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

**GUIDANCE DOCUMENT**

**GENERAL INSTRUCTIONS**

* The accompanying consent form template and this guidance document are 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.

**How to Use this Guidance Document**

* Headings in **bold black font** and subheadings in *italics black font* denote sections of the Consent Form.
* Text in black font should be included.
* Instructions are indicated in green font.
* Sample text/examples provided in in blue/teal font may be adapted to the study or omitted if they are not relevant to the specific study.
* Specific sample language for your 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.
* 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.

**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).

**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).

**Title of Research Study**

* Provide study title as it appears on the REB application form.

**Names of Investigators**

* Use a CMCC phone number and email address, *never a personal number or email address*. Only study specific mobile/cell numbers may be included.
* Use the following formats for the principal investigator and all co-investigators:

*Principal Investigator*

Full name

Affiliation

CMCC phone number

CMCC email address

*Co-Investigator(s)*

Name

Affiliation

Email address

**Funder/Sponsor (if applicable)**

* Provide name of organization(s)/agency(ies), including CMCC if supported by Internal Research Support Fund, that have provided financial support for this project.
* Include the grant/funding number if known.

 **Introduction**

**Purpose and Procedure**

* This section must include the subsections *Purpose* and *Procedures*.

*Purpose*

* If relevant, describe any background information pertaining to the current study such as the experience to date, data from other studies that led to the development of this study.
* Limit this to 100 words and only include the most useful and relevant information.
* Provide the purpose of the study.
* Main features of the population should describe how the participant meets the criteria for participation.

*Procedures*

* Describe all study procedures (including interventions if applicable) and data collection methods, as the participants would experience during the study.
* Use subheadings where necessary and appropriate (e.g., instruments, protocol).
* Provide information for supplier(s) of instruments used for data collection (e.g., electronic survey platform, video conferencing platform, motion capture)
* Indicate the number of study visits and procedures.
* Give an estimate of the length of time entailed by participating in **each** study procedure and the overall project.
* For studies with multiple visits, the table below can help to summarize the procedures:

|  |  |  |
| --- | --- | --- |
| **Visit**  | **Study procedure/tests/interventions** | **Duration of visit**  |
| Visit 1  |  |  |
| Visit 2 |  |  |

* Provide the number of participants taking part in the study.
* Explain the study related responsibilities of the participant.
* Indicate where the research will take place. If it will take place in another location other than the one where the participant will read or have the consent form read to them.

**Potential Benefits**

* Describe any direct benefits to the participant, as well as any indirect benefits (e.g., potential for benefit to society, further research, etc.). If benefits from participation exist, indicate so without overstating.
* **It is important to note that compensation for study participation is not a potential benefit to the study.** Study compensation must be described in the Compensation and Reimbursement section of the consent.

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

* Fully describe any reasonably foreseeable risks (physical, psychological/emotional, social/legal) both for the participant and in general that are associated with the procedures described above.
* State the likelihood of these risks if known (e.g., rare, common, infrequent).
* Describe any steps that will be taken to minimize those risks (e.g., if your study includes a safety or emergency plan, training protocols, or safety procedures, describe it).
* If the research project extends over a significant length of time, include a statement to the effect that the researcher will advise the participant of any new information that could have a bearing on their decision to participate or willingness to continue participating. Participants should be informed about the process by which ongoing consent will be sought.
* For studies that use deception, describe the procedures that will be in place for debriefing including, where appropriate, referrals for counseling and other services.

**Use and Storage of Data**

* Will the data be anonymized, deidentified, or aggregated? If so, state this and describe how the anonymization, deidentification, or aggregation will be done.
* Describe how all data will be stored (e.g., password-protected digital file, encrypted digital file, password-protected computer, locked cabinet, etc.).
* Identify who will have access to the data.
* Define the length of storage time. If parts of the data will be destroyed and parts of it will be kept for a longer term describe the storage time for each of the different data storage components. For example, personally identifying information may be destroyed before deidentified study data.
* Describe if/how data will be appropriately destroyed when that data is no longer required.
* Will data be shared outside of the institution (e.g., data shared with a non-CMCC collaborator who is part of study team)? If yes, describe the format in which the data will be shared and how the information will be transmitted (e.g., anonymous or anonymized; encrypted devices; secure file transfer protocol).
* For sponsor/industry-initiated studies, indicate if the study sponsor or industry will receive any research data and a rationale for sharing the data. If yes, describe the format in which the data will be shared (e.g., anonymous or anonymized).

