the section in the application form that is titled Conflict of Interest.*

If there are no conflicts of interest, state: There are no conflicts of interest related to this study to declare.

**Commercialization (if applicable)**

[Insert company name] intends to claim sole ownership of any results that would come from this study. You will not receive any financial benefit that might come from the results of this study.

**Compensation, Reimbursement, and Incentives**

[Insert information on any participant compensation]

*Please refer to the section in the application form that is titled Reimbursement/Incentive.*

If participants will not receive compensation, state: You will not be paid or receive any other incentive for taking part in this study.

**Dissemination of Results**

[Insert details on how participants will be informed of the results of the study]

*Please refer to the section in the application form that is titled Providing Participants with Study Results*

**Participant Rights and Concerns**

Please read this consent form carefully and feel free to ask the researcher any questions that you might have about the study. If you have any questions about your rights as a participant in this study, complaints, or adverse events, please contact the Office of Research Administration at (647) 805-2022 or at ora@cmcc.ca.

If you have any questions concerning the research study or experience any discomfort related to the study, please contact the researcher [Insert Principal Investigator’s full name] at [Insert Principal Investigator’s CMCC phone number] or [Insert Principal Investigator’s CMCC email address].

By signing this form, you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Consent to Participate**

Choose any of these wordings that apply to the method by which consent will be obtained.

**Written Consent**

1. I have read the consent form and understand the study being described;
2. I have had an opportunity to ask questions and those questions have been answered. I am free to ask questions about the study in the future;
3. I freely consent to participate in the research study, understanding that I may discontinue participation at any time without penalty. A copy of this consent form has been made available to me.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Print Study Participant’s Name Signature Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Print Name of Person Obtaining Signature Date

**If the use of third party authorization, or substitute decision maker, include the following section:**

This consent form is addressed to the participant. However, in the occasion that the participant is unable to or does not have the capacity to provide consent for themselves, this form is to be carefully read and signed by you acting as their substitute decision maker for whom informed consent will be obtained for participating in the study.

After considering the wishes, values, and goals of the study participant, they would permit the study team to perform study procedures and data collection. I can reverse this decision at any time.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Name of Substitute Decision Maker Signature Date

Relationship to Participant

My signature means that I have explained the study to the participant named above. I have answered all questions.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Print Name of Person Obtaining Signature Date

**Oral Consent**

1. I have read the consent form to the participant and they have indicated that he/she understands the study being described.
2. The participant has had an opportunity to ask questions and these questions have been answered. The participant is free to ask questions about the study in the future.
3. The participant freely consents to participate in the research study, understanding that he/she may discontinue participation at any time without penalty. A physical/digital consent form has been made available to him/her.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Print Name of Witness Signature Date

Relationship to Participant

**Online Consent**

1. I have read the consent form and understand the study being described.
2. [If applicable] I have had an opportunity to ask questions and my questions have been answered.  I am free to ask questions about the study in the future.
3. I freely consent to participate in the research study, understanding that I may discontinue participation at any time without penalty. A copy of this Consent Form has been made available to me.

[ ]  I agree

**Optional Secondary Use of Research for Future Research Purposes**

1. I understand the possible need for secondary research uses of my research data for future research use and provide consent for the use of my data to be used in future studies.

2. The research team has informed me that a separate REB application will be submitted for the secondary use of data for any future research purposes.

Participant must initial \_\_\_\_\_\_\_\_ Yes \_\_\_\_\_\_\_\_No