How to use this template:

- Text highlighted in grey is a fillable or optional field and should be replaced or removed from the final version.
- Footnotes are guidance for customizing the informed consent form, they should be deleted from the final version.
- This document should be written in plain language. This means that all technical or scientific language should be explained or replaced with everyday language.
- All elements not relevant to the present study should be deleted from the final version.

[Title of Study]
[Name of Principal Investigator]
[Name of Funder]

What do you need to know about participating in research?

Your participation is voluntary.

Participating in any research is your decision. That means you can choose to participate but you also have the right to refuse to participate. By agreeing to participate, you are giving your consent. Before making your decision, you are welcome to discuss this study with your care team and others that are close to you and can guide you including [e.g. family, elders, spiritual and faith leaders, and friends][1].

At all times, researchers must conduct research with integrity which means working honestly and upholding their professional ethics principles. They are responsible for the safety of the participants during this study. They protect your information [and biological samples][2] and keep your information confidential.

You can stop participating at any time.

You may choose to stop participating at any time. If you stop, there will be no consequences or impact on your [e.g., health care, academic standing, employment, or any other situation that may be applicable][3]. If you choose to stop participating, no more information will be collected about you from that point on.

If your information has already been shared or published, or if we can no longer link your information to you, it may not be possible to remove it from the study. If we learn anything that is relevant to your decision to continue or stop participating in this study, we will share it with you.

Ask the research team about removing information [or biological samples][4] that has already been collected.

[1] Specify others that potential participants may want to consult, depending on the study population.

[2] Only include information about biological samples if applicable.

[3] This field should describe any entitlements that may apply to the population, such as health care for patients, academic standing for students, employment if applicable, and so on. More than one entitlement may be listed if applicable.

[4] Only include information about biological samples if applicable.

What does participating in this study involve?

Purpose of this study
The purpose of this research study is [purpose].[5]

What you will be asked to do as a participant in this study
Participating in this study means that you will be expected to do the following:

- [Point form list of what the study asks the participant to do].[6]

The length of this study is [length of time].

There are approximately [number] of participants taking part in this study.

Research procedures
[Sufficient description of research procedures].[7]

Compensation or Reimbursements
You [will or will not] be paid to participate in this study.
[Describe any compensation or honoraria the participant will receive. Describe any anticipated costs to be incurred by participants. Describe whether those costs will be reimbursed].[8]

Stopping the study early
We may stop your participation in this study early if [list stopping rules].

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[5] Purpose of the study should be as succinct as possible. Technical and scientific words are explained or replaced by everyday words.

[6] Each new idea or action should be separated by a new bullet point. If applicable, include:
(a) detailed directions for use of the study products;
(b) statement about refraining from taking other medications without consulting the study team or alerting them to the use of other medications;
(c) statement about discussing lifestyle or dietary changes required by or unrelated to the trial with the study team. This includes pregnancy as a condition for exclusion from the trial and the requirement of pregnancy tests. Birth control measures should also be listed, or the individual can be directed to speak to their physician about birth control options;
(d) a visit or other relevant schedule as an appendix to this document (i.e., the research package) and refer to the schedule here.

[7] Procedures should be written in plain language. Technical or scientific words should be explained or replaced by everyday words. If applicable:
(a) provide summary description ONLY of investigational products, placebo, comparator. Full detail may be provided in an appendix to this document if required.
(b) define study design with implications for participants (eg., randomized, blinded, cross-over, etc.), which must include probability for random assignment to each treatment and an explicit statement of which aspects of the trial are experimental.
(c) If biological materials are being collected, include the type and amount that will be taken, the manner in which they will be taken, and the safety and invasiveness of the procedures for acquisition.

[8] If applicable, describe incentives and reimbursements. Describe any additional costs that may result from participation, such as travel and parking costs, internet usage, etc.

Publication of study results
When this study is complete, we will publish the results on [repository recommended by researcher's institution].[9]

Alternatives to participating in this study
Alternatives to participating in this study include the following:
[List alternatives to participation and important risks of harm and benefits of each].[10]

What are the possible harms and benefits of participating in this study?

There are possible harms and benefits that you could experience through participation in this study.
Possible harms include:

- [Point form list of all reasonably foreseeable harms arising from participation in the research study].[11]

Possible benefits include:

- [Point form list of all reasonably foreseeable benefits arising from participation in the research study].[12]

[9] If US Regulated, use clinicaltrials.gov.

[10] Only applicable to trials subject to ICH guidelines, including Health Canada and US regulated clinical trials.

[11] Technical and scientific language should be explained or replaced by everyday words as much as possible. This section should not be a product monograph list of harms, but should be a succinct summary of possible harms that meet a threshold of likelihood.
(a) Do not include potential harms associated with standard of care; these distract from the actual risks of participation.
(b) If applicable, include a summary description of side effects from investigational products, placebo, or comparator. Description should be proportional to incurred risk.
(c) If applicable, list any contraindicated medications to investigational drug, placebo risks, or comparator. Do not need to state if there are no known contraindicated medications.
(d) If applicable, list any rescue medications.
(e) If proportionally important, state that there may be unknown risks of harm. Otherwise, do not need to state this information.
(f) If applicable, include discussion of plan to address any material incidental findings, using the following guidance: https://ethics.gc.ca/eng/incidental_findings.html
(g) For Phase 1 clinical trials: Consent procedures shall ensure participants are aware of the untested nature of the therapy and that participants do not accept, because of the incentives being offered, risks they would otherwise refuse.
(h) For Phase 2 clinical trials onward: if applicable, researchers shall provide details on access to the new drug upon trial completion.
(i) Use of placebo: if applicable, participants should be informed about any intervention or therapy that will be withdrawn or withheld for purposes of the research, and the anticipated consequences of doing so. Participants should be also told about rescue therapies offered during the study if applicable.
(j) Critical inquiry: in the case of critical inquiry, if permission is not sought from the person's institution/group to conduct this research, the individual should be told about any risks this may pose to them.

[12] Benefits include that the study aims to provide direct benefit to the participant or benefit others like them in the future, for example. There may also be no benefits to list. Studies subject to Good Clinical Practice guidelines should state if there is no intended clinical benefit of the research.

How will your information be kept safe?

During your participation in this study, we will collect a variety of information about you. This may include [personal information about you / biological samples / genetic information][13]. Your information will be stored, shared, and used according to the strict privacy and security standards of [University/ hospital/health authority/other research institution].[14] In line with [institution] policies[15], your information will be stored at [location]for [time], as required by [PI's institution].

Information that does not identify you may be published. It may be shared with other researchers from around the world for research studies. Sometimes, information that could identify you, such as your health information, may need to be shared for auditing, quality control, or other reasons to assess your safety and that the study is being done correctly. For example, the research ethics board may need to review progress of a study if safety concerns arise. In those cases, your information will only be shared with people in organizations that have data protection policies and security measures in place. More information is provided in the table below.[16]

In this study, we will collect the following information that could identify you[17]:

What information is being collected?	Why is the information being collected and what is going to be done with it?	Who will have access to this information and where are they located?	Link to privacy policy if using an app or platform not under the control of the study team[18]
e.g., Personal health number	*e.g., Link the information we collect about you during this study to your health records.*	• *e.g., Local study team, Health Authority, City, Country* • *e.g., Study coordinating site, University, City, Country*	*Link to data collection platform privacy policy.*

[13] Only include types of data that are being collected in your study. If you are collecting genetic information, use the genetic core consent template: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9828931/.

[14] Include link to institutional privacy and security standards.

[15] Complete these fields according to your institutional policies and other applicable regulatory requirements. State whether there are different institutional or regulatory requirements for biological materials.

[16] If study is seeking broad consent for future use of data, include a general description of the repository and its governance, a statement regarding participants' preference to being recontacted for future research, whether data or biological samples could be shared with researchers not subject to TCPS2, whether the research will or might include whole genome sequencing or similar technologies that may pose a significant risk of re-identification of participant or material incidental findings, and, whether linkage of data is anticipated.

[17] (a) Create a new line for each distinct piece of information you are collecting. For example, blood samples could go on the first line, and identifiable demographic information could go on the second line.
(b) If collecting biological materials, include anticipated linkage of biological materials with information about the participant.

[18] Delete this column if not applicable.

Who can you contact if you have questions?
Before you agree to participate, feel free to ask the study team any questions.

If you experience side effects or medical distress, meaning you are not feeling well either physically or emotionally, contact:
[Name]
[Email or phone, choose whichever is the most efficient means of communication].
In the event of an emergency, call 9-1-1 or go to an emergency room.[19]

If you are having thoughts about suicide or hurting yourself or others, contact [local suicide hotline].

If you have questions about this study, please contact:
[Name]
[Contact information eg., phone, email, social media contact, etc.].[20]

If you have questions about your privacy or your rights as a research participant please contact:
[Name]
[Email or phone].[21]

If you are injured as a result of taking part in this study and need medical treatment, please talk with the research team right away about your treatment options. Medical care will be provided or you will be referred for appropriate medical care at no cost to you. [Describe compensation for injuries].[22]

[19] Only include for interventional studies.

[20] Research team contact information.

[21] REB contact information.

[22] Only include if appropriate. If applicable, describe any compensation offered for injuries incurred during participation in the study.

Giving your consent to participate in this study

Participating in this research project is voluntary, meaning you participate only if you want to. If you have reviewed the details of this study and would like to participate, you can give your consent by [consent action].[23] Agreeing to participate does not mean you have given up any legal rights including the right to bring legal action if you are injured or harmed because of this study.

I CONSENT[24]

[23] This should reflect the way consent is being collected, which could include signature, clicking a button on an online form, verbal consent, or another format approved by your local institution and REB. See footnote 24 below.

[24] (a) Consent can be documented according to requirements of the researcher's institution and local regulatory environment. Consent for research can be an indication (checkbox, e-signature, completion of a form) or acknowledgment and does not necessarily require a signature. This form should also include signature lines for witnesses, authorized third parties, etc. when relevant.
(b) Health Canada requires a written, signed, and dated consent form and statement that the subject has read and understood the entire form. This statement about reading and understanding the form can be used instead of an initial on each page. Research studies subject to Good Clinical Practice guidelines must include the signature of the person obtaining consent.
(c) Please insert signature lines as required based on local regulatory and organizational requirements.