*Additional considerations*

* If audio or video data are being transcribed, describe the safeguards that are in place during the transcription process and identify if the original data will be kept or destroyed.
* For online surveys, describe where the platform is hosted, where data will be stored, compliance with privacy legislation, and who will have access to the data.

*Collection of personally identifying information*

* Explain what information will be collected about the identities of participants/other personal information, personal health information, and/or biological materials and for what purpose(s) it will be collected.
* Explain what demographic information will be collected, if that information can be identifying and for what purpose(s) it will be collected.
* Describe procedures for handling aggregate demographic data when there is the possibility of participant identification.

**Incidental Findings (if applicable)**

* Describe the plan for managing incidental findings.

**Confidentiality**

* Describe the procedures that will be used to safeguard the confidentiality and anonymity of participants, as well as any limitations on the degree to which confidentiality and anonymity can be guaranteed (e.g., focus groups, rare instances including potential harm).
* Describe the procedures for handling aggregate demographic data when there is a possibility of participant identification.

**Voluntary Participation**

**Right to Withdraw**

* Describe the processes by which a participant can withdraw from the study (e.g., contact investigator or research assistant, verbally during data collection).
* For studies with a longer duration of study participation, indicate what will happen to the study information when a participant withdraws from the study.
* For studies with a defined withdrawal date or timeline, inform participants of that date or timeline.
* For studies that collect anonymous data, inform the participant that data cannot be withdrawn after they have completed the study and let participants know if the data is kept or removed if they stop answering questions or close an online browser early.
* If there are limits on withdrawal, provide reasons why the person’s data cannot be withdrawn.
* If relevant, inform participants that it may be impracticable to withdraw results once they have been published or otherwise disseminated.
* For interventional/clinical trial studies, include information on stopping rules and when researchers may remove participants from the study.

**Secondary Use of Data**

* If there is the potential to use data for a secondary research purpose inform the participants of this and that permission will be asked in an optional section at the end of the consent. In addition, the consent must indicate the PI will submit a separate application form to the REB for the secondary use of data for future research use.
* **IMPORTANT NOTE:** All future secondary use of data requires a new submission to the REB once the project scope has been defined. If it is defined in the original application, it is not secondary use of data – so the implication is that if it is secondary use of data, it automatically requires REB approval for the study, except where exempt based on other rules described by the TCPS 2022.

**Conflict of Interest**

* This section must include details of any real, perceived, or potential conflicts of interest concerning this study if applicable (e.g., past consultation, past service on advisory board, financial, stocks, project support etc.).

**Commercialization (if applicable)**

* Indicate if there is any intent to commercialize aspects of the study.
* Include the statement:
	+ [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**

* Include whether participants will incur any expenses as a result of their participation in the study.
* Indicate if there is reimbursement for reasonable study related costs (e.g. travel, transportation).
* Include any remuneration (e.g., payments, gifts in-kind, vouchers, etc.) to participants and how reimbursement will be pro-rated if participants leave the study early.
* The schedule for compensation/reimbursement (e.g., lump-sum, pro-rated) should be consistent with the REB application. It is up to the investigators to describe the schedule for compensation/reimbursement.
* The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

**Dissemination of Results**

* Indicate how the participants will be informed of the results of the study, if interested.
* Include a description of how the results will be published and how the participants will be informed of the publication.
* If participants are interested in learning of the results, provide them with an opportunity to contact the researcher.

**Participant Rights and Concerns**

**Consent to Participate**

* Consent to study participation may be obtained in various ways such as: written, oral, use of a substitute decision maker, or online.
* Choose the wording that applies to the method(s) in which consent was obtained (i.e., written consent with or without substitute decision maker, oral consent, online consent, consent for secondary use).
* Delete wording that is not applicable.