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

**TEMPLATE**

**RETROSPECTIVE CASE REPORT**

**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 Retrospective Case Report**

**Title of Case Report**

[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 participate in this case report because [Insert specific reason this case report is being written]. We wish to write and publish a report based on your case. This consent form provides information to help you make an informed choice. Please read this document carefully. 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, and you can decline to participate in any aspect of the research without impact on your medical care.

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

**Purpose**

The purpose of this study is to communicate [Insert details, including information as to why this case should be published].

**Procedures**

You do not need to do anything other than provide informed consent. There will be no additional clinical tests or visits.

**Potential Benefits and Risks**

There are no risks or direct benefits to your participation, but we hope that the information learned from this case report can be used in the future to help clinicians and other people with [Insert details, such as a similar health condition/situation, or specify as needed].

**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.

If you decide to participate in this study, the research team will only use the information that is needed. This case report will be limited to information from [Insert details from medical record and/or other data sources]. The following information will be used [Insert all identifiable and demographic data being used]. All information about you will be de-identified, which means any information used to produce the case report will be kept confidential and not shared with anyone else except with members of the case report team. The study team will make every effort to keep your personally identifying information private and confidential in accordance with all applicable privacy legislation. Data will be stored securely on [Insert details of where data will be stored] for [Insert data retention duration], after which they will be [Insert plan for data destruction or rationale for data storage].

It is expected that the information used in 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.

CMCC’s Research Ethics Board may request access to study-related records to monitor the ethical conduct of the research.

**Right to Withdraw**

You can change your mind about participation at any time prior to publication of the case report. You do not need to give a reason, and withdrawing will not have any impact on your current or future health care. You may also ask for some of the data used in the case report to be withdrawn. [Insert details of who to contact and how a person can request to either completely or partially withdraw from the study].

**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.

**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 case report. If you have any questions about your rights as a participant in this case report or complaints, please contact the Office of Research Administration at (647) 805-2022 or at ora@cmcc.ca.

If you have any questions concerning the case report, 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 why my case is of interest for being written and published;
2. I have had an opportunity to ask questions and those questions have been answered. I am free to ask questions about the case report 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 case report.

After considering the wishes, values, and goals of the study participant, they would permit the study team to write and publish the case report. I can reverse this decision at any time.

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